
**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): May 5, 2026

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37590
(Commission File Number)

45-0705648
(IRS Employer Identification No.)

1500 Liberty Ridge Drive, Suite 321, Wayne, Pennsylvania 19087

(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (410) 522-8707

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:

- 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 |
|---------------------------------|-------------------|---|
| Common Stock, \$0.001 Par Value | AVTX | 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 8.01 Other Events.

On May 5, 2026, Avalo Therapeutics, Inc. (the “Company”) issued a press release announcing positive topline results from its Phase 2 LOTUS trial evaluating the efficacy, safety and tolerability of abdakibart in patients with moderate to severe hidradenitis suppurativa. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, except paragraphs two and five.

On May 5, 2026, the Company posted a presentation to its website relating to the positive topline results from the Phase 2 LOTUS trial. A copy of the presentation is filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1 and 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

The following exhibits are being filed herewith:

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release, dated May 5, 2026. |
| 99.2 | Presentation, dated May 5, 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.

AVALO THERAPEUTICS, INC.

Date: May 5, 2026

By: /s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer



Avalo Therapeutics Achieves Positive Topline Results in Phase 2 LOTUS Trial of Abdakibart (AVTX-009) in Moderate to Severe Hidradenitis Suppurativa

- *Successfully met primary endpoint of HiSCR75 for both doses studied, demonstrating response rates of 42.2% for 150 mg dose ($p=0.018$) and 42.9% for 300 mg dose ($p=0.015$) at Week 16, which are the highest rates observed in a trial of this size or larger*
- *Statistically significant benefit was demonstrated on key secondary endpoints of HiSCR50, change in IHS4 and change in draining tunnel count*
- *Abdakibart was well tolerated with a favorable safety profile*
- *Avalo plans to advance abdakibart into a registrational phase 3 program*

WAYNE, PA, May 5, 2026 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company fully dedicated to developing IL-1 β based treatments for immune-mediated inflammatory diseases, today announced positive topline results from its Phase 2 LOTUS trial evaluating the efficacy and safety of abdakibart in adults with moderate to severe hidradenitis suppurativa (HS). The LOTUS trial successfully met its primary endpoint at both doses studied. Based on these data, Avalo plans to advance abdakibart into a registrational phase 3 program.

"We are proud to report that abdakibart has delivered a strong, consistent, and deep response across both the HiSCR75 and HiSCR50 endpoints in our Phase 2 trial. This achievement powerfully validates the clinical promise of IL-1 β inhibition for hidradenitis suppurativa," said Garry Neil, MD, Chief Executive Officer of Avalo Therapeutics. "This de-risking data set gives us tremendous confidence to advance abdakibart into a pivotal phase 3 registrational program. With a differentiated and patient friendly potential monthly dosing regimen, we aim to offer a truly innovative mechanism of action to the HS community. Our heartfelt thank you goes to the patients, caregivers, investigators, and site teams whose dedication made this successful Phase 2 trial possible."

The LOTUS trial (NCT06603077), which enrolled 253 adults, was a randomized, double-blind, placebo-controlled parallel-group Phase 2 trial to evaluate the efficacy, safety and tolerability of abdakibart across two dose regimens and placebo in a 1:1:1 ratio over a 16-week treatment period. Subjects received either a 600mg loading dose of abdakibart followed by 300mg every four weeks or a 300mg loading dose followed by 150mg every two weeks. The trial's primary efficacy endpoint was the proportion of patients achieving HiSCR75 at Week 16.

The Phase 2 LOTUS trial successfully met its primary endpoint at both doses studied ($p=0.018$ 150mg, $p=0.015$ 300mg and $p=0.004$ combined), demonstrating a 42.2% and 42.9% absolute improvement in HiSCR75 response rates at Week 16, respectively (42.5% combined, placebo rate 25.6%). This was the highest absolute improvement in HiSCR75 and HiSCR50 in clinical trials of this size or larger at each individual dose and on a combined dose basis. Abdakibart regimens also demonstrated statistically significant benefit across the key secondary endpoints in HiSCR50, change in IHS4 and change in draining tunnel count. Numerically favorable responder rates were observed across all other key secondary endpoints. The HiSCR75 response was similar in patients with and without prior biologic exposure.

"These Phase 2 results are highly promising for the HS community," said Dr. John Frew, Professor of Dermatology, University of New South Wales, Sydney, Australia. "Achieving this level of improvement suggests that IL-1 β inhibition with abdakibart may offer a meaningful new therapeutic option for people with HS who continue to struggle with this disease. The physical and emotional burden of HS is profound, and I am encouraged to see an investigational therapy showing such robust and clinically relevant results."

Across the study, abdakibart was well tolerated. The percentage of subjects with treatment-emergent adverse events (TEAE) were similar across abdakibart treatment arms and placebo with the most common being headache and nausea. Most adverse events were mild to moderate, and no unexpected safety findings emerged during the 16-week treatment period. There were no adverse events related to neutropenia, serious infections, or opportunistic infections.

Avalo expects to present full results from the LOTUS trial at an upcoming medical congress.

About Avalo Therapeutics

Avalo Therapeutics (Nasdaq: AVTX) is a clinical stage biotechnology company fully dedicated to developing IL-1 β -based treatments for immune-mediated inflammatory diseases. Our lead asset, abdakibart, is an anti-IL-1 β monoclonal antibody (mAb). Positive topline data was recently reported for abdakibart in a Phase 2 clinical trial in hidradenitis suppurativa (HS). We're also exploring additional opportunities to make an impact in prevalent indications that have significant remaining unmet needs. For more information about Avalo, please visit www.avalotx.com.

