UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 or 15(d) of the
SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): June 21, 2026

MOONLAKE IMMUNOTHERAPEUTICS
(Exact Name of Registrant as Specified in Its Charter)

Cayman Islands	**001-39630**	**98-1711963**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Dorfstrasse 29
6300 Zug
Switzerland
(Address of principal executive offices and Zip Code)

41 415108022
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A ordinary share, par value $0.0001 per share	MLTX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On June 21, 2026, MoonLake Immunotherapeutics (the "Company") issued a press release announcing the Week 52 results from its Phase 3 VELA clinical trials (VELA-1 and VELA-2) evaluating the efficacy and safety of the Nanobody® sonelokimab ("SLK") in adult patients with moderate-to-severe hidradenitis suppurativa ("HS"), as well as an interim analysis of its Phase 3 VELA-TEEN trial in adolescents with HS. The Company is hosting a webcast today, Monday, June 22, 2026 at 8:00 am, Eastern Time, to discuss the data results.

A copy of the press release and the webcast presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein. The exhibits furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

Results from the Phase 3 VELA clinical trials at Week 52

Week 52 data for SLK showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with SLK achieved Hidradenitis Suppurativa Clinical Response ("HiSCR") 75 and 33.1% of patients achieved HiSCR100 at Week 52 (n=396). The results were consistent across both trials (VELA-1: 68.3% HiSCR75, 31.2% HiSCR100; VELA-2: 66.0% HiSCR75, 35.1% HiSCR100). At Week 52, 26.0% of patients (n=396) achieved an International Hidradenitis Suppurativa Severity Score System ("IHS4")-100 response (VELA-1: 24.4%, VELA-2: 27.7%), reflecting inflammatory remission, defined as a 100% reduction in abscesses (A100), nodules (N100) and draining tunnels (DT100). The long-term results of the VELA program are higher than in previous Phase 3 HS programs with competing agents (using the same pooled, as observed, end of parental trial data analysis). Relative to the competitor IL-17-A & F inhibitor monoclonal antibody, the SLK Nanobody®, for example, showed responses with over ~10% more responding patients for HiSCR75, HiSCR100 or IHS4-100.

The strong long-term clinical responses observed with SLK were accompanied by sustained improvements in Patient-Reported Outcomes, which are considered to matter most to patients living with HS and their treating physicians. Patients treated with SLK consistently showed the largest reductions in the HS-specific Quality of Life score ("HiSQOL") at Week 52, with a -15.3 mean score difference between end of trial and baseline in VELA-1, and -14.8 in VELA-2 (as observed, n=395). The broader skin Dermatology Life Quality Index ("DLQI") score confirmed the HiSQOL results and showed clinically meaningful response (≥4-point improvement from baseline) in 75.0% (VELA-1) and 69.4% (VELA-2) of patients (as observed, in patients with baseline DLQI ≥4, n=363). Responses for both these quality of life metrics were higher than previously demonstrated in competitor pivotal HS studies. In line with these data, 46.5% of patients experienced a marked reduction in pain, measured as at least a 3-point reduction from baseline in the worst skin pain Numerical Rating Scale (VELA-1: 48.4%, VELA-2: 44.3%; as observed, in patients with baseline worst skin pain score of ≥3, n=241).

These findings demonstrate leading and durable improvements across outcomes of key relevance for patients, including quality of life, pain and long-term disease control.

Responses seen in patients crossing over from placebo (switch to SLK at Week 16) confirm and validate these findings. After 4 Weeks of SLK treatment, HiSCR75 rates increased by ~20 percentage points across both studies. At the end of the VELA program (i.e., after 36 weeks of SLK treatment), cross-over patients ("Placebo-to-SLK") showed HiSCR75 rates similar to those observed after 36 weeks of treatment in the "SLK-to-SLK" arms (~60%, as observed).

The high acceptance rate and good tolerability of SLK across the VELA program was confirmed by the rate of patients rolling over into the VELA-OLE (two-year open-label extension) following the parental trials (~90% across all arms) further validating the convenience of the 120mg Q4W (once every four weeks) dosing regimen.

Interim Week 24 data from the Phase 3 VELA-TEEN trial

Furthermore, data from the VELA-TEEN clinical trial showed rapid onset and high response rates in adolescent patients with HS. Interim analysis of Week 24 data show that ~68% of patients treated with SLK achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, n=22). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. SLK was generally well tolerated in this vulnerable patient population, and no new safety signals were observed. These promising results highlight the relevance and opportunity of an early treatment of HS with the goal to slow down the progression to irreversible tissue damage.

The safety profile of SLK in the VELA clinical programs including VELA-TEEN remains consistent over time, with no new safety signals detected.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated June 21, 2026
99.2	Slide Presentation, dated June 22, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MOONLAKE IMMUNOTHERAPEUTICS

Date: **June 22, 2026**

By: /s/ Matthias Bodenstedt
Name: Matthias Bodenstedt
Title: Chief Financial Officer

Exhibit 99.1

MoonLake Announces Week 52 Results of Sonelokimab from its Phase 3 VELA Program in Hidradenitis Suppurativa and Confirms Investor Day on June 22, 2026

- *Results from the Phase 3 VELA clinical trials at Week 52 in adults with moderate-to-severe hidradenitis suppurativa (HS) demonstrate sonelokimab's (SLK) potential best-in-class and best-in-disease profile, with consistent responses that are higher than those observed in trials of competing agents at the end of their respective parental trials*

- *Namely, ~67% of patients treated with SLK achieved HiSCR75 at the one-year mark, with more than one quarter of patients achieving inflammatory remission (IHS4-100), and around one third reaching HiSCR100*

- *Patients treated with SLK likewise showed substantial improvement in HiSQOL at Week 52, with a mean score difference between end of trial and baseline of -15.0 points, indicating an average change from "severe" to "mild" impairment of the HS-related quality of life*

- *Almost half of the patients experienced a marked reduction in pain (at least a 3-point improvement from baseline in the worst skin pain Numerical Rating Scale (NRS))*

- *No new safety signals were detected in the VELA trials to date, supporting a consistent safety profile through Week 52*

- *Data from the VELA-TEEN trial in adolescent HS patients show strong therapeutic response and no new safety signals in adolescent patients, with nearly 70% of patients achieving HiSCR75 at Week 24 and almost half of patients reaching HiSCR100*

- *Submission of the Biologics License Application (BLA) for SLK in HS, including data from adolescent patients, is expected at the end of September 2026, and will follow previous agency guidance on the label strategy*

- *An Investor Day webcast will be held on June 22, 2026, 8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET), to discuss these data and provide guidance on upcoming events*

ZUG, Switzerland, June 21, 2026 – MoonLake Immunotherapeutics (NASDAQ: MLTX) (MoonLake or the Company), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced the Week 52 results of the Phase 3 VELA-1 and VELA-2 clinical trials of its registrational global program in patients with moderate-to-severe HS. The Company also announced that it will host an Investor Day webcast on June 22, 2026, 8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET), including an open Q&A session.

Results from the Phase 3 VELA clinical trials at Week 52

Week 52 data for SLK showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with SLK achieved HiSCR75 and 33.1% of patients achieved HiSCR100 at Week 52 (n=396). The results were consistent across both trials (VELA-1: 68.3% HiSCR75, 31.2% HiSCR100; VELA-2: 66.0% HiSCR75, 35.1% HiSCR100). At Week 52, 26.0% of patients (n=396) achieved an IHS4-100 response (VELA-1: 24.4%, VELA-2: 27.7%), reflecting inflammatory remission, defined as a 100% reduction in abscesses (A100), nodules (N100) and draining tunnels (DT100). The long-term results of the VELA program are higher than in previous Phase 3 HS programs with competing agents (using the same pooled, as observed, end of parental trial data analysis). Relative to the competitor IL-17-A & F inhibitor monoclonal antibody, the SLK Nanobody®, for example, showed responses with over ~10% more responding patients for HiSCR75, HiSCR100 or IHS4-100.

The strong long-term clinical responses observed with SLK were accompanied by sustained improvements in Patient-Reported Outcomes, which are considered to matter most to patients living with HS and their treating physicians. Patients treated with SLK consistently showed the largest reductions in the HS-specific Quality of Life score (HiSQOL) at Week 52, with a -15.3 mean score difference between end of trial and baseline in VELA-1, and -14.8 in VELA-2 (as observed, n=395). The broader skin DLQI score confirmed the HiSQOL results and showed clinically meaningful response (≥4-point improvement from baseline) in 75.0% (VELA-1) and 69.4% (VELA-2) of patients (as observed, in patients with baseline DLQI ≥4, n=363). Responses for both these quality of life metrics were higher than previously demonstrated in competitor pivotal HS studies. In line with these data, 46.5% of patients experienced a marked reduction in pain, measured as at least a 3-point reduction from baseline in the worst skin pain NRS (VELA-1: 48.4%, VELA-2: 44.3%; as observed, in patients with baseline worst skin pain score of ≥3, n=241).

These findings demonstrate leading and durable improvements across outcomes of key relevance for patients, including quality of life, pain and long-term disease control.

Responses seen in patients crossing over from placebo (switch to SLK at Week 16) confirm and validate these findings. After 4 Weeks of SLK treatment, HiSCR75 rates increased by ~20 percentage points across both studies. At the end of the VELA program (i.e., after 36 weeks of SLK treatment), cross-over patients ("Placebo-to-SLK") showed HiSCR75 rates similar to those observed after 36 weeks of treatment in the "SLK-to-SLK" arms (~60%, as observed).

The high acceptance rate and good tolerability of SLK across the VELA program was confirmed by the rate of patients rolling over into the VELA-OLE (two-year open-label extension) following the parental trials (~90% across all arms) further validating the convenience of the 120mg Q4W (once every four weeks) dosing regimen.

Interim Week 24 data from the Phase 3 VELA-TEEN trial

Furthermore, data from the VELA-TEEN clinical trial showed rapid onset and high response rates in adolescent patients with HS. Interim analysis of Week 24 data show that ~68% of patients treated with SLK achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, n=22). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. SLK was generally well tolerated in this vulnerable patient population, and no new safety signals were observed. These promising results highlight the relevance and opportunity of an early treatment of HS with the goal to slow down the progression to irreversible tissue damage.

The safety profile of SLK in the VELA clinical programs including VELA-TEEN remains consistent over time, with no new safety signals detected.

Dr. Jorge Santos da Silva, Founder and Chief Executive Officer of MoonLake Immunotherapeutics, said: *"The final Week 52 data from the VELA program confirm the strength of SLK across most, if not all, metrics that matter in HS: strong early efficacy, sustained and leading improvement over time, a consistent safety profile and great convenience in dosing. All this, not just for adult patients but also for adolescent patients. Together with the alignment we have reached with the FDA on our HS label strategy, these data support the potential for a highly differentiated label profile and reinforce our conviction that SLK has the potential to become a best-in-class and best-in-disease therapy for those living with HS."*

Prof. Kristian Reich, Founder and Chief Scientific Officer of MoonLake Immunotherapeutics, added: *"What is particularly compelling in the final Week 52 dataset is how consistently the strong clinical efficacy of SLK is reflected in Patient-Reported Outcomes. The sustained improvements we observed across HiSQOL, pain and broader quality of life measures are highly meaningful in HS, where the burden of disease extends far beyond lesion counts. In our view, these data highlight the potential of SLK to redefine long-term outcomes in HS by delivering durable disease control and meaningful improvements of the daily lives of patients combined with a favourable safety profile."*

Next steps and anticipated BLA submission

MoonLake plans to submit the BLA for HS to the FDA at the end of September 2026. The pre-BLA process is concluded and no more regulatory meetings with the FDA will take place. Clarity on the Prescription Drug User Fee Act (PDUFA) date is currently expected by the end of November 2026, concurrent with the FDA's acceptance of the BLA. The Company plans to submit a request for Priority Review for this BLA based on SLK's potential best-in-class profile as well as its VELA-TEEN adolescent data; the FDA's decision on the Priority Review request would be included in the application's PDUFA date allocation/filing letter. Priority Review remains an upside scenario for MoonLake, subject to FDA resource and capacity considerations. If Priority Review is not granted, MoonLake expects a third or fourth quarter 2027 launch for SLK. Should Priority Review be granted, it is estimated that the time-to-market for SLK may be reduced by approximately one quarter.