About Abdakibart

Abdakibart is a humanized monoclonal antibody (IgG4) that binds to interleukin-1 β (IL-1 β) with high affinity and neutralizes its activity. IL-1 β is a pro-inflammatory cytokine that plays a central role in the pathogenesis of a wide range of human diseases.¹ It activates immune cells that generate proinflammatory cytokines, including IL-6, TNF- α , and IL-17. Dysregulated IL-1 β signaling is a major driver of inflammation, contributing to the progression of autoimmune disorders. IL-1 β inhibition has proven effective in multiple immune-mediated inflammatory diseases.¹⁻³

About the LOTUS Trial

The LOTUS trial is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two dose regimens to evaluate the efficacy, safety and tolerability of abdakibart in approximately 250 adults with moderate to severe hidradenitis suppurativa. Subjects were randomized (1:1:1) to receive either one of two dosing regimens of abdakibart or placebo during a 16-week treatment phase. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Secondary objectives include but are not limited to: the proportion of patients achieving HiSCR50 and HiSCR90 as well as change from baseline in: International HS Severity Score System (IHS4), draining tunnel count, abscess and inflammatory nodule (AN) count, and patients achieving at least a 30% reduction on a numerical rating scale in Patient's Global Assessment of Skin Pain (PGA Skin Pain). For additional information about this trial ([NCT06603077](https://clinicaltrials.gov/ct2/show/study/NCT06603077)), please visit www.clinicaltrials.gov or www.lotustrial.com.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic, progressive, often debilitating inflammatory skin disease that causes painful nodules, abscesses, and tunnels to form under the skin.^{4-6,8} Areas commonly affected by HS include the nape of the neck, breasts, chest, armpits, abdomen, buttocks and anus, groin and genitals, and inner thighs.⁷ If not adequately and promptly treated, the chronic inflammation characteristic of HS may progress to tissue destruction and permanent scarring.^{4-6,9} HS typically first presents in late adolescence or early adulthood and is estimated to affect 0.7–1.2% of the U.S. population, though some sources suggest the prevalence may be as high as 2–4%.^{10,11,12}

References:¹Dinarelli CA. *Immunol Rev*. 2018;281(1):8-27. ²Kany S et al. *Int J Mol Sci*. 2019;20(23):6008. ³Kimball AB et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA. ⁴Diaz MJ, et al. *Curr Iss Mol Bio*. 2023;45:4400-4415. ⁵Agnese ER, et al. *Cureus*. 2023;15(11):e49390. ⁶de Oliveira ASLE, et al. *Biomolecules*. 2022;12(10):1371. ⁷Ingram JR, et al. *J Eur Acad Dermatol Venereol*. 2022;36(9):1597-160. ⁸Sabat R, et al. *The Lancet*. 2025;405(10476):P420-438. ⁹Jemec GB. *Clinicalpractice. Hidradenitis suppurativa*. *N Engl J Med*. 2012;366(2):158–164. ¹⁰Garg A, Kirby JS, Lavian J, Lin G, Strunk A. Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. *JAMA Dermatol*. 2017;153(8):760–764. doi:10.1001/jamadermatol.2017.0201. ¹¹Ingram, John R. *British Journal of Dermatology*. doi:10.1111/bjd.19435. ¹²Nguyen TV, et al. *J Eur Acad Dermatol Venereol*. 2021;35(1):50-61.

Forward-Looking Statements

This press release includes forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond our control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar

expressions (including their use in the negative), or by discussions of future matters such as: therapeutic potential, clinical benefits and safety profiles of abdakibart (AVTX-009); plans to advance abdakibart into a registrational phase 3 program; expectations regarding timing, success and data announcements of ongoing preclinical studies and clinical trials; drug development costs, reliance on investigators and enrollment of patients in clinical trials; and our plans to develop and commercialize our current and any future product candidates and the implementation of our business model and strategic plans for our business.

Any forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements including, without limitation, risks associated with: the timing and anticipated results of our current and future preclinical studies and clinical trials, supply chain, strategy and future operations; the delay of any current and future preclinical studies or clinical trials or the development of our product candidates; the risk that the results of prior preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical studies and clinical trials, including those for abdakibart; the risk that cross-trial comparisons may not be reliable as no head-to-head trials of abdakibart have been conducted; the timing and outcome of any interactions with regulatory authorities; obtaining, maintaining and protecting our intellectual property; the availability of funding sufficient for our operating expenses and capital expenditure requirements, reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the war in Ukraine and the Middle East; and those other risks detailed in our filings with the Securities and Exchange Commission, available at www.sec.gov. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking statements represent our view only as of today and should not be relied upon as representing its views as of any subsequent date. You should not rely upon forward-looking statements as predictions of future events and actual results or events could differ materially from the plans, intentions and expectations disclosed herein. Except as required by applicable law, we expressly disclaim any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

For media and investor inquiries

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avalo
THERAPEUTICS



Abdakibart (AVTX-009) in Moderate-to-Severe Hidradenitis Suppurativa

Positive Topline Results from the Phase 2 LOTUS Study

May 2026 | AVALO THERAPEUTICS, INC. (AVTX)

Forward-Looking Statements

This presentation includes forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond our control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “might,” “will,” “could,” “would,” “should,” “continue,” “seeks,” “aims,” “predicts,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” or similar expressions (including their use in the negative), or by discussions of future matters such as: therapeutic potential, clinical benefits and safety profiles of abdakibart (AVTX-009); expectations regarding timing, success and data announcements of ongoing preclinical studies and clinical trials; the preliminary cross-study assessments comparing non-head-to-head clinical data of abdakibart to published data for lutikizumab, sonelokimab, povorcitinib, bimekizumab, secukinumab and adalimumab; integration of abdakibart into our operations; drug development costs, reliance on investigators and enrollment of patients in clinical trials; our plans to develop and commercialize our current and any future product candidates and the implementation of our business model and strategic plans for our business, current; and any future product candidates.