Investor Day, June 22, 2026

The Company will hold an Investor Day for investors and analysts on **June 22, 2026**. The webcast will take place from **8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET),** including an open Q&A session. A recording will be made available post-event. **Webcast Access:** https://edge.media-server.com/mmc/p/ke4wbinp

In this session, MoonLake's CEO, Jorge Santos da Silva, CSO, Kristian Reich, and CFO, Matthias Bodenstedt, will present the final Week 52 data from the Phase 3 VELA program in HS and provide an update on the VELA-TEEN clinical trial in adolescent HS, a recap of the proposed label, the Company's view on its commercialization plan, as well as an outlook on H2 2026 events, including the readout of IZAR-1 Phase 3 trial in psoriatic arthritis (PsA).

Important upcoming anticipated milestones for MoonLake:

- Mid 2026: Primary endpoint readout of the Phase 3 IZAR-1 trial in PsA
- Late Sep. 2026: Submission of a BLA for HS
- Late Nov. 2026: Expected PDUFA date allocation for HS BLA
- H2 2026: Primary endpoint readout of the Phase 3 IZAR-2 trial in PsA
- H2 2026: Interim readout of the Phase 2 P-OLARIS trial in PsA and axSpA

-Ends-

MoonLake Immunotherapeutics

MoonLake Immunotherapeutics is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational Nanobody® for the treatment of inflammatory disease, to revolutionize outcomes for patients. Sonelokimab inhibits IL-17A and IL-17F by inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation. The Company's focus is on inflammatory diseases with a major unmet need, including hidradenitis suppurativa, psoriatic arthritis, axial spondyloarthritis and palmoplantar pustulosis – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake was founded in 2021 and is headquartered in Zug, Switzerland. Further information is available at www.moonlaketx.com.

About Nanobodies®

Nanobodies® represent a new generation of antibody-derived targeted therapies. They consist of one or more domains based on the small antigen-binding variable regions of heavy-chain-only antibodies (VHH). Nanobodies® have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHHs covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

Sonelokimab is being assessed in two lead indications, hidradenitis suppurativa (HS) and psoriatic arthritis (PsA), and the Company is pursuing other indications in dermatology and rheumatology, including adolescent HS, palmoplantar pustulosis (PPP) and axial spondyloarthritis (axSpA).

For adults with HS, sonelokimab is being assessed in two identical Phase 3 trials, the VELA-1 and VELA-2 trials, using the higher clinical response level of HS Clinical Response (HiSCR) 75 as the primary endpoint, which defines a response as an at least 75% reduction in abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count. In September 2025, the primary endpoint data from the VELA-1 and VELA-2 clinical trials were announced. In the combined VELA program, patients treated with SLK experienced a clinically meaningful and statistically significant improvement across all primary and key secondary endpoints using both pre-specified strategies ($p<0.001$). In VELA-1, SLK achieved statistical significance for all primary and key secondary endpoints using both pre-specified strategies (HiSCR75, delta to placebo of 17%, $p<0.001$). In VELA-2, intercurrent events in the higher-than-expected placebo arm precluded the study from achieving statistical significance in the Week 16 primary endpoint using the composite strategy (HiSCR75, delta to placebo of 9%, $p=0.053$). In June 2026, Week 52 Results of SLK from the VELA-1 and VELA-2 clinical trials were announced. Week 52 data for SLK showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with SLK achieved HiSCR75 and 33.1% of patients achieved HiSCR100 at Week 52 (as observed, n=396). The safety profile of sonelokimab in the VELA trials was consistent with previous trials with no new safety signals detected.

Sonelokimab is currently undergoing evaluation in the VELA-TEEN Phase 3 trial, which is the first clinical study specifically focused on adolescent patients with moderate-to-severe HS. In June 2026, interim Week 24 data from the Phase 3 VELA-TEEN trial were announced. Interim analysis of Week 24 data show that ~68% of patients treated with SLK achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, n=22). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. SLK was generally well tolerated in this vulnerable patient population, and no new safety signals were observed.

For PsA, sonelokimab is being assessed in the Phase 3 trials, IZAR-1 and IZAR-2, following the announcement in March 2024 of the full dataset from the global Phase 2 ARGO trial (M1095-PSA-201) evaluating the efficacy and safety of the Nanobody® sonelokimab over 24 weeks in patients with active PsA. Significant improvements were observed across all key outcomes, including approximately 60% of patients treated with sonelokimab achieving an American College of Rheumatology (ACR) 50 response and Minimal Disease Activity (MDA) at Week 24. This followed the positive top-line results in November 2023, where the trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an ACR50 response compared to those on placebo at Week 12. All key secondary endpoints in the trial were met for the 60mg and 120mg doses with induction. The safety profile of sonelokimab in the ARGO trial was consistent with previous trials with no new safety signals detected.

Sonelokimab is also being assessed in PPP, a debilitating inflammatory skin condition affecting a significant number of patients, including in the completed Phase 2 LEDA program. In the Phase 2 LEDA clinical trial in PPP, SLK demonstrated clinically meaningful and statistically significant benefit. Patients treated with SLK achieved a mean percent change from baseline in the Palmoplantar Pustular Psoriasis Area and Severity Index (PPPASI) of 64% at Week 16, and 39% of patients achieved a ≥75% reduction in the PPPASI (PPPASI75), suggesting that SLK could provide clinically meaningful improvements in this disease for which there are currently no approved therapies. The safety profile of SLK in the LEDA trial was consistent with previous trials with no new safety signals detected.

Additionally, sonelokimab is being assessed in the ongoing Phase 2 S-OLARIS and P-OLARIS trials for active axSpA and PsA, respectively. Both trials feature an innovative design complementing traditional clinical outcomes with cellular imaging techniques.

Sonelokimab has also been assessed in a randomized, placebo-controlled third-party Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis. High threshold clinical responses (Investigator's Global Assessment Score 0 or 1, and Psoriasis Area and Severity Index 90/100) were observed in patients with moderate-to-severe plaque-type psoriasis. Sonelokimab generally presented a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

In an earlier third-party Phase 1 trial in patients with moderate-to-severe plaque-type psoriasis, sonelokimab decreased (to normal skin levels) the cutaneous gene expression of pro-inflammatory cytokines and chemokines (Svecova D. J Am Acad Dermatol. 2019; 81:196–203).

About the VELA program

The Phase 3 VELA program recruited a total of 838 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, and placebo-controlled trials are identical in design evaluating the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in adult patients with active moderate-to-severe hidradenitis suppurativa. Similar to the design of the landmark Phase 2 MIRA trial, the primary endpoint is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response (HiSCR) 75, defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trials also evaluate a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total reduction of ≥4, the proportion of patients achieving at least 50% reduction from baseline in Numerical Rating Scale (NRS50) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain) and complete resolution of Draining Tunnels (DT100). The VELA protocols and statistical analysis plans were prepared in accordance with regulatory agency advice and include two analysis strategies. The composite strategy for the VELA trials (also referred to as the primary estimand) is the primary statistical analysis. The protocol specifies the treatment policy strategy as the alternative method of handling intercurrent events to test the robustness of the VELA data. The trials compare a single 120mg dose of sonelokimab to placebo with HiSCR75 reading out at Week 16. Results of the Week 16 data were announced in September 2025. Results of the Week 52 data were announced in June 2026. Further details are available under NCT06411899 and NCT06411379 at www.clinicaltrials.gov.

About the MIRA trial

The MIRA trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in the treatment of adult patients with active moderate-to-severe hidradenitis suppurativa. The trial recruited 234 patients, with the aim to evaluate two different doses of sonelokimab (120mg and 240mg) with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluated a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale (NRS30) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Further details are available under NCT05322473 at www.clinicaltrials.gov.

About the VELA-TEEN trial

The Phase 3 VELA-TEEN trial is an open-label, single-arm trial designed to evaluate sonelokimab 120mg administered subcutaneously once every two weeks (Q2W) until week six and once every four weeks (Q4W) from week eight onwards. The trial enrolled 35 adolescents, aged 12-17, with moderate-to-severe hidradenitis suppurativa, from U.S. sites experienced in clinical trials and pediatric dermatology. The primary trial phase will be 24 weeks with a primary endpoint evaluating the pharmacokinetics, safety, and tolerability of sonelokimab. VELA-TEEN will also evaluate several secondary endpoints, including the proportion of patients achieving the higher clinical response measure of the Hidradenitis Suppurativa Clinical Response (HiSCR) 75, in addition to HiSCR50. Other outcomes are the change from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4), which includes the quantitative measure of draining tunnels, and the proportion of patients achieving a meaningful reduction of the Children's Dermatology Life Quality Index (CDLQI) and the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Results of the interim Week 24 data were announced in June 2026. Further details are available under NCT06768671 at www.clinicaltrials.gov.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a severely debilitating chronic skin condition resulting in irreversible tissue destruction. HS manifests as painful inflammatory skin lesions, typically around the armpits, groin, and buttocks. Over time, uncontrolled and inadequately treated inflammation can result in irreversible tissue destruction and scarring. The disease affects an estimated 2% of the population, with three times more females affected than males. Real-world data in the United States indicate that at least 2 million unique patients have been diagnosed with and treated for HS between 2016 and 2023 alone, highlighting a significant unmet need and impact on healthcare systems, and a market opportunity projected to reach $15bn by 2035. Onset typically occurs in early adulthood and HS has a profound negative impact on quality of life, with a higher morbidity than other dermatologic conditions. There is increasing scientific evidence to support IL-17A- and IL-17F-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

About the IZAR Program

IZAR-1 and IZAR-2 are global, randomized, double-blind, placebo-controlled Phase 3 trials designed to evaluate the efficacy and safety of sonelokimab compared with placebo in a total of approximately 1,500 adults with active psoriatic arthritis (PsA), with a primary endpoint of superiority to placebo in American College of Rheumatology (ACR) 50 response at Week 16. IZAR-1 is expected to enroll biologic-naïve patients and include an evaluation of radiographic progression, while IZAR-2 is expected to enroll patients with an inadequate response to tumor necrosis factor-α inhibitors (TNF-IR) – reflecting patients commonly seen in clinical practice – and is the first PsA trial to include a risankizumab active reference arm. Both trials will also assess a range of secondary endpoints reflecting the multiple disease manifestations characteristic of PsA. These include skin and nail outcomes, multidomain outcomes, and Patient-Reported Outcome measures such as pain and quality of life assessments. Further details are available under NCT06641076 and NCT06641089 at http://www.clinicaltrials.gov.

About the P-OLARIS trial

The P-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60mg administered subcutaneously in adult patients with active psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) with a focus on characterizing how sonelokimab affects markers of inflammation and tissue damage within joints. The trial aims to recruit approximately 20 patients with PsA and 10 patients with axSpA. The primary endpoint is the change in disease activity at Week 12, as measured by [68Ga]-fibroblast activation protein inhibitor (FAPI)-tracer uptake (SUVmax) on FAPI-positron emission tomography (PET)/low-dose computed tomography (CT) scans, a novel imaging modality able to detect inflammation and early tissue damage within joints. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes, as well as patient reported outcomes that assess the impact of disease signs and symptoms. The trial also features an innovative exploratory peripheral blood and tissue biomarker program.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in PsA as well as the Phase 2 S-OLARIS trial in axSpA which demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-514504-13-00 at https://euclinicaltrials.eu.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive and complex inflammatory disease that manifests across multiple domains, leading to substantial functional impairment and decreased quality of life. The clinical features of PsA are diverse, comprising both musculoskeletal (peripheral arthritis, spondylitis, dactylitis, and enthesitis) and non-musculoskeletal (skin and nail disease) domains. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. Although the exact mechanism of disease is not fully understood, evidence suggests that activation of the IL-17 pathway plays an important role in the disease pathophysiology.

About the S-OLARIS trial

The S-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60mg administered subcutaneously in adult patients with active axial spondyloarthritis (axSpA). The trial recruited 26 patients. The primary endpoint is the change from baseline (CfB) in 18F-NaF SUVmax signals at Week 12 in the sacroiliac joints and spine as detected by PET. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes (e.g., ASAS), scores related to physical function, spinal mobility, and enthesitis as well as patient reported outcomes. The trial also features an innovative exploratory peripheral blood and tissue biomarker program.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in psoriatic arthritis, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513498-36-00 at https://euclinicaltrials.eu.