Any forward-looking statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements including, without limitation, risks associated with: the timing and anticipated results of our current and future preclinical studies and clinical trials, supply chain, strategy and future operations; the delay of any current and future preclinical studies or clinical trials or the development of our product candidates; the risk that the results of prior preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical studies and clinical trials, including those for abdakibart, the risk that cross-trial comparisons may not be reliable as no head-to-head trials have been conducted comparing abdakibart to lutikizumab, sonelokimab, povorcitinib, bimekizumab, secukinumab and adalimumab, and Phase 3 clinical data for abdakibart may not be directly comparable to clinical data of lutikizumab, sonelokimab, povorcitinib, bimekizumab, secukinumab and adalimumab due to differences in molecule composition, trial protocols, dosing regimens, and patient populations and characteristics; the timing and outcome of any interactions with regulatory authorities; obtaining, maintaining and protecting our intellectual property; the availability of funding sufficient for our operating expenses and capital expenditure requirements, reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the war in Ukraine and the Middle East; and those other risks detailed in our filings with the Securities and Exchange Commission, available at www.sec.gov. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking statements represent our view only as of today and should not be relied upon as representing its views as of any subsequent date. You should not rely upon forward-looking statements as predictions of future events and actual results or events could differ materially from the plans, intentions and expectations disclosed herein. Except as required by applicable law, we expressly disclaim any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

Certain information contained in this presentation and statements made orally during this presentation relate to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. This presentation contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

Building a New Standard in HS



Abdakibart
(AVTX-009)
highly potent,
specific inhibitor
of IL-1 β

Compelling Efficacy

- **42.5% (p=0.004) combined HiSCR75 and 61.7% (p=0.0009) combined HiSCR50**, the highest absolute response rates observed in a study of this size or larger

Consistent Response

- All secondary endpoints were statistically significant or numerically favorable
- Response rates similar across doses and regardless of prior biologic exposure

Favorable Safety

- Abdakibart was well-tolerated. No adverse events related to neutropenia, serious or opportunistic infections

Simple Monthly Dosing

- Potential for differentiated and patient friendly monthly dosing regimen starting at treatment initiation

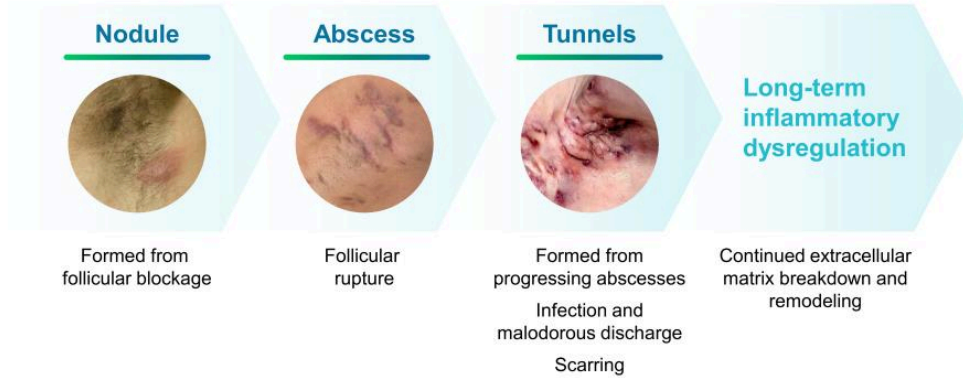
NEXT STEPS

Avalo plans to initiate a Phase 3 registrational program in HS

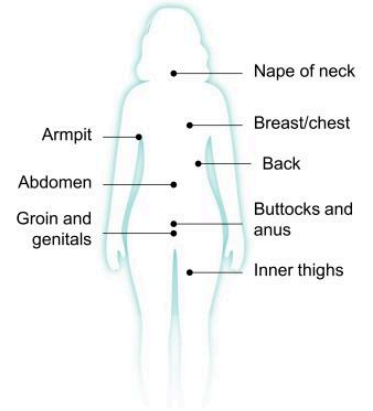
HS is a Chronic and Debilitating Inflammatory Skin Disease

Chronic Inflammation in HS Progresses to Tissue Destruction

DISEASE PROGRESSION →



Areas commonly affected by HS include*:



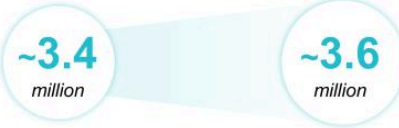
HS Projected to be a \$10B+ Global Therapeutics Market by 2035¹

U.S. adult HS patients

2026¹

2035¹
projected

*Prevalence*²



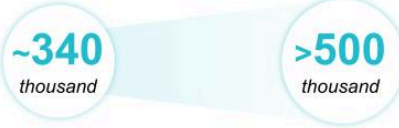
HS affects an estimated 1–4% of the population globally; 0.5% US population CAGR

*Diagnosed & Treated*³



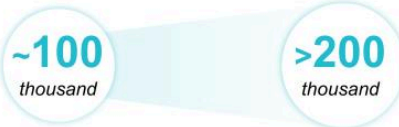
Growth in the number of diagnosed and treated patients from ~30% to ~45% of the total population, driven by new development and visibility with HCPs and patients

Moderate-to-Severe^{1,4}



Increased recognition of disease leads to 60% growth of identified moderate to severe HS

*Biologic Treated*⁵



New approvals are expected to lead to more patients being treated with biologics, increasing to ~40% share of segment (evidenced by the recent quickly growing use of Cosentyx® and Bimzelx®)

HCP, healthcare provider; HS, hidradenitis suppurativa; U.S., United States.

1. HS Market Research 2026. Avalo Data on File. Projected figures are based on management estimates and internal analyses, which rely on certain assumptions regarding growth in diagnosis and treated populations, biologic penetration rates and market dynamics; 2. Nguyen TV, et al. *J Eur Acad Dermatol Venereol.* 2021;35(1):50-61; 3. Garg AX, et al. *Dermatol Ther.* 2022;3:581-594; 4. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605; 5. Rinderknecht FB, Naik HB. *Int J Womens Dermatol.* 2024;10(1):e130.