About Axial Spondyloarthritis

Axial Spondyloarthritis (axSpA) typically impacts young people, with diagnosis based on chronic inflammatory back pain lasting more than three months with onset under 45 years of age. Advanced disease can lead to progressive and pathologic bone formation and joint fusion, severely limiting spinal mobility. Global reported prevalence of axSpA ranges from 0.5% to 1.5%. AxSpA can be categorized by disease progression into two subtypes: non-radiographic axSpA and ankylosing spondylitis (AS), also known as radiographic axSpA, which is diagnosed based on radiographic evidence of structural changes to the sacroiliac joints. Patients with axSpA experience fatigue, persistent morning stiffness, and pain that worsens at night and can disrupt sleep. Many patients also face the burden of comorbidities such as psoriatic arthritis and psoriasis. Studies have found elevated IL-17 levels in the blood and synovial fluid of patients with axSpA, and IL-17A and IL-17F are both thought to be key contributors to pathogenesis across the spondyloarthropathies.

About the LEDA Trial

The LEDA trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 120mg administered subcutaneously in adult patients with palmoplantar pustulosis (PPP). The trial recruited 32 patients. The primary endpoint of the trial is percent change from baseline in Palmoplantar Psoriasis Area and Severity Index (ppPASI) with important secondary endpoints including ppPASI75 (at least 75% improvement in the ppPASI). The LEDA trial features an innovative translational research program using peripheral blood and tissue biomarkers as trial controls.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 MIRA trial in hidradenitis suppurativa, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513305-32-00 at https://euclinicaltrials.eu.

About Palmoplantar Pustulosis

Palmoplantar Pustulosis (PPP) is characterized by the development of blister-like pustules within erythematous, scaly plaques on the palms and the soles of the feet. PPP typically develops in adulthood and more frequently impacts females. Patients frequently experience significant pain, burning, and itching sensations on the palms and soles of the feet which can be debilitating and impair their ability to work, sleep, or perform other activities of daily living. Currently, the treatment of PPP is challenging with a significant unmet need for novel therapies to reduce the symptom burden for patients. Evidence suggests that activation of the IL-17 pathway has an important role in disease pathophysiology.

Cautionary Statement Regarding Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding MoonLake's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: the efficacy and safety of sonelokimab for the treatment of moderate-to-severe HS; the anticipated interactions with regulatory authorities, including the FDA, and the anticipated BLA-submission, PDUFA date and request for Priority Review; the proposed label and labeling discussions with the FDA for sonelokimab in HS, including potential inclusion of clinical data from the MIRA trial; potential market opportunities for sonelokimab; upcoming anticipated clinical milestones, including the primary endpoint readouts of the Phase 3 IZAR-1 trial in PsA and Phase 3 IZAR-2 trial in PsA, interim endpoint readout of the Phase 2 P-OLARIS trial in PsA and axSPA and submission of a BLA for HS; the FDA's decision on Priority Review designation; and timing of first commercial launch in the United States. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Forward-looking statements are based on current expectations and assumptions that, while considered reasonable by MoonLake and its management, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with MoonLake's business in general and limited operating history; difficulty enrolling patients in clinical trials; state and federal healthcare reform measures that could result in reduced demand for MoonLake's product candidates; reliance on third parties to conduct and support its preclinical studies and clinical trials; and the other risks described in or incorporated by reference into MoonLake's Annual Report on Form 10-K for the year ended December 31, 2025, Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, and subsequent filings with the Securities and Exchange Commission.

Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. MoonLake does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or in the events, conditions or circumstances on which any such statement is based.

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MoonLake Immunotherapeutics

Investor Day

June 22nd, 2026

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Welcome to our Investor Day

MoonLake

Date: June 22nd, 2026
Time: 8.00 am EST

Agenda

Topic	Sub-topics	Speaker	Timing
Introduction	Welcome MLTX & SLK summary	Jorge	10 mins
Final data from the VELA program in HS	Final Week 52 Phase 3 VELA data Update on VELA-TEEN data	Kristian	30 mins
BLA strategy	Proposed Label Update on BLA progress	Jorge	20 mins
Commercializing SLK in HS	Update on HS market view Why MLTX can win commercially in HS	Matthias	10 mins
Closing remarks	Summary & Guidance on H2 2026 Expectations for IZAR-1 readout	Jorge	5 mins

The presentation will be followed by a short Q&A session – please submit your questions via the dedicated Q&A function in the portal, in case of issues please e-mail ir@moonlaketx.com

Source: MoonLake Corporate Strategy

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Disclaimer

Forward Looking Statements

Certain statements in this presentation may constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding our expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for clinical trials and regulatory submissions, including expected BLA submissions for SLK; the anticipated timing of the results from those trials; the anticipated timing of BLA submission, review and approval; the proposed FDA label and anticipated differentiation potential for the FDA label for SLK; potential market opportunities, estimates of market size, and estimates of market growth; potential indications; the timing of regulatory meetings; the occurrence and timing of market engagement; expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations; the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development and commercialization efforts; and effects on liquidity and capital resources, including cash position. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate", "believe", continue", "could", "estimate", "expect", "intend", "may", "might", "plan", "possible", "potential", "predict", "project", "should", " strive", "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that such statement is not forward looking. Forward-looking statements are based on current expectations and assumptions that, while we and our management consider reasonable, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management's control including general economic conditions and other risks, uncertainties and factors set forth in the section entitled "Risk Factors" and "Note on Forward-Looking Statements" in our Annual Report on Form 10-K that was filed with the U.S. Securities and Exchange Commission (the "SEC") on February 25, 2026, Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, as filed with the SEC on May 11, 2026, as well as factors associated with companies, such as MoonLake Immunotherapeutics, that operate in the biopharma industry. Nothing in this presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this presentation, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. We neither undertake nor accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in our expectations or in the events, conditions or circumstances on which any such statement is based. This presentation does not purport to summarize all of the conditions, risks and other attributes of MoonLake Immunotherapeutics.

Industry and Market Data

Certain information contained in this presentation relates to or is based on studies, publications, surveys and our own internal estimates and research. In this presentation, we rely on, and refer to, publicly available information and statistics regarding market participants in the sector in which we compete and other industry data. Any comparison of us to any other entity assumes the reliability of the information available to us. We obtained this information and statistics from third-party sources, including reports by market research firms and company filings. In addition, all of the market data included in this presentation involve a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our internal research is reliable, such research has not been verified by any independent source and we have not independently verified the information.

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Source: MoonLake Legal

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- **Founded in 2021** in Switzerland
- **Unique molecule with SLK**, tri-specific IL-17A & F Nanobody® to elevate treatment in inflammation in markets with **significant unmet needs** and **multi-bn $ potential**
- **Public on Nasdaq** since April 2022 with cash runway to end **of 2027 –** further access to up to $400 m in non-dilutive funds
- Driven by a top-tier team, aim is to unlock a **pipeline-in-a-product across indications**
- **Phase 3 studies completed in HS and PsA with data read-outs expected over coming months –** further Phase 2 studies completed in PPP, axSpA and PsO
- **First BLA submission** for SLK in HS expected in **Q3 2026 –** pre-commercial activities ramping up

Source: MoonLake Corporate Strategy

A differentiated IL-17A and F molecule: Do you still Antibody?

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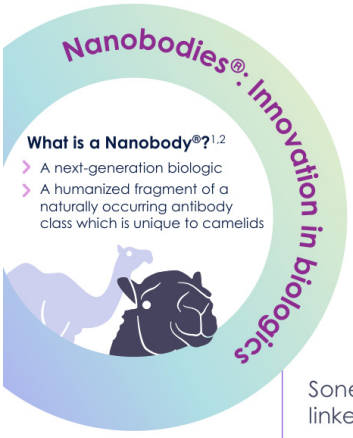
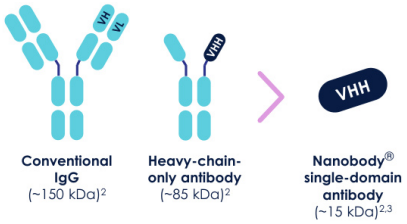
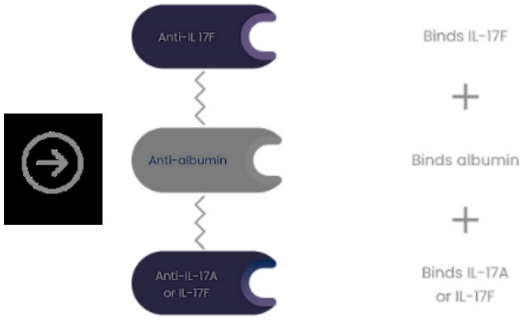


Nanobodies® are much smaller than traditional antibodies



They can be designed to have multiple and different binding domains



Sonelokimab

Sonelokimab (SLK) is a ~40kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible spacers - around a **third/quarter of the size of traditional antibodies**

With 2 domains, it binds with high affinity to **IL-17A and IL-17F** – a third domain binds human **albumin**

Subcutaneous administration, **Q4W**

SLK is the only asset that binds **all IL-17A and F dimers with leading and similar affinity** (shown in 2023)

Ig, immunoglobulin; VH, heavy chain variable domain; VHH, variable heavy domain of heavy chain; VL, light chain variable domain; 1 Hamers-Casterman, C., et al. Nature. 1993; 363:446–448; 2 Jovčevska I, Muyldermans S. BioDrugs. 2020;34:11–26; 3 Tijink BM, et al. Mol Cancer Ther. 2008;7:2288–2297; For reference in this presentation: The terms Nanobody® and Nanobodies® are registered trademarks of Ablynx, a Sanofi company

Source: MoonLake Medical Affairs & Research

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MLTX is **approaching registration** in Derm and Rheum indications

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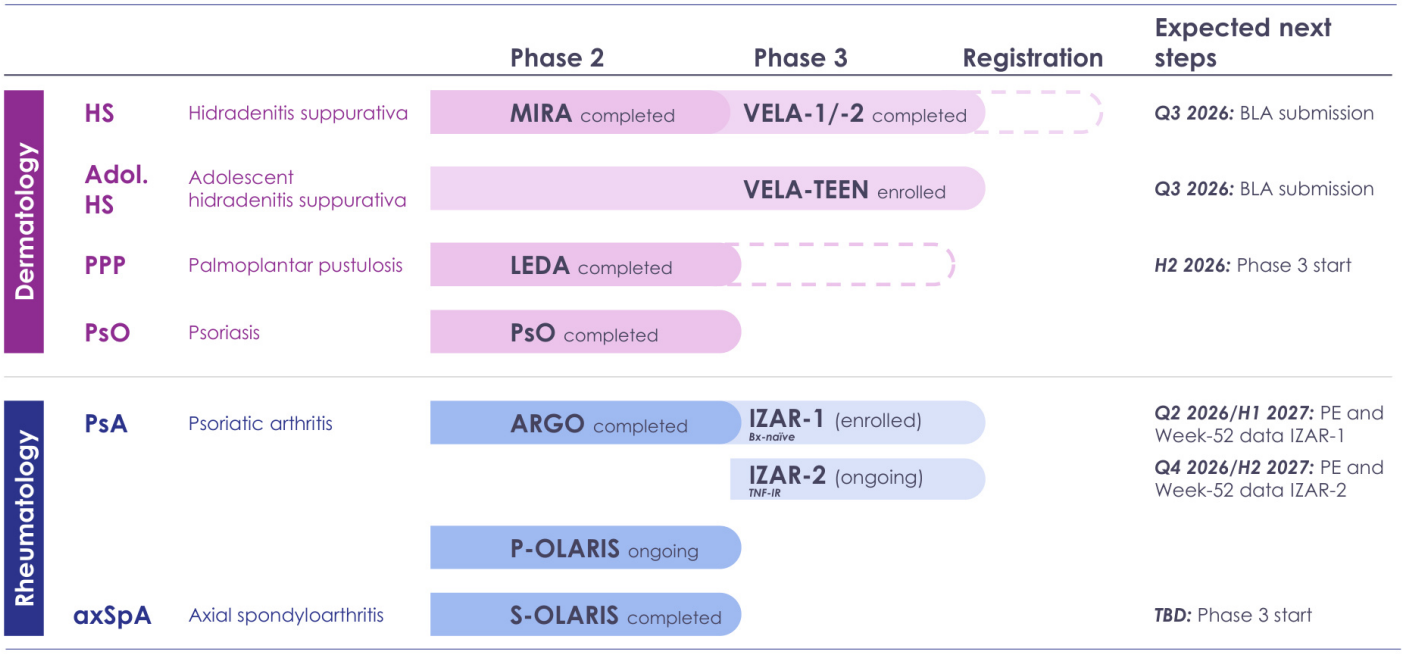