Phase 2 LOTUS Study Designed to Evaluate the Efficacy and Safety of Abdakibart Treatment in Participants with Moderate-to-Severe HS



Primary Study Endpoint

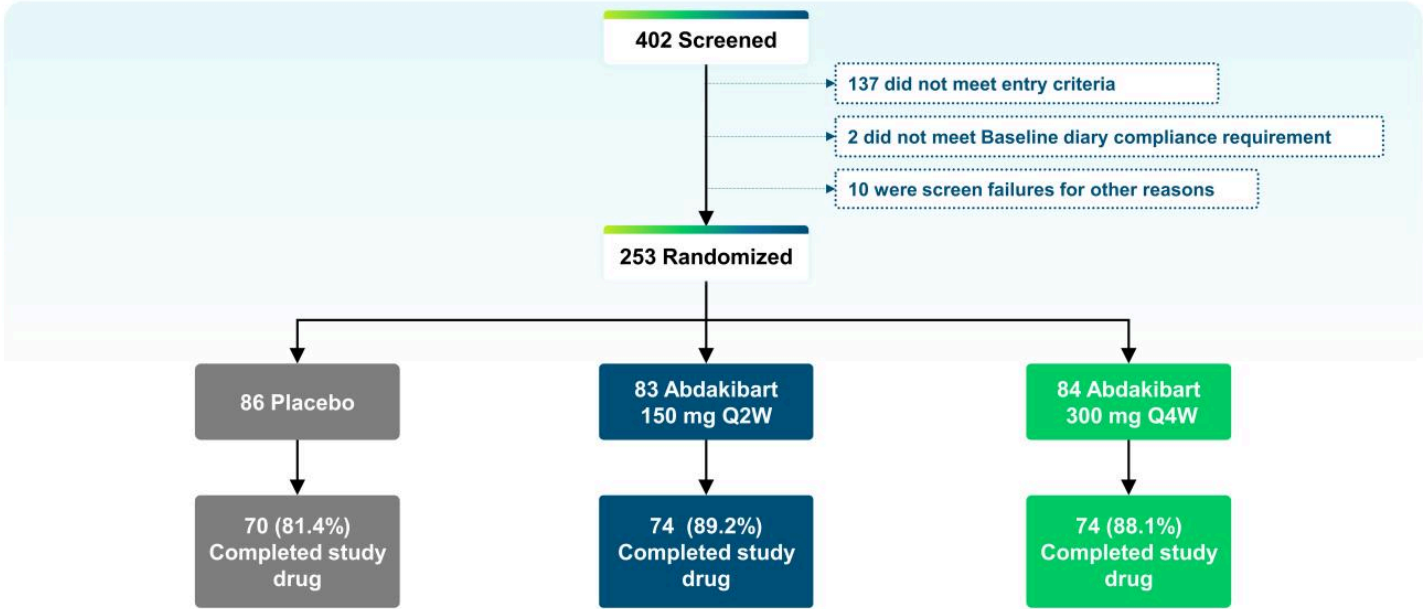
Primary Endpoint: Proportion of participants achieving HiSCR75 at 16 weeks

Key Inclusion Criteria

- HS symptoms for ≥ 6 months prior to screening
- Total AN count of ≥ 5 at baseline
- HS lesions must be present in ≥ 2 distinct anatomic areas
- At least one HS lesion that is Hurley stage II or III
- Enrollment of patients who are both biologic naïve and biologic experienced



Overall Study Completion Rates were High



Demographic and Baseline Characteristics



| | Placebo | Abdakibart | | | All Subjects |
|---|---------|-------------------|-------------------|-------------------|--------------|
| | N=86 | 150mg Q2W N=83 | 300mg Q4W N=84 | Combined N=167 | N=253 |
| Age (years, mean) | 37.7 | 38.4 | 39.0 | 38.7 | 38.4 |
| Gender, female (%) | 52.3 | 66.3 | 63.1 | 64.7 | 60.5 |
| Race, white (%) | 66.3 | 65.1 | 75.0 | 70.1 | 68.8 |
| BMI (kg/m ² , mean) | 33.9 | 36.4 | 34.9 | 35.7 | 35.1 |
| Current smoker (%) | 47.7 | 38.6 | 42.9 | 40.7 | 43.1 |
| Duration HS diagnosis (years, mean) | 6.9 | 9.1 | 7.8 | 8.4 | 7.9 |
| Prior biologics use* (%) | 30.2 | 39.8 | 39.3 | 39.5 | 36.4 |
| Concomitant Oral Antibiotic for HS (%) | 5.8 | 7.2 | 4.8 | 6.0 | 5.9 |
| Hurley Stage III (%) | 40.7 | 42.2 | 44.0 | 43.1 | 42.3 |
| AN count (mean) | 13.8 | 13.5 | 14.0 | 13.8 | 13.8 |
| DT count (mean) | 2.8 | 2.7 | 3.2 | 3.0 | 2.9 |
| Pain (NRS, mean) | 5.5 | 5.1 | 5.2 | 5.2 | 5.3 |
| hs-CRP (mg/L, mean) | 17.5 | 13.6 | 13.3 | 13.5 | 14.8 |