PE, primary endpoint

Source: MoonLake Corporate Strategy

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SLK consistently shows **a leading profile** across multiple indications

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	Dermatology			Rheumatology	
	HS (incl. Adol)	**PPP**	**PsO**	**PsA**	**axSpA**
Estimated Market size ($, 2035)	**10-15bn** (14-18% p.a. growth from '26)	**3-4bn** (15-20% p.a. growth from '26)	**20-25bn** (6-8% p.a. growth from '26)	**10-15bn** (6-8% p.a. growth from '26)	**10-15bn** (7-9% p.a. growth from '26)
Key primary endpoint responses	*Phase 2 and 3* **34-43%** **HiSCR75** response at Week 12/16[1]	*Phase 2* *(Phase 3 to start soon)* **40%+** **PPPGA0/1** response at Week 16[2]	*Phase 2* **70%+** **PASI90** response at Week 12[3]	*Phase 2* *(Phase 3 ongoing)* **45%+** **ACR50** response at Week 12[4]	*Phase 2* **80%+** **ASAS40** response at Week 12[5]
Where MLTX elevates responses	**HiSCR75, HiSQOL**	**PPPGA0/1** and **PPPASI75**	**PASI90-100**	**ACR70 + PASI100, MDA**	**ASDAS-CRP, MRI/PET**

Robust benefit-risk profile – absence of signals of events of interest

Patient convenience – fewer injections, shorter injection time, lower volumes vs mAbs

Approximate responses; Selected data subject to change until final CSR is issued. 1 mNRI 120mg (VELA), ITT-NRI 120mg (MIRA): 34.4% for VELA-1 at Week 16, 34.1% for VELA-2 at Week 16, 43.3% for MIRA at Week 12; 2 mNRI 120mg; 3 ITT-NRI 120mg; 4 ITT-NRI, 60mg; 5 ITT-mNRI, 60mg

Source: MoonLake Corporate Strategy

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2026 is a **catalyst-rich year** for MLTX

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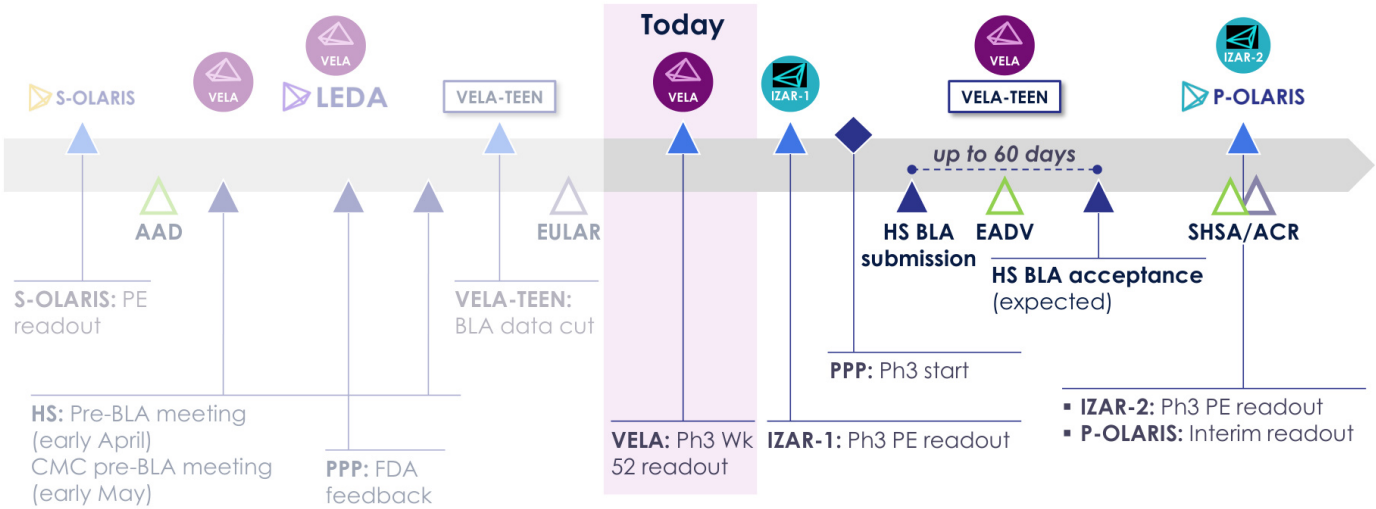
▲ FDA interaction ▲ Trial data △ Derm event △ Rheum event

2026

Q1 Mid-year Q4



Timeline not scaled, non-exhaustive; All future milestones are anticipated dates

Source: MoonLake Corporate Strategy

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We believe **SLK is on schedule** to be a **potential best-in-class in HS**

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Broader Label

First molecule clinically tested in adolescent HS allowing earlier therapy to avoid irreversible damage

~1 in 2 patients reach HiSCR100

No new safety signals in adolescents

Leading Efficacy

Leading performance across elevated treatment goals & time points incl. lesion counts, quality of life & pain scores

67% HiSCR75 at 1 year

~1 in 3 reach HiSCR100 & ~1 in 4 remission at 1 yr

Expected 22-23 pp delta-to-placebo on label

Advantageous Benefit Ratio

Rapid onset, durable response Nanobody® with safety profile of traditional IL-17s & differentiation to other IL-17F inhibitors

No SIB, Liver, IBD and other signals versus placebo

Consistent long-term safety profile

Improved convenience

Faster, lower volume, monthly Nanobody® injections vs. bi-weekly or high volume

Two-month induction only with 5 fast 1 ml injections

Monthly single fast 1ml injection

Unique mode of action

Leading IL-17A & F inhibitor with unique Nanobody® binding and functional properties

Source: MoonLake Corporate Strategy

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Final data from the VELA program in HS

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HS is a **major I&I challenge** with very significant unmet needs

HS is **progressive** and results in **irreversible tissue destruction** over time…[1]

…we need HS therapies that treat **all types of lesions**, with the **opportunity for inflammatory remission**

Delayed and insufficient treatment are **critical gaps** in disease management…[2]

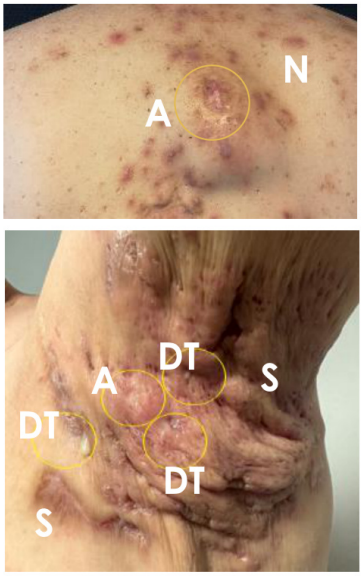
…we need HS therapies that provide **sustained and significant improvements** to patients' lives

2% Est. global prevalence

Delayed and **underdiagnosis** drive conservative prevalence estimates…[2,3]

…we need HS therapies that are **developed with all (many millions) patients in mind**

Advanced disease stages with nodules (N), deep dermal abscesses (A), draining tunnels (DT) and scarring (S)



1 Sabat R et al. Nat Rev Dis Primers. 2020; 6:18; 2 Krueger JG et al. Br J Dermatol. 2024; 190:149–162; 3 Ingram J et al. EADV 2023, Poster P0046; pictures courtesy of Dr. N. Kirsten, France, and Prof. M. Augustin, Germany, used with permission

Source: MoonLake Medical Affairs & Research

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Recap: Phase 3 design and endpoints of VELA trials

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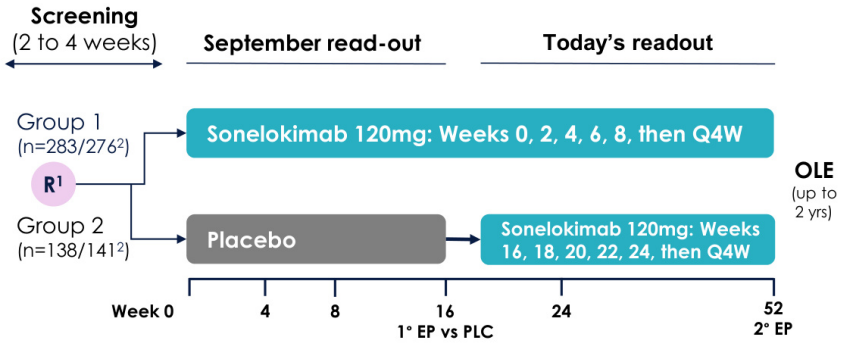
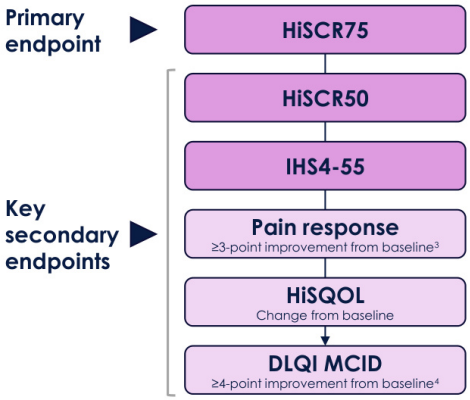
Phase 3 study design for VELA-1 and VELA-2 – identical, global, randomized, double-blind, placebo-controlled 52-week trials



VELA-1 and VELA-2 (n=838 patients) both used the same protocol

Lesions PROs

Endpoints – SLK vs Placebo W16



High-bar primary endpoint (i.e., HiSCR75 vs. historical HiSCR50), a **clinically relevant patient population,** and a **convenient, consistent dosing** regimen

A safety follow-up period follows the end-of-trial visit for patients who do not enter the long-term extension; VELA-1: NCT06411899, VELA-2: NCT06411379; 1 Randomization stratified by Hurley stage status (II vs. III), prior biologic use (Y/N) and geographic region (NA/EU). Patients in Hurley stage III limited to ~40% EoPh2. End of Phase 2; 2 n for VELA-1 and VELA-2 respectively; 3 Baseline worst skin pain score of ≥3; 4 Baseline DLQI of ≥4

Source: MoonLake Clinical

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SLK pivotal trials: Consistent & high HiSCR75 response in pivotal trials

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	SLK HS Pivotal trials		
	MIRA	**VELA-1**	**VELA-2**
HiSCR75 response in SLK treated patients (%)	**43.3** (week 12)	**34.4** (week 16)	**34.1** (week 16)
HiSCR75 response in PBO treated patients (%)	**14.7** (week 12)	**17.5** (week 16)	**24.9** (week 16)
p-value (pre-specified analyses)	p<0.001 (NRI analysis)	p<0.001 (composite strategy) p<0.001 (treatment policy)	p=0.053 (composite strategy) p=0.033 (treatment policy))
	Trials selected for demonstration of Substantial Evidence of Effectiveness (SEE)		

Week 16 data showed **consistent HiSCR75 response with SLK** across both VELA trials and early onset of response
VELA-2 experienced a **spike in placebo response at Week 16 –** no stat sig on composite strategy pre-specified analysis
In both VELA-1 and VELA-2, patient-reported outcomes differences to placebo were **highly statistically significant** (p<0.01)[1]

HiSCR75 responders, MIRA ITT-NRI: SLK 120mg arm (n=67), PBO arm (n=68), VELA-1 mNRI: SLK 120mg arm (n=283), PBO arm (n=138), VELA-2 mNRI: SLK 120mg arm (n=276), PBO arm (n=141); Data subject to change until final CSR is issued; 1 VELA-1 achieved statistical significance multiplicity-controlled, VELA-2 achieved nominal statistical significance

Source: MoonLake Corporate Strategy

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VELA is a **landmark HS program** with **high patient retention rate**

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Largest treatment arms in a Phase 3 for HS

VELA-1	VELA-2
283 sonelokimab	**276** sonelokimab
138 placebo	**141** placebo

Participants randomized at baseline and treated

High retention rates in the VELA trials

Low drop-out rate – through the end of parental VELA trials[1] ~26%

High roll-over to VELA-OLE (2 years) ~88%

Two **identical, global Phase 3 trials** with a **higher-bar primary endpoint** (HiSCR75 vs. historical HiSCR50), and **clinically relevant patient population**

Convenient dosing
High VELA-OLE acceptance reflects confidence in strength of 120mg in Q4W maintenance dosing