Cross-Trial Comparison of Baseline Characteristics



| | Abdakibart ¹ | Lutikizumab ^{2,3} | | Sonelokimab ⁴ | | | Povorcitinib ^{5,6} | | | Bimekizumab ^{7,8} | | | Secukinumab ⁹ | | Adalimumab ¹⁰ | |
|-------------------------------------|-------------------------|----------------------------|---------------------|--------------------------|---------------|-------------|-----------------------------|-----------------|------|----------------------------|--------------------|------|--------------------------|----------------|--------------------------|-------------------|
| | Ph2 LOTUS | Ph2 | Ph2 OL Bio-Naïve | Ph3 VELA-1 | Ph3 VELA-2 | Ph2 MIRA | Ph3 STOP-HS1 | Ph3 STOP-HS2 | Ph2 | Ph3 BE HEARD I | Ph3 BE HEARD II | Ph2 | Ph3 SUNSHINE | Ph3 SUNRISE | Ph3 PIONEER I | Ph3 PIONEER II |
| N | 253 | 153 | 47 | 421 | 417 | 234 | 608 | 619 | 209 | 505 | 509 | 88 | 541 | 543 | 307 | 326 |
| Age (yrs, mean) | 38.4 | 40.5 | 34.4 | 37.1 | 37.5 | 37.6 | 37.7 | 36.9 | 37.1 | 36.7 | 36.6 | 36.7 | 36.1 | 36.3 | 37.0 | 35.5 |
| Female (%) | 60.5 | 61.4 | 70.2 | 62.5 | 52.0 | 59.8 | 66.3 | 59.3 | 75.6 | 63.0 | 50.7 | 69.0 | 56.2 | 56.4 | 63.8 | 67.8 |
| White (%) | 68.8 | 74.5 | 61.7 | 77.4 | 82.7 | 85.0 | 72.0 | 77.1 | 70.3 | 77.8 | 81.5 | NR | 79.5 | 76.4 | 76.2 | 83.7 |
| BMI (kg/m², mean) | 35.1 | 33.6 | 35.8 | 33.8 | 33.0 | 33.8 | 34.6 | 33.4 | 35.7 | 33.8 | 32.3 | 34.8 | 32.5 | 31.8 | 33.8 | 32.1 |
| Current smoker (%) | 43.1 | 36.6 | 25.5 | 41.9 | 53.1 | 46.6 | 48.8 | 45.7 | 43.5 | 43.0 | 48.1 | NR | 54.0 | 54.0 | 56.4 | 65.6 |
| Duration of HS (yrs, mean) | 7.9 | 11.9 | 8.8 | 8.2 | 7.5 | 7.8 | 10.6 | 10.1 | 10.3 | 9.0 | 7.0 | 9.0 | 7.2 | 7.4 | 9.1 | 9.5 |
| Prior biologics use* (%) | 36.4 | 100.0 | 0.0 | 17.1 | 20.1 | 16.2 | 35.9 | 38.6 | 23.9 | 25.1 | 13.0 | NR | 23.8 | 23.2 | NR | NR |
| Antibiotics use (%) | 5.9 | NR | NR | 6.6 | 8.6 | 11.5 | 0.0 | 0.0 | 0.0 | 7.9 | 9.0 | NR | 12.8 | 10.7 | 0.0 | 19.0 |
| Hurley Stage III (%) | 42.3 | 70.6 | 25.5 | 39.8 | 35.4 | 33.8 | 38.7 | 31.7 | 23.0 | 49.7 | 38.9 | 51.0 | 34.0 | 40.5 | 47.6 | 46.3 |
| AN count (mean) | 13.8 | 18.2 | 13.7 | 13.9 | 14.3 | 14.0 | 12.5 | 11.6 | 11.6 | 16.0 | 16.5 | 17.7 | 12.8 | 13.3 | 14.4 | 11.3 |
| DT count (mean) | 2.9 | 6.3 | 1.9 | 3.3 | 3.8 | 3.5 | 2.9 | 2.7 | 2.1 | 3.8 | 3.4 | NR | 2.6 | 2.7 | 4.2 | 3.4 |
| Pain (NRS, mean) | 5.3 | 6.0 | 5.0 | 4.8 | 4.9 | 4.4 | 5.1 | 5.0 | 5.1 | 5.7 | 5.3 | 5.2 | 5.0 | 5.3 | 6.0 | 6.0 |

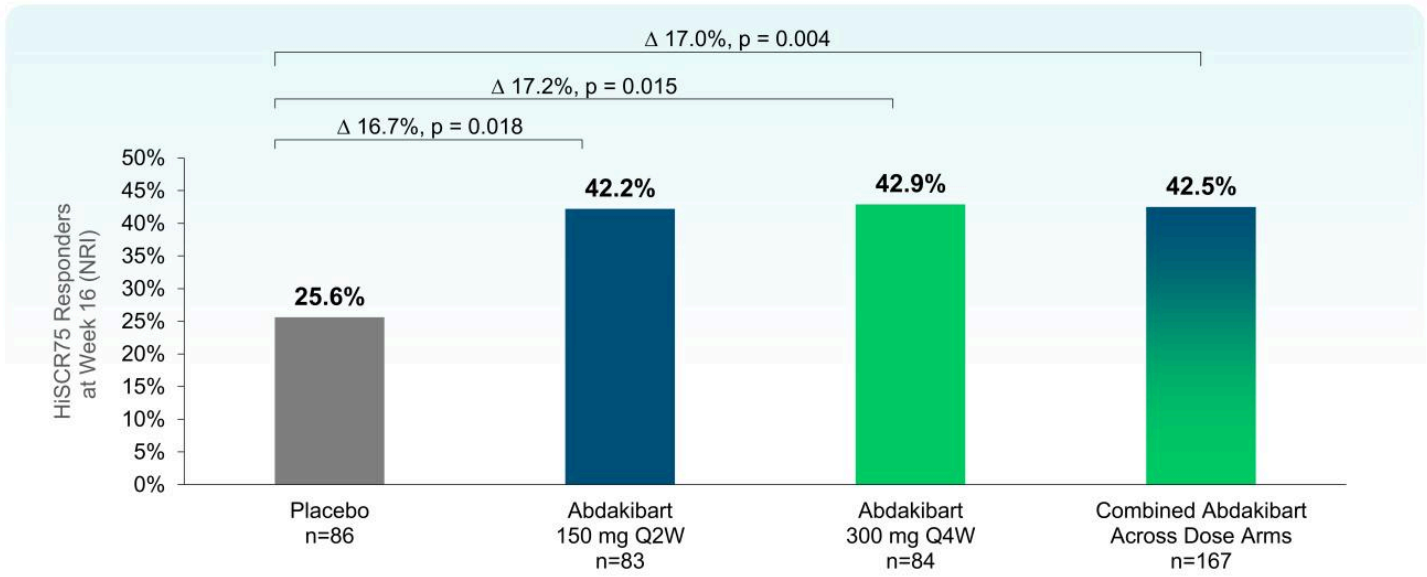
OL, open label; NR, not reported; AN, abscess and inflammatory nodule; BMI, body mass index; DT, draining tunnel; NRS, Numerical Rating Scale.

*Prior treatment with adalimumab, secukinumab, and/or bimekizumab for the treatment of HS, applicable for abdakibart only.

Note: Data are derived from separate clinical trials with differences in design and patient populations. No head-to-head clinical trials have been conducted to date; cross-trial comparison limitations exist.

1. LOTUS study. Avalo, unpublished data; 2. Kimball AB, et al. *JAMA Dermatol*. Published online March 18, 2026; 3. Kimball AB, et al. EADV Congress 2025, FC06.1D; 4. MoonLake Capital Markets Day, April 29, 2025; 5. Incyte STOP-HS1/2 Readout, March 17, 2025; 6. Kirby JS, et al. *JAAD*. 2024;90(3):521-529; 7. Glatt S, et al. *JAMA Dermatol*. 2021;157(11):1279-1288; 8. Kimball AB, et al. *Lancet*. 2024;403(10443):2504-2519; 9. Kimball AB, et al. *Lancet*. 2023;401(10378):747-761; 10. Kimball AB, et al. *N Engl J Med*. 2016;375:422-434.

Primary Endpoint of HiSCR75 at Week 16 was Met for Each Active Dose Group and Both Groups Combined

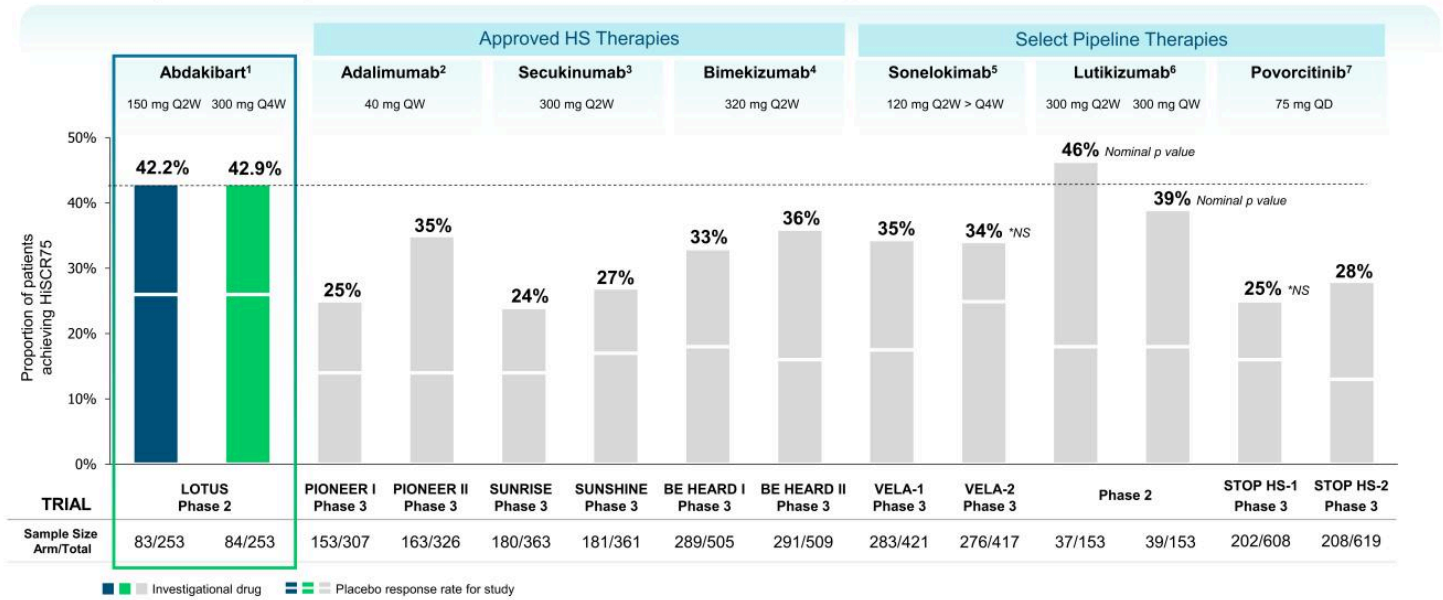


Δ Difference between treatment arm and placebo; NRI: Non-response Imputation, Q2W, every 2 weeks; Q4W, every 4 weeks.

Subjects who experience an intercurrent event using the composite strategy (i.e., use of rescue antibiotics or steroids before Week 16, discontinuation of study treatment due to an adverse event or lack of efficacy) are treated as non-responders following the intercurrent event. Subjects with missing data are imputed as non-responders.

Difference in responder rate and p-value are obtained using a Mantel-Haenszel (MH) test stratified by the randomization stratification factors.

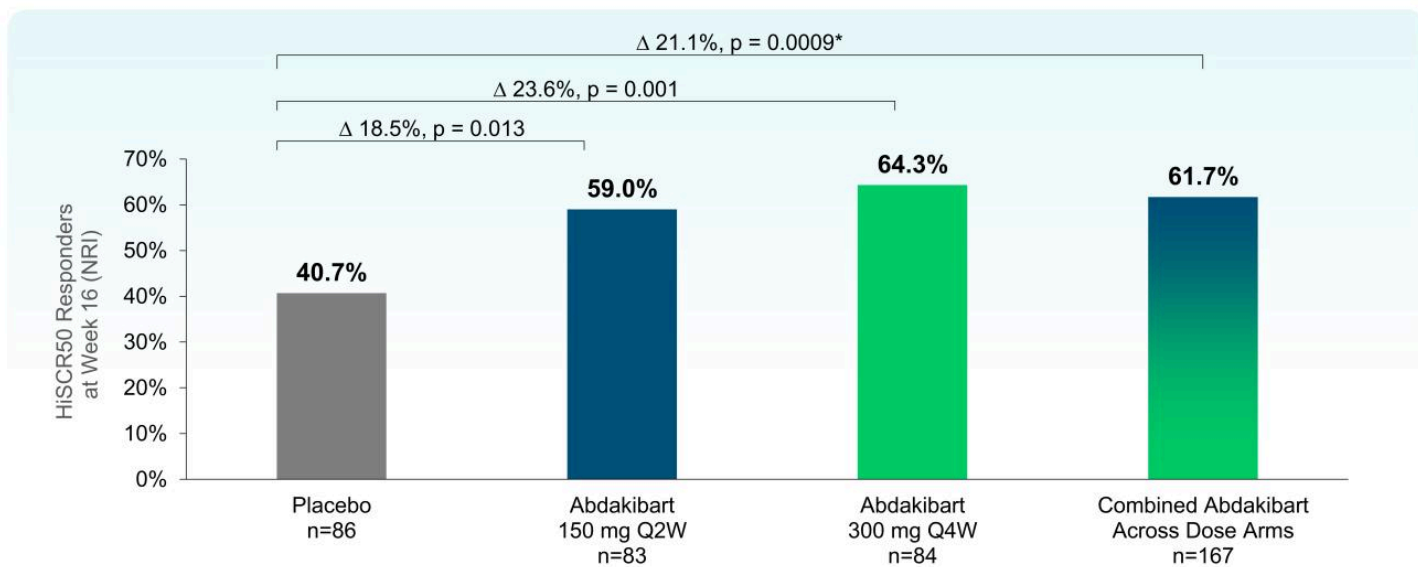
Cross-Trial HiSCR75 Comparison Demonstrates Strong Efficacy Among Trials of Same Size or Larger