1 Trial end at Week 52; Data subject to change until final CSR is issued

Source: MoonLake Clinical

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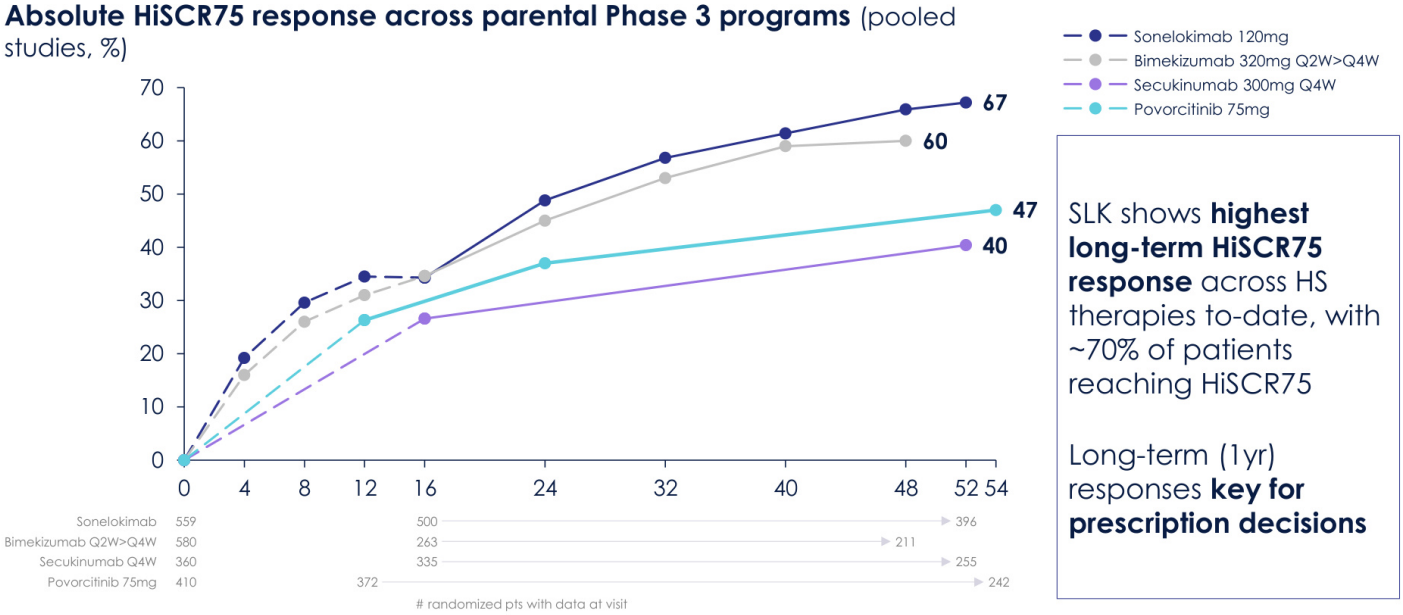
VELA program demonstrates **leading SLK long-term HiSCR75 efficacy**

Absolute HiSCR75 response across parental Phase 3 programs (pooled studies, %)



SLK shows **highest long-term HiSCR75 response** across HS therapies to-date, with ~70% of patients reaching HiSCR75

Long-term (1yr) responses **key for prescription decisions**

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Data shown as per length of parental trials: SLK and SEC 52-wk, BKZ 48-wk, POVO 54-wk; Data only from patients on continuous active treatment with (m)NRI until primary endpoint (dashed lines), then as observed (solid lines); Patient counts shown: Wk 0 counts were used for (m)NRI analyses, Week 12/16 and 48/52/54 counts are the respective number of patients at the beginning and end of the presented as observed analyses; Doses shown: SLK 120mg (ITT-mNRI until Week 16), BKZ 320mg Q2W until Wk 16 (ITT-mNRI, all-ABX) and Q4W thereafter, SEC 300mg Q4W (ITT-mNRI until Wk 16), POVO 75mg (NRI until Wk 12); ADA HiSCR75 AO data not available; BKZ data for Wks other than 16 and 48 estimated from a graph; BKZ data until Wk 16 refers to all patients with 320mg Q2W, as of Wk 16 refers to patients switching from Q2W to Q4W; Data subject to change until final CSR is issued; Sources: Kimball et al. EADV 2023, Porter et al. SHSA 2025; Porter et al. AAD 2026; Kimball A et al. Lancet 2024; 403:2504-2519; Zouboulis et al. EHSF 2026

Source: MoonLake Clinical

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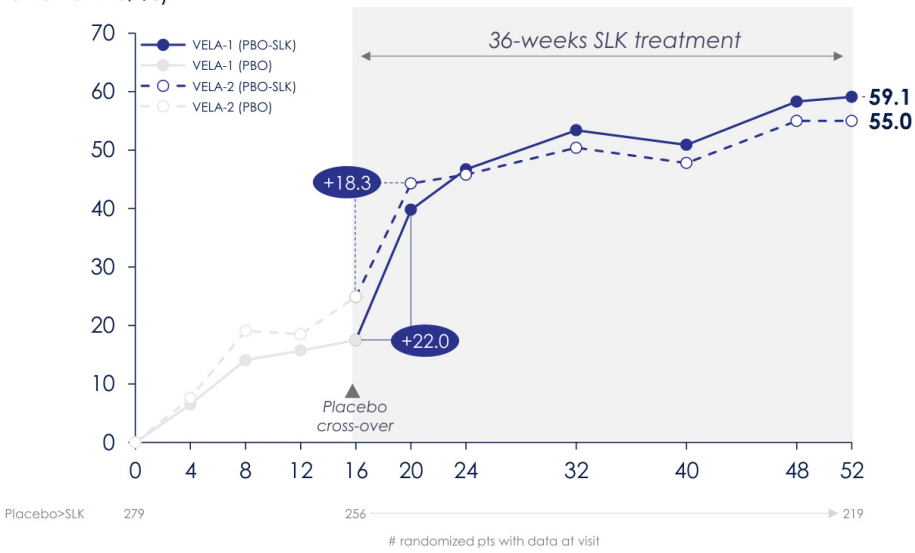
Crossover arms in VELA show **consistently high responses**

Absolute HiSCR75 response across parental VELA program (cross-over arms, %)



SLK responds **consistently across trials and arms** (including placebo to SLK cross-overs)

After 36 weeks of SLK treatment, patients who crossed over from **placebo achieved a response similar to that observed during the first 36 weeks** in patients treated with SLK from baseline (~60% HiSCR75)

SLK treatment **shows consistent responses** post cross-over, despite high placebo rate in VELA-2 at week 16

Data subject to change until final CSR is issued; Data shown: (m)NRI until primary endpoint (grey), then as observed (blue); Cross-over percentage point increase shown for "AO to AO"; Patient counts shown: Week 0 counts were used for (m)NRI analyses, Week 16 and 52 counts are the respective number of patients at the beginning and end of the presented as observed analyses

Source: MoonLake Clinical

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SLK shows the scorecard of a **potential best-in-class drug in HS**

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Parental trial responses (as observed)

		SLK with highest HS data to-date	**VELA** (pooled, active arms) n=396	**BE HEARD** (pooled, active arms) n=211	**Relative SLK advantage** in % increase in response
PE VELA[3]	HiSCR75, in %		67.2	60.2	11.6
HiSCR	HiSCR50, in %		78.0	80.6	-3.2
	HiSCR100, in %		33.1	28.9	14.5
IHS4	IHS4-55, in %		77.5	75.8	2.2
	IHS4-75, in %		62.9	59.2	6.3
	IHS4-100, in %		26.0	23.7	9.7
HiSQOL	Mean score difference between end of trial and baseline, absolute		-15.0[4]	-13.1[5]	14.5
DLQI	≥4-point improvement from baseline, in %[8]		72.2[6]	63.5[2]	13.7
Pain	≥3-point improvement from baseline, in %[1]		46.5[7]	NR	N/A

Across the scorecard, SLK achieves highest HS responses to-date

This is observed across **lesion efficacy scores and patient reported outcome efficacy** endpoints

1 in 3 patients reach HiSCR100 and **1 in 4** reach IHS4-100 (10%+ more than the competitor)

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Data subject to change until final CSR is issued; The VELA parental trials were 52-week while the Bimekizumab parental trials were 48-week studies; Doses shown: SLK-SLK 120mg, BKZ-BKZ 320mg (Q2W>Q4W); 1 Baseline worst skin pain score of ≥3; 2 n=178; 3 HiSCR75 was PE for VELA trials at Week 16; 4 Baseline HiSQOL of 27.2, n=558 for HiSQOL at baseline, n=395 for HiSQOL at Week 52; 5 Baseline HiSQOL of 24.5, n=292 at baseline (numbers with non-missing HiSQOL data not available); 6 n=363; 7 n=241; 8 Baseline DLQI of ≥4; PE, primary endpoint; Sources: HiSCR 50/75/100: Zouboulis EADV 2023; IHS4: Tzellos T et al. J Eur Acad Dermatol Venereol. 2026;doi:10.1111/jdv.70356; HiSQOL and DLQI: Shi V et al. Dermatol Ther. 2025;15:2553; Mayo SHSA 2023

Source: MoonLake Clinical

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SLK demonstrates a **favorable safety profile at Week 16**

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SLK advantageous versus IL-17A & F mAb

Treatment-emergent adverse events (TEAE), %	Week 16		
	VELA-1/-2 to Week 16		BE HEARD I/II to Week 16[1]
	Placebo patients N=279	Sonelokimab patients N=559	Bimekizumab 320 mg Q2W N=576[2]
Any TEAE	55.9%	67.6%	65.8%
Any Serious TEAE	1.8%	2.7%	2.6%
Any TEAE leading to treatment discontinuation	1.8%	3.4%	3.8%
Common TEAE[D]			
Hidradenitis	2.9%	2.3%	7.6%
Oral candidiasis	0.4%	7.3%	7.1%
Headache	5.0%	5.0%	6.9%
Diarrhea[A]	0.7%	2.9%	6.3%
TEAEs of interest SLK			
Serious infection	0.7%	0.7%	0.2%
Hepatic event[B]	0.7%	0.9%	2.4%
Definite or probable adjudicated inflammatory bowel disease (IBD)	0%	0%	0.2%
Adjudicated suicidal ideation and behavior (SIB)	0%	0%	0.2%
Serious hypersensitivity reaction[C]	0%	0%	0%
Adjudicated major adverse cardiovascular event (MACE)	0%	0%	0%

No IBD or SIB – hepatic events similar to placebo

SLK is observed to have a favorable safety profile without imbalances at Week 16 – enabling potentially a label without warnings of inflammatory bowel disease and suicidal ideation and behavior

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; SLK and BKZ comparison based on numerical incidence rates; Methods to describe safety events may differ (e.g., diarrhea); Data subject to change until final CSR is issued; 1 Kimball A et al. Lancet 2024; 403:2504-2519; 2 Pooled data from BKZ BE HEARD I/II Q2W dose arms until Week 16; A For SLK: Includes infectious (diarrhea infectious, viral diarrhea, bacterial diarrhea) and non-infectious diarrhea; B For SLK: SMQ Drug related hepatic disorders – comprehensive search (Narrow); C SMQ Hypersensitivity (Narrow); D Common TEAEs based on the most commonly reported in BE HEARD studies (excluding COVID-19)

Source: MoonLake Medical & Safety

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No new signals emerged post Week-16

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SLK advantageous versus IL-17A & F mAb

Treatment-emergent adverse events (TEAE), %	Week 52 / 48	
	VELA-1/-2 to Week 52	BE HEARD I/II to Week 48[1]
	All patients (SLK; Part A and B) N=816	BKZ Q4W maintenance (BKZ; Part A and B) N=576[2]
Any TEAE	80.5%	84.5%
Any Serious TEAE	6.5%	5.7%
Any TEAE leading to treatment discontinuation	4.4%	7.1%
Common TEAE[D]		
Hidradenitis	5.5%	20.8%
Oral candidiasis	12.4%	11.8%
Headache	6.3%	9.2%
Diarrhea[A]	3.9%	9.4%
TEAEs of interest SLK		
Serious infection	1.6%	1.2%
Hepatic event[B]	2.0%	4.0%
Definite or probable adjudicated inflammatory bowel disease (IBD)	0.1%	0.9%
Adjudicated suicidal ideation and behavior (SIB)	0.2%[E]	0.7%
Serious hypersensitivity reaction[C]	0%	0%
Adjudicated major adverse cardiovascular event (MACE)	0.2%	0.2%

SLK shows an advantageous long-term benefit-risk ratio, with **no new safety signals and low rates of SIB, IBD and Hepatic events**

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; SLK and BKZ comparison based on numerical incidence rates; Methods to describe safety events may differ (e.g., diarrhea); Data subject to change until final CSR is issued; 1 Kimball A et al. Lancet 2024; 403:2504-2519; 2 Pooled data from BKZ BE HEARD I/II Q2W/Q4W and Q4W/Q4W dose arms; A For SLK: Includes infectious (diarrhea infectious, viral diarrhea, bacterial diarrhea) and non-infectious diarrhea; B For SLK: SMQ Drug related hepatic disorders – comprehensive search (Narrow); C SMQ Hypersensitivity (Narrow); D Common TEAEs based on the most commonly reported in BE HEARD studies (excluding COVID-19); E Adjudicated as not-related

Source: MoonLake Medical & Safety

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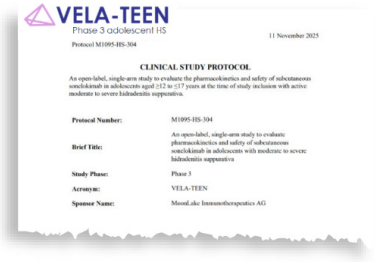
VELA-TEEN **met** its endpoint


VELA-TEEN
Phase 3 adolescent HS
11 November 2025
Protocol M1095-HS-304
CLINICAL STUDY PROTOCOL
An open-label, single-arm study to evaluate the pharmacokinetics and safety of subcutaneous sonelokimab in adolescents aged ≥12 to ≤17 years at the time of study inclusion with active moderate to severe hidradenitis suppurativa
Protocol Number: M1095-HS-304
Brief Title: An open-label, single-arm study to evaluate pharmacokinetics and safety of subcutaneous sonelokimab in adolescents with moderate to severe hidradenitis suppurativa
Study Phase: Phase 3
Acronym: VELA-TEEN
Sponsor Name: MoonLake Immunotherapeutics AG

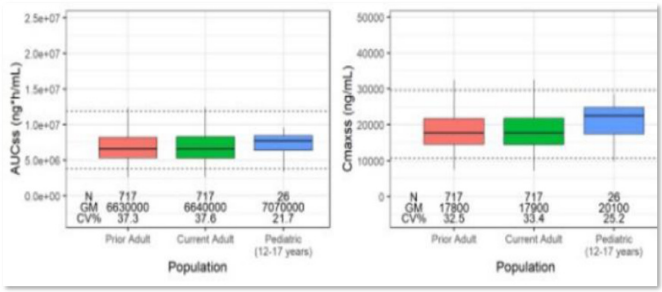
Co-primary endpoints:

- **PK**
- **Safety** (signal detection)

Study enrollment completed (n=35)

PK analysis of VELA-TEEN – results

- Results indicate that **adolescent estimates are within the range of adult exposures** and are **supportive of exposure matching**
- Adolescent data show **less variability than the adult dataset**
- Given adolescent exposures are likely to be within the adult 90% CI **no new dose-limiting toxicities were anticipated**



C_{max} and AUC_{ss} at steady state from analysis of adolescent (blue bar) compared to adult (green and red bar) PK data

Prior Adult model: based on all Phase I and Phase II data, including MIRA. Current Adult model: updated model including VELA Week 16 data.

Source: MoonLake Regulatory

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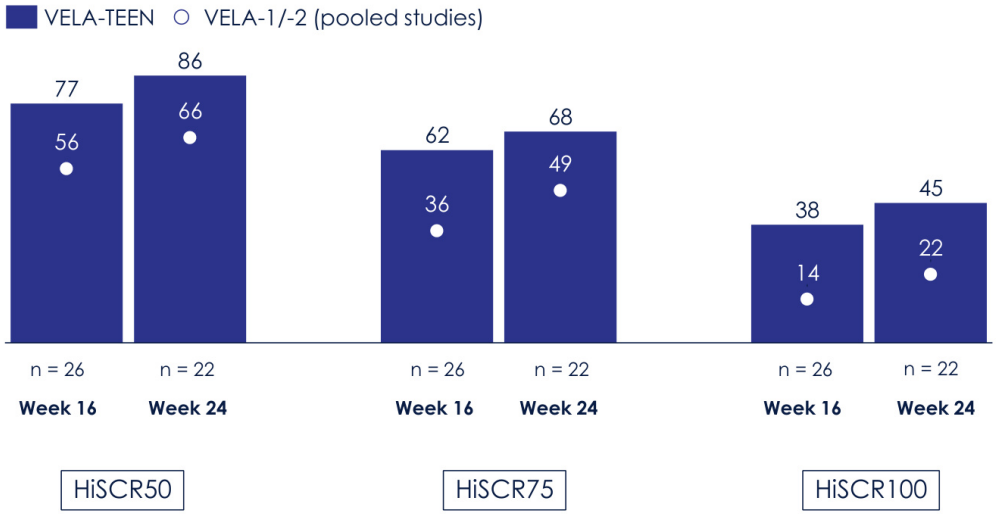
SLK shows **rapid onset and high response rates** in adolescents

HiSCR response rates over time (in % of patients, as observed)



VELA-TEEN is the **only dedicated study in adolescent HS** to date and demonstrates **breakthrough efficacy with SLK** – almost 70% of adolescents achieve HiSCR75 at Week 24, 45% reach HiSCR100

Total participants at each timepoint; VELA-TEEN trial is ongoing with the number of participants reaching W16 and W24 expected to increase over time; VELA-TEEN and VELA-1/-2 as observed data at Week 16 and Week 24; Data subject to change until final CSR is issued

Source: MoonLake Clinical

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VELA-TEEN data shows **favorable safety profile with no new signals**

Treatment-emergent adverse events (TEAE), n (%)	VELA-TEEN to Week 28
	Sonelokimab 120 mg N=35[1]
Any TEAE	17 (48.6)
Any Serious TEAE	0
Any TEAE leading to discontinuation	1 (2.9)
Most frequent TEAEs of SLK (≥5% with active treatment)	
Oropharyngeal pain	4 (11.4)
Nasopharyngitis	3 (8.6)
Injection site reaction	3 (8.6)
Acne	2 (5.7)
Oral candidiasis	2 (5.7)
Vulvovaginal candidiasis	2 (5.7)
Pruritus	2 (5.7)
TEAEs of interest	
Dermatitis	1 (2.9)
Eczema	0
Serious infection	0
Diarrhea (non-infectious)	1 (2.9)
Hepatic event	0
Inflammatory bowel disease (IBD)	0
Suicidal ideation and behavior (SIB)	0
Serious hypersensitivity	0
Major adverse cardiovascular event (MACE)	0

Data subject to change until final CSR is issued; 1 VELA-TEEN trial is ongoing – not all patients reached Week 28 yet

Source: MoonLake Medical & Safety

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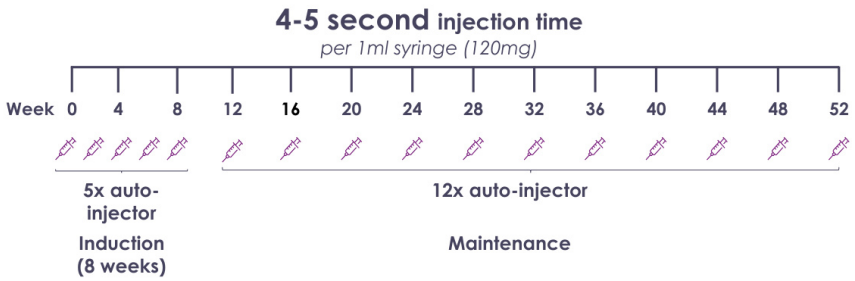
Convenience: SLK offers convenience in induction and maintenance

Sonelokimab dosing regimen is advantageous



Available treatment options with **up to 18 syringes in induction phase, longer induction phase (4 months)** and **longer injection time (up to 25 seconds)**

These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations.

Source: MoonLake Medical, BKZ Instructions for Use and FDA label

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BLA strategy

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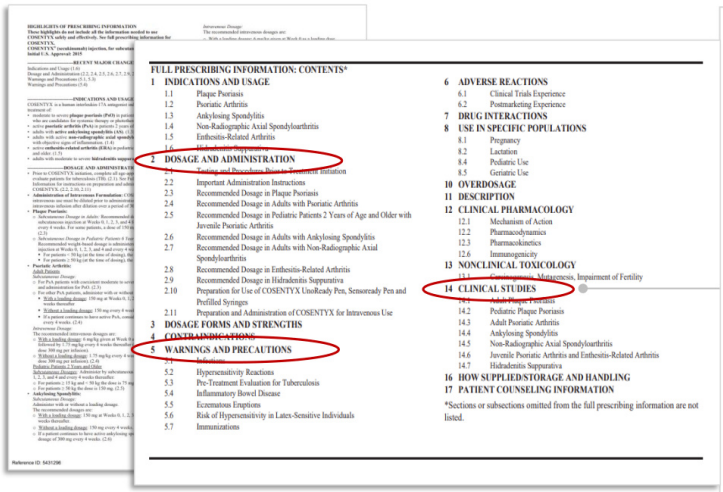
What matters in a label: Sections 14, 5 and 2

FDA label example, *secukinumab example*



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- 1.6 Hidradenitis Suppurativa

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16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

Potential areas of differentiation

Section 14 **Clinical response of trials incl. supplementary text, figures and additional clinical data –** enabling potential differentiation on efficacy and PROs (where SEE is primarily reflected), competitors only with HiSCR

Section 5 **Warnings and precautions –** enabling potential differentiation of safety-benefit ratio

Section 2 **Required dosing scheme –** enabling potential differentiation in number, time and volume of injections

Source: MoonLake Regulatory

Competitor data leaves **space for SLK to compete** as the leading drug

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Section 14

p-values are not included in respective labels

Delta-to-placebo not shown in SEC label

...ase at Week 16 (Trials HS-1 and HS-2)

...trials, a higher proportion of BIMZELX-treated subjects achieved HiSCR50 and HiSCR75 compared to placebo (see Table 11).

Table 11: Efficacy Results in Adults with HS in Trials HS-1 and HS-2 at Week 16 [a]

	Trial HS-1		Trial HS-2	
	BIMZELX 320mg Q2W (N=289)	Placebo (N=72)	BIMZELX 320 mg Q2W (N=291)	Placebo (N=74)
HiSCR50	48%	29%	52%	32%
Difference (95% CI)	18% (6%, 30%)		20% (8%, 32%)	
HiSCR75	33%	18%	36%	16%
Difference (95% CI)	15% (4%, 27%)		20% (10%, 31%)	

[a] Subjects who initiated systemic antibiotics (new antibiotic or change in the dose/type of current antibiotic) for any reason or who discontinued due to adverse event or lack of efficacy are treated as non-responders at all subsequent visits. Other missing data were imputed via multiple imputation.

Bimzelx® (bimekizumab)

...Clinical Response at Week 16 in Adults with Hidradenitis Suppurativa in HS Trial 1 and HS Trial 2[1]

	HS Trial 1			HS Trial 2		
	Placebo (n = 180)	COSENTYX 300 mg every 4 weeks[2] (n = 180)	COSENTYX 300 mg every 2 weeks[2] (n = 181)	Placebo (n = 183)	COSENTYX 300 mg every 4 weeks[2] (n = 180)	COSENTYX 300 mg every 2 weeks[2] (n = 180)
HiSCR50	29.4%	41.3%	44.5%*	26.1%	42.5%*	38.3%*

[1] Multiple imputation was implemented for missing data.
[2] Subjects received COSENTYX 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks (Q4W) or every 2 weeks (Q2W).
*Statistically significant versus placebo based on the pre-de...

Cosentyx® (secukinumab)

SEC does **not demonstrate statistical significance** for the 300 mg Q4W dose arm in its label

Section 5

5 WARNINGS AND PRECAUTIONS
5.1 Suicidal Ideation and Behavior
An increased incidence of new onset or worsening suicidal ideation and behavior was observed in subjects treated with BIMZELX. A causal association between treatment with BIMZELX and increased risk of suicidal ideation and behavior has not been definitively established.

Suicidal ideation and behavior were prospectively monitored using the Columbia Suicide Severity Rating Scale (C-SSRS) in clinical trials. The C-SSRS is an interview-based instrument used to monitor for the presence and severity of suicidal ideation (ranging from "none" to "active suicidal ideation with specific... plan and intent") and behaviors (rating the injury and potential lethality...

5 WARNINGS AND PRECAUTIONS
5.1 Infections
COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe PsO, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed in subjects treated with COSENTYX compared to placebo-treated subjects. A similar increase in risk of infection in subjects treated with COSENTYX was seen in placebo-controlled trials in subjects with PsA, AS and nr-axSpA. The incidence of some types of infections, including fungal infections, appeared to be dose-dependent in clinical trials *[see Adverse Reactions (6.1)]*.