*NS, not statistically significant; HiSCR, hidradenitis suppurativa clinical response; IL, interleukin; JAK1, janus kinase 1; TNF, tumor necrosis factor; QD, daily; QW, weekly; Q2W, every other week; Q4W, every 4 weeks. Note: Data are derived from separate clinical trials with differences in design and patient populations. No head-to-head clinical trials have been conducted to date; cross-trial comparison limitations exist. All timepoints are at week 16 with the exception of povorcitinib (week 12).

1. LOTUS study. Avalo, unpublished data; 2. Porter M, et al. SHSA 2022, Poster 3814; 3. Kimball AB, et al. EADV Congress 2023, Abstract 4992; 4. Kimball AB, et al. *Lancet*. 2024;403(10443):2504-2519; 5. MoonLake VELA 1/2 Readout, September 29, 2025; 6. Kimball AB, et al. *JAMA Dermatol*. Published online March 18, 2026; 7. Incyte STOP-HS1/2 Readout, March 17, 2025.

HiSCR50 Response Rates were Statistically Significant Compared to Placebo in Both Abdakibart Arms



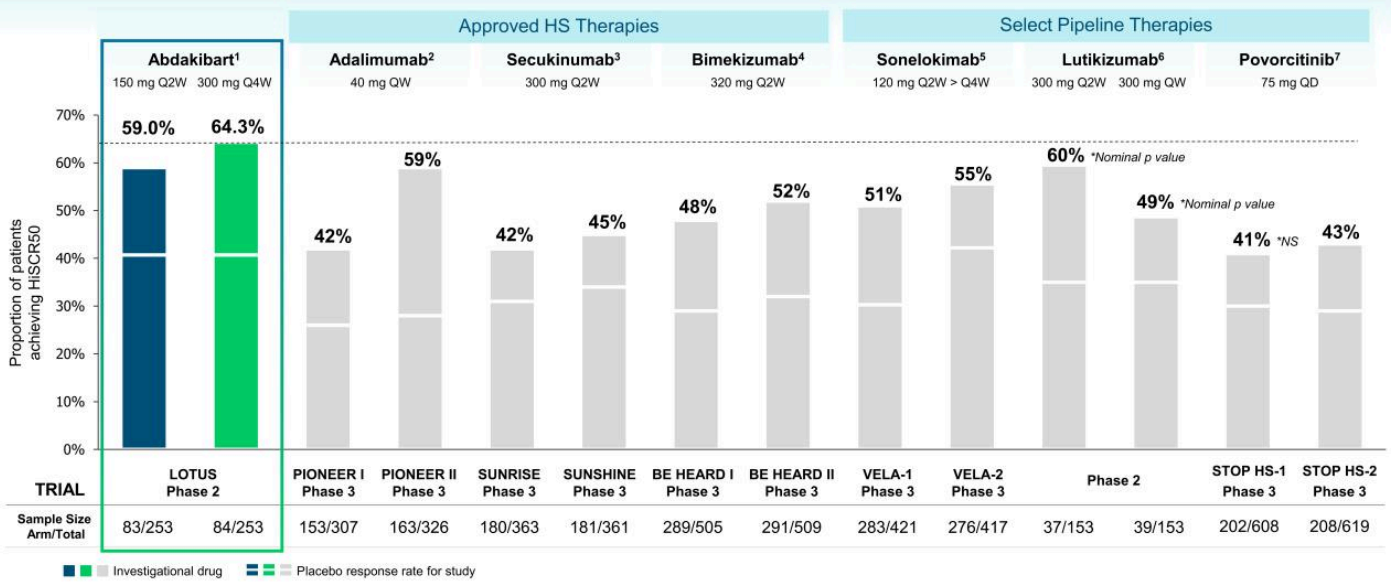
Δ Difference between treatment arm and placebo; NRI: Non-response Imputation, Q2W, every 2 weeks; Q4W, every 4 weeks.

*The combined abdakibart versus placebo analysis was performed post-hoc.

Subjects who experience an intercurrent event using the composite strategy (i.e., use of rescue antibiotics or steroids before Week 16, discontinuation of study treatment due to an adverse event or lack of efficacy) are treated as non-responders following the intercurrent event. Subjects with missing data are imputed as non-responders.