Warnings and precautions related to SIB, IBD, Liver and others

Section 2

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Evaluations and Immunization Prior to Treatment Initiation
- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX *[see Warnings and Precautions (5.3)]*.
- Test liver enzymes, alkaline phosphatase and bilirubin prior to initiating treatment with BIMZELX *[see Warnings and Precautions (5.4)]*.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines *[see Warning and Precautions (5.6)]*.

2.2 Recommended Dosage for Plaque Psoriasis
The recommended dosage is 320 mg by subcutaneous...

2 DOSAGE AND ADMINISTRATION
2.1 Testing and Procedures Prior to Treatment Initiation
Perform the following evaluations prior to COSENTYX initiation:
- Evaluate for active or latent tuberculosis (TB). COSENTYX initiation is not recommended in patients with active TB infection. Initiate treatment of latent TB prior to initiation of COSENTYX *[see Warnings and Precautions (5.3)]*.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with COSENTYX *[see Warnings and Precautions (5.7)]*.

2.2 Important Administration Instructions
- COSENTYX is for use under the guidance and supervi...

Source: MoonLake Regulatory

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Building on feedback, this is our **base scenario for Sec. 14 table**

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Efficacy data relevant for potential label *(in brackets delta to placebo)*	**SLK proposed table for Sec. 14**		**IL-17A and F mAb**	
	HS trial 1 *(Corresponds to VELA-1)*	**HS trial 2** (Corresponds to MIRA)	HS trial 1	HS trial 2
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)	**33** (15)	**36** (20)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)	**48** (18)	**52** (20)
Pain NRS-3, %	*These endpoints likely as narrative points of Section 14*		*Note on improvement in patient-reported worst skin pain (lesion pain) compared to placebo at Week 16 (despite not meeting stat sig in BH1 and for one dose in BH2)*	
HiSQOL, CfB[1]			*No HiSQOL, no IHS4 notes*	
IHS4-55, %				

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 pp**)*

For illustrative purposes only; Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Potential label options for sonelokimab reflecting MLTX's current views based on data and prior regulatory correspondence; Absolute responses shown, delta to placebo in brackets; Data reflects composite strategy (ITT-mNRI) for VELA and ITT-NRI for MIRA; VELA-1 and VELA-2 results for Week 16, MIRA results for Week 12; IHS4-55, Pain NRS-3, HiSQOL were not ranked endpoints in MIRA; Bimekizumab data as per FDA label for HS (Section 14); Data subject to change until final CSR is issued; 1 Baseline numbers would be included

Source: MoonLake Regulatory

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"Upside case" also includes other HS responses in Sec. 14 table

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Efficacy data relevant for potential label *(in brackets delta to placebo)*	**SLK proposed table for Sec. 14**		**IL-17A and F mAb**	
	HS trial 1 *(Corresponds to VELA-1)*	**HS trial 2** *(Corresponds to MIRA)*	HS trial 1	HS trial 2
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)	**33** (15)	**36** (20)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)	**48** (18)	**52** (20)
Pain NRS-3, %	**28.3** (16.8)	**22.0** (19.9)		
HiSQOL, CfB[1]	**-8.7** (-5.7)	**-9.4** (-4.4)		
IHS4-55, %	**53.3** (19.4)	**62.7** (33.3)		

Note on improvement in patient-reported worst skin pain (lesion pain) compared to placebo at Week 16 (despite not meeting stat sig in BH1 and for one dose in BH2)

No HiSQOL, no IHS4 notes

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 ppt**)*
"Upside case" would feature specific PRO results for **first time in an HS label**

For illustrative purposes only; Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Potential label options for sonelokimab reflecting MLTX's current views based on data and prior regulatory correspondence; Absolute responses shown, delta to placebo in brackets; Data reflects composite strategy (ITT-mNRI) for VELA and ITT-NRI for MIRA; VELA-1 and VELA-2 results for Week 16, MIRA results for Week 12; IHS4-55, Pain NRS-3, HiSQOL were not ranked endpoints in MIRA; Bimekizumab data as per FDA label for HS (Section 14); Data subject to change until final CSR is issued; 1 Baseline numbers would be included

Source: MoonLake Regulatory

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SLK has **further differentiation potential** in Sec. 5 and Sec. 2

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	Bimzelx® (bimekizumab)	Cosentyx® (secukinumab)	SLK differentiation potential
Section 5 Warnings and Precautions	▪ *Suicidal Ideation and Behavior* ▪ *Infections* ▪ *Tuberculosis* ▪ *Liver Biochemical Abnormalities* ▪ *Inflammatory Bowel Disease* ▪ *Immunization*	▪ *Infections* ▪ *Hypersensitivity Reactions* ▪ *Pre-Treatment Evaluation for Tuberculosis* ▪ *Inflammatory Bowel Disease* ▪ *Eczematous Eruptions* ▪ *Risk of Hypersensitivity in Latex-Sensitive Individuals* ▪ *Immunization*	✓ No TEAEs of SIB reported in controlled part of trial[1]. C-SSRS validated for risk identification/monitoring responses ✓ No signal for hepatic events including elevated transaminases in SLK clinical trials ✓ No signal for IBD in SLK trials ✓ No evidence of association between IL-17 inhibition and TB reactivation. Clinical trials and post-marketing data show no increased TB risk
Section 2 Dosage and Administration	▪ *320 mg by subcutaneous injection* ▪ *Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter*	▪ *300 mg by subcutaneous injection* ▪ *Weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter* ▪ *If patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks*	✓ Low injection volume: 120mg subcutaneous injection ✓ Few induction injections: 5 injections for induction period ✓ Short induction duration: 8 weeks induction period
Additional potential differentiation points			✓ *Low eczema and dermatitis signals long-term* ✓ *Lower diarrhea rates*

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; 1 Two TEAEs of SIB reported after controlled part of the trial (post Week 16) – both adjudicated as not-related

Source: MoonLake Regulatory

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VELA-TEEN provides **potential for Priority Review** of the HS BLA

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FDA Priority Review

Priority Review

Prior to approval, each drug marketed in the United States must go through a detailed FDA review process. In 1992, under the Prescription Drug User Act (PDUFA), FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – *Standard Review* and *Priority Review*. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

A *Priority Review* designation will direct overs[illegible]

Eligibility criteria:

1. "Evidence of **increased effectiveness** in treatment, prevention, or diagnosis of condition"
2. "Elimination or substantial **reduction of a treatment-limiting drug reaction"**
3. **"Documented enhancement of patient compliance** that is expected to lead to an **improvement in serious outcomes**"
4. **"Evidence of safety and effectiveness in a new subpopulation**"

- High unmet need exists across adolescent HS population with **limited approved treatment options for adolescent patients**[1]
- **VELA-TEEN is the first dedicated study** in adolescent HS patients (no extrapolation)
- **Designation of Priority Review is not guaranteed –** potential FDA capacity constraints
- MLTX therefore sees granting of a Priority Review for the HS BLA as **an "upside case"**

1 Secukinumab received FDA approval for adolescent HS population in March 2026

Source: MoonLake Regulatory

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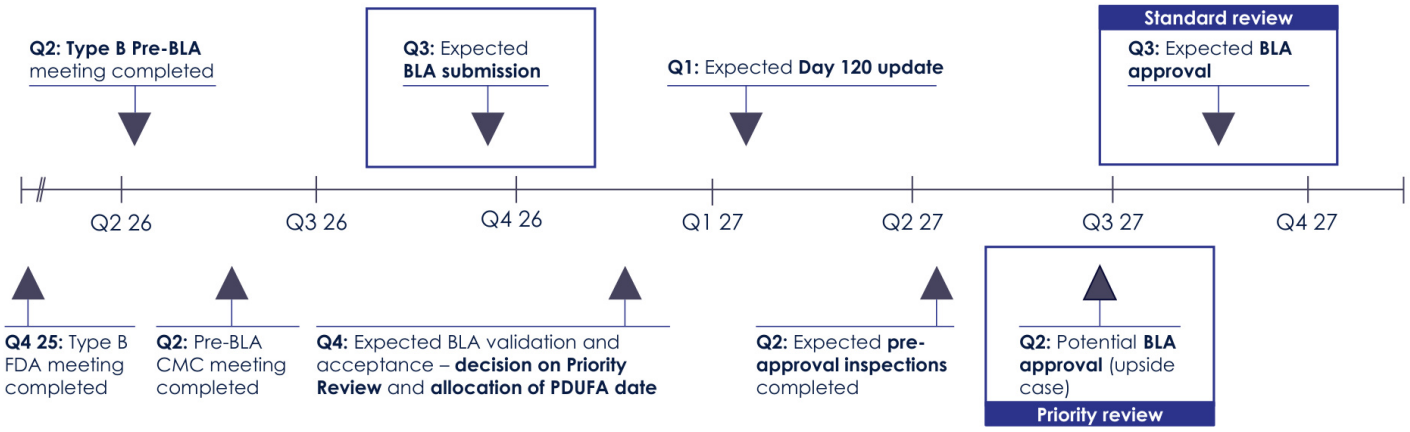
HS BLA timeline: BLA acceptance expected by end of November 2026



FDA pre-BLA process expected to be fully completed with submission at **end of Sep 2026**
Granting of PDUFA date as well as decision on Priority Review expected at **end of Nov 2026** – potentially accelerating SLK launch by **~4 months**

Timeline not scaled; All future milestones are anticipated dates; PDUFA, Prescription Drug User Fee Act

Source: MoonLake Regulatory

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Commercializing SLK in HS

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Continued growth in real-world data confirms **market potential at $10bn+**

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Market trends continue to show strong growth & large potential

Large existing prevalence:
Unique diagnosed & treated patients[1]

~2.9m in Q1 2026
(+25% vs Q4 2015)

Strong growth in new patients:
New diagnosed and treated pts. (previously undiagnosed)[2]

~310k
(LTM Q1 2026)

Higher prices in HS:
List price of approved HS dose of Bimekizumab

$217k
(2026)

Penetration still low
Share of biologics in treated patients in Q1'26 vs Q4'23

Still 3%
(growing as fast diagnosis)

Market potential now consistently understood to be $10bn+

MoonLake

2035 $10-15bn

US HS Biologics Market

- Prevalence at 2% in 2035
- Biologics use increasing (30% YoY)
- HS with 2x price level vs. PsO

UCB

2035 $10bn+

HS Biologics Market

Estimated to be $5B by 2029

avalo THERAPEUTICS

2035 $10bn+

US HS Biologics Market

- >200k treated with biologics 2035
- Prevalence 2026 3.4m patients

COWEN

OPPENHEIMER

CANTOR Fitzgerald

2035 $10bn+

US HS Biologics Market

"…potential for a commercial opportunity in excess of $10bn+, and capable of supporting multiple blockbuster therapies"

Diagnosed & treated patients with HS diagnosis (ICD-10 L73.2); Applied ~75% coverage rate of U.S. claims; Applied claims collection lag extrapolation for last 12 months; 1 Patients ≥18 years with a HS diagnosis; 2 Net new diagnosed HS patients

Source: Company information. Analyst research. MoonLake IR. Unique U.S. patients from prescription data, MoonLake Commercial. © 2026 Komodo Health, Inc. All rights reserved

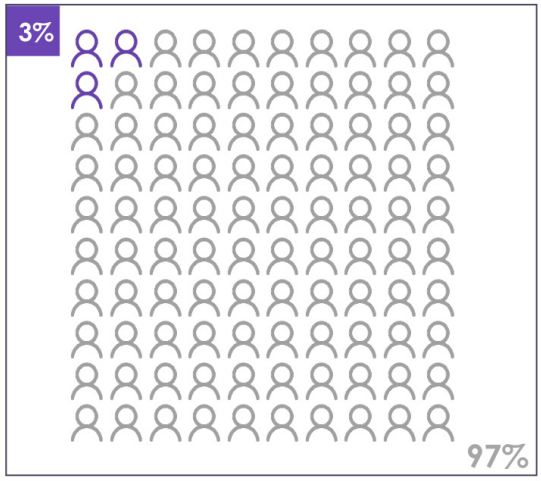
HS is a naïve market with **great conditions for a biotech launch**

HS is a naïve market where the leading drug is not defined

Only 3% of HS patients treated with biologics today: *players not going to fight over the same treated patients (not a "switch market" any time soon)*

The jury is still out for the leading drug: *research shows that prescribers look for a balanced profile with strong efficacy and safety*

+2.9m patients diagnosed with HS *in the US*



HS is an attractive market for Biotech

- In contrast to other major I&I markets, HS with **limited number of drugs available**
- Due to limited treatment options and irreversible tissue damage, **HS less closely managed by payors** and with high medical exception rates
- **1L drugs with limited efficacy or limited durability** (e.g., Humira median time on therapy: 11 months)
- **Highly concentrated prescriber base** enabling focused GTM approach
- **1/3 of launches** now done by Biotechs (not Pharma) in last 5 years[1]
- **75% of Biotech launches** above expectations in last 5 years[2,3]

1 Based on McKinsey report published November 2024; and additional MLTX analyses for the 2024-26 period; 2 First-time launches since 2016 based on Evaluate Pharma database analysis as of May 2026 – with minimum peak based on latest actuals/estimates of at least $1000m in the US; 3 Based on expectations at launch vs. actuals of first 3 calendar years (incl. first partial year)

Source: MoonLake Commercial, Cantor, Evaluate Pharma, Unique U.S. patients from prescription data; MoonLake Commercial, © 2026 Komodo Health, Inc. All rights reserved. MMIT 2026

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US prescribers look for a **balanced profile** to treat HS patients

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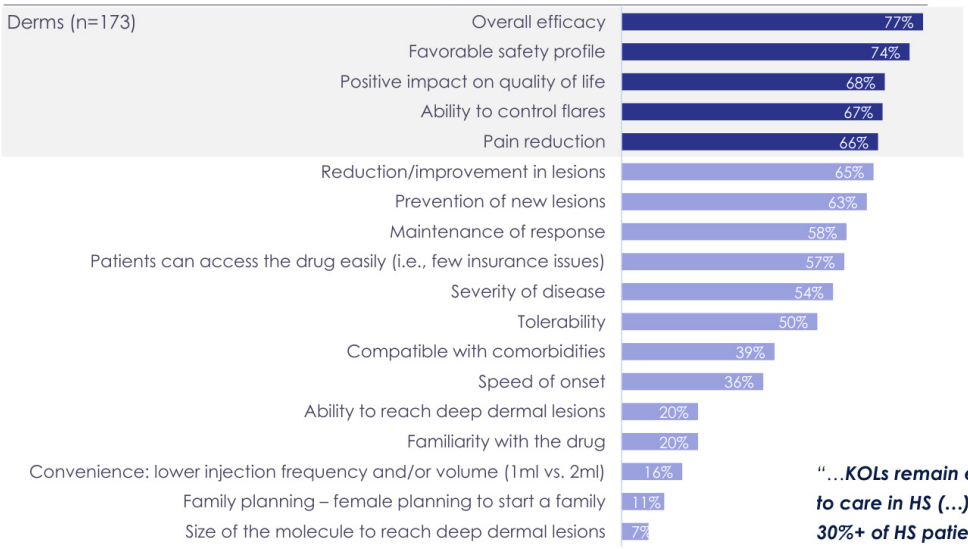
US Derm market research ranked important attributes for Bx selection in HS



Dermatologists report **significant remaining unmet medical need**

Dermatologists look for a **balance between high efficacy** (focus on absolute response rates, quality of life, pain) **and a favorable safety profile** (Cosentyx considered "safest option" among approved drugs)

A **conjoint analysis** (n=250)

- ~25% of physicians intend to prescribe SLK based on current data (Week 16 and full-year data)
- Advantages "re": Liver monitoring, inclusion of pain or HiSQoL data or "lighter" warnings will make SLK the leading prescribed drug

"…KOLs remain enthusiastic about SLK's potential to contribute to care in HS (…) surveyed physicians expect to use SLK in 30%+ of HS patients."

TD Cowen
a division of TD Securities

Survey results were derived from the question "Which of the following attributes are important in your decision when selecting a biologic treatment for moderate to severe HS? Select ten factors"

Source: US Dermatology Survey Fielded August 2025 (n=173); US Dermatology Conjoint Study Fielded between December 2025 and February 2026 (n=250); TD Cowen research (May 11, 2026)

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We are **on track** to seize the opportunity in HS in the US

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Groundwork for commercialization is established

- ✓ **US entity incorporated**
- ✓ **Distribution operation setup** (state licenses, 3PL / SP setup, serialization, 1st commercial batches ready)
- ✓ **Strategic positioning and GTM model** with focus on access pull through, incl. pricing model
- ✓ **Collaboration network** with top decile KOLs, patient advocacy groups and HS Foundation
- ✓ **Market access partnership planning** with key decision makers at payors and PBMs
- ✓ **Creation of brand identity** (name and visuals)

Expected milestones ahead

- **US headquarters** location announcement
- **US leadership** appointment
- **Commercial team expansion** including setup of a pre-launch field team
- **Expansion of full US team** including access, medical & marketing (to total of ~150 FTE)
- **Lock unique MLTX partnerships** with key stakeholders such as PBMs, payors
- **Pre-launch campaign** ramp-up
- More commercial **batch manufacturing**

Balance sheet provides runway to the end of 2027 + access to up to $400m from facility with Hercules Capital

Source: MoonLake Commercial

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Closing remarks

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MLTX has gathered the data to propose **a leading label**

Key label sections	SLK potential competitive position
Section 14 *Clinical studies*	Strongest HiSCR75 absolute response on label and inclusion of adolescent patients (as of 12 years of age) – expected SLK delta-to-placebo of 22-23 pp
Section 5 *Warnings & precautions*	No signal observed for SIB, hepatic events or TB reactivation – possible advantages also in other dimensions, e.g., diarrhea, IBD
Section 2 *Dosage & administration*	Convenient dosing and administration versus competitor mAb – fewer injections, shorter induction vs currently available therapies to make it easier for patients and physicians

Source: MoonLake Corporate Strategy

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Overall SLK data in HS supports **strong payor value story**

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SLK demonstrates potential for leadership in HS

Relative advantage vs. IL-17A/F competitor – in % increase in response, as observed end of parental trial data

Efficacy	HiSCR75	12
	HiSCR100	15
	IHS4-100	10
PROs	HiSQOL	15
	DLQI	14
	Pain	*No equivalent data*

Clear potential for a leading HS label

SLK proposed table for Sec. 14

Efficacy data relevant for potential label *(in brackets delta to placebo)*	**HS trial 1** *(Corresponds to VELA-1)*	**HS trial 2** *(Corresponds to MIRA)*
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)
Pain NRS-3, %	**28.3** (16.8)	**22.0** (19.9)
HiSQOL, CfB[1]	**-8.7** (-5.7)	**-9.4** (-4.4)
IHS4-55, %	**53.3** (19.4)	**62.7** (33.3)

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 ppt**)*
"Upside case" would feature specific PRO results for **first time in an HS label**

Proposed label – subject to FDA review

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; The VELA parental trials were 52-week while the Bimekizumab parental trials were 48-week studies; Doses shown: SLK-SLK 120mg, pooled, as observed, n=396 (Baseline HiSQOL of 27.2, n=558 for HiSQOL at baseline, n=395 for HiSQOL at Week 52; n=363 for DLQI; n=241 for pain), BKZ-BKZ 320mg, pooled, as observed, n=211, Q2W>Q4W (HiSQOL: Baseline HiSQOL of 24.5, n=292 at baseline (numbers with non-missing HiSQOL data not available); DLQI: n=178); HiSQOL: Mean score difference between end of trial and baseline; DLQI definition: ≥4-point improvement from baseline, baseline DLQI of ≥4; Pain: ≥3-point improvement from baseline, baseline worst skin pain score of ≥3; Data subject to change until final CSR is issued; Sources: HiSCR 75/100: Zouboulis EADV 2023; IHS4: Tzellos T et al. J Eur Acad Dermatol Venereol. 2026;doi:10.1111/jdv.70356; HiSQOL and DLQI: Shi V et al. Dermatol Ther. 2025;15:2553; Mayo SHSA 2023

Source: MoonLake Corporate Strategy

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Catalyst-rich year: Rheumatology (PsA) starts reading pivotal data soon

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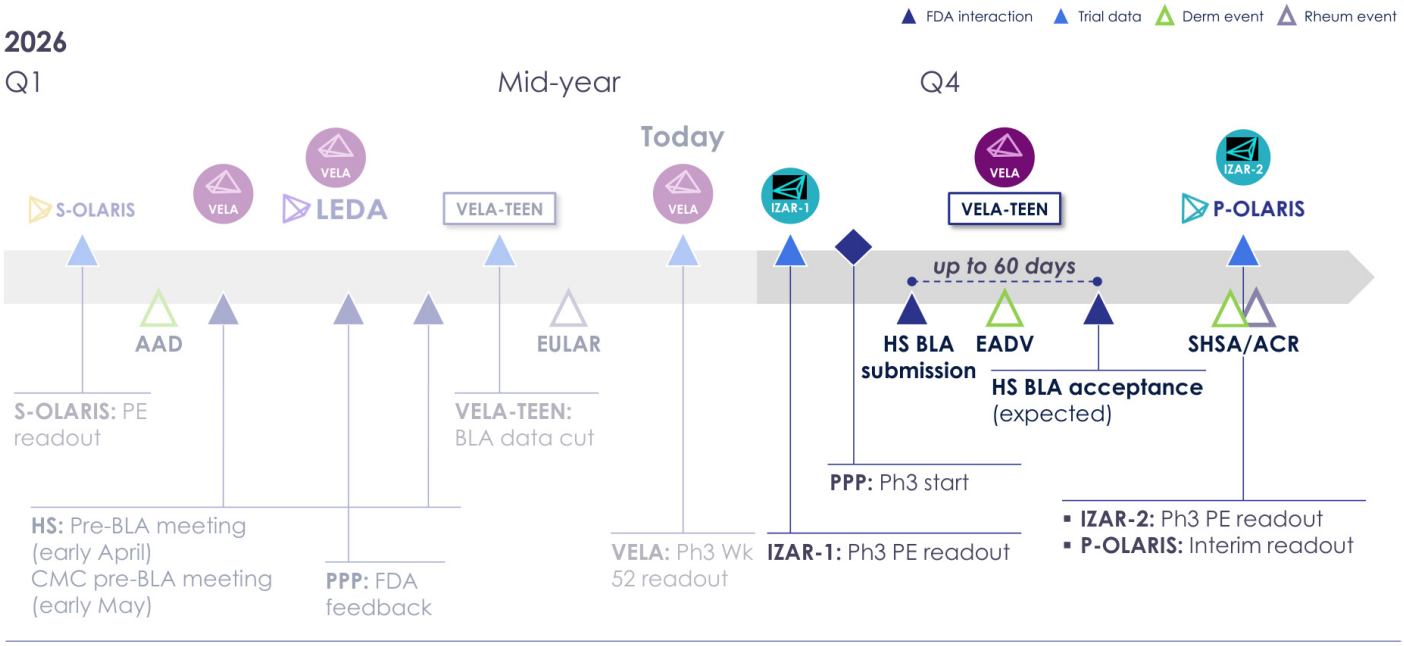

Timeline not scaled, non-exhaustive; All future milestones are anticipated dates

Source: MoonLake Corporate Strategy

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What to expect from the **IZAR-1 readout in PsA**

General disclosures in PsA

- **Recent disclosures of PsA data, e.g., bimekizumab showed only limited information –** mainly focusing on "stat sig" descriptions without disclosing absolute results of active or placebo arm
- This is usual, to **avoid unduly unblinding** the studies and is a prerogative of the FDA
- Specific guidance from **FDA is to not disclose any comparative data –** protecting integrity of data collected after read-out

Expected disclosures on IZAR-1

Disclosures expected in a **Q3 2026 press release**, incl. "met" vs. "did not meet" endpoint reference, in line with prior competitor disclosures

Disclosure of **absolute responses across key endpoints** (incl. ACR50, MDA, PASI90) is expected for SLK 60mg (with induction), ensuring deeper understanding of data vs. usual disclosure of peers

Aligned approach to keep blinding across the various 52-week arms – IZAR-1 (3 arms) and IZAR-2 (4 arms)

Responses across different endpoints, in the IZAR-1 bio-naïve population, in line with ARGO are a **clear success for SLK**

In PsA, **absolute response levels are key** as the placebo is heavily influenced by concomitant medications (e.g., methotrexate)

Source: MoonLake Corporate Strategy

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Q & A

Please submit your questions via the dedicated Q&A function in the portal

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