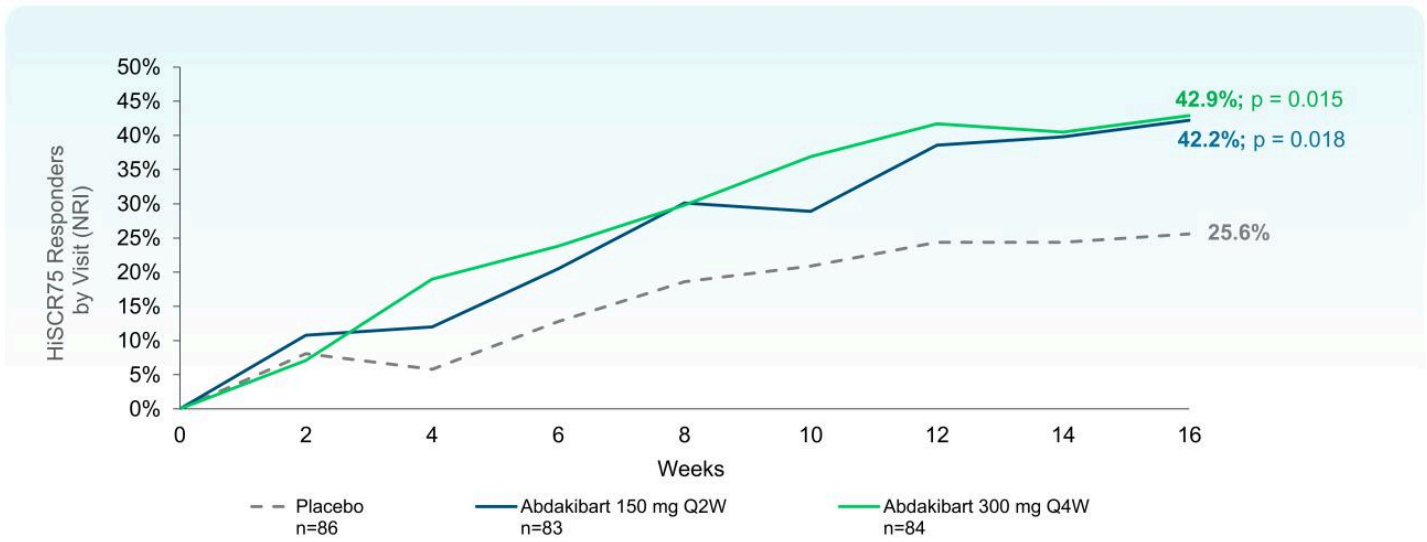
Difference in responder rate and p-value are obtained using a Mantel-Haenszel (MH) test stratified by the randomization stratification factors.

Cross-Trial HiSCR50 Comparison Demonstrates Strong Efficacy Among Trials of Same Size or Larger



*NS, not statistically significant; HiSCR, hidradenitis suppurativa clinical response; IL, interleukin; JAK1, janus kinase 1; TNF, tumor necrosis factor; QD, daily; QW, weekly, Q2W, every other week; Q4W, every 4 weeks.
 Note: Data are derived from separate clinical trials with differences in design and patient populations. No head-to-head clinical trials have been conducted to date; cross-trial comparison limitations exist. All timepoints are at week 16 with the exception of povorcitinib (week 12) 1. LOTUS study. Avalo, unpublished data; 2. Kimball AB, et al. N Engl J Med. 2016;375:422-434; 3. Kimball AB, et al. Lancet. 2023;401(10378):747-761; 4. Kimball AB, et al. Lancet. 2024;403(10443):2504-2519; 5. MoonLake VELA 1/2 Readout, September 29, 2025; 6. Kimball AB, et al. JAMA Dermatol. Published online March 18, 2026; 7. Incyte STOP-HS1/2 Readout, March 17, 2025.

HiSCR75 Improvement Over Placebo Seen as Early as Week 4 for Both Abdakibart Treatment Groups

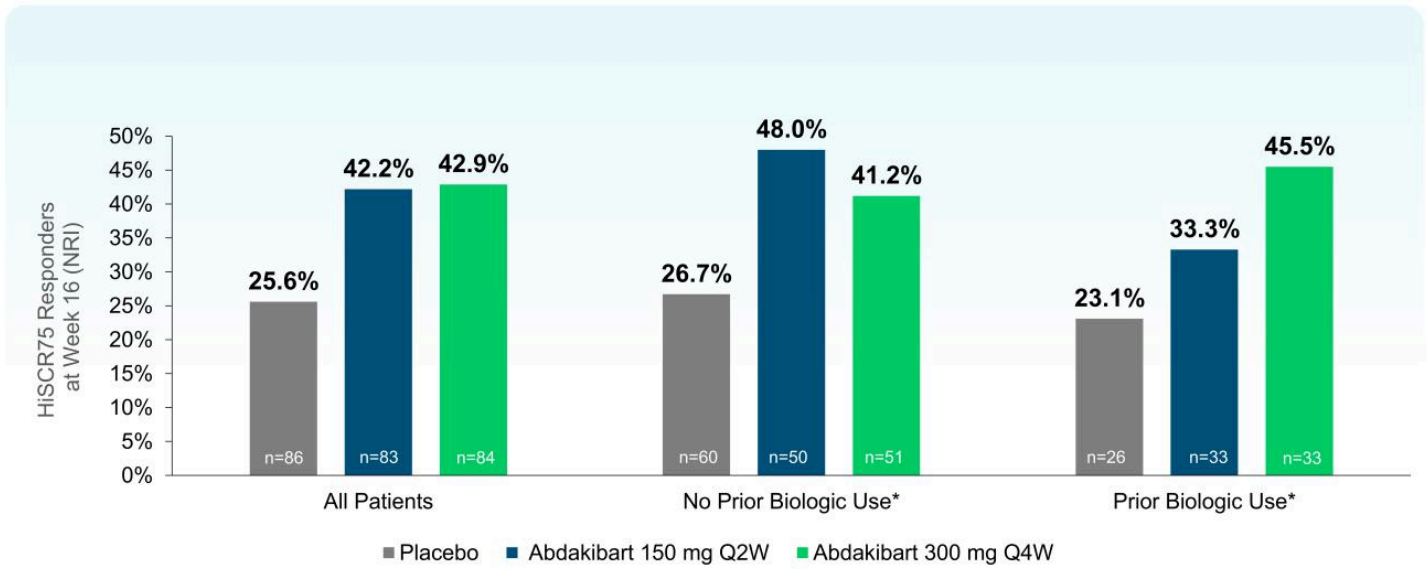


NRI: Non-response Imputation; Q2W, every 2 weeks; Q4W, every 4 weeks.

Subjects who experience an intercurrent event using the composite strategy (i.e., use of rescue antibiotics or steroids before Week 16, discontinuation of study treatment due to an adverse event or lack of efficacy) are treated as non-responders following the intercurrent event. Subjects with missing data are imputed as non-responders.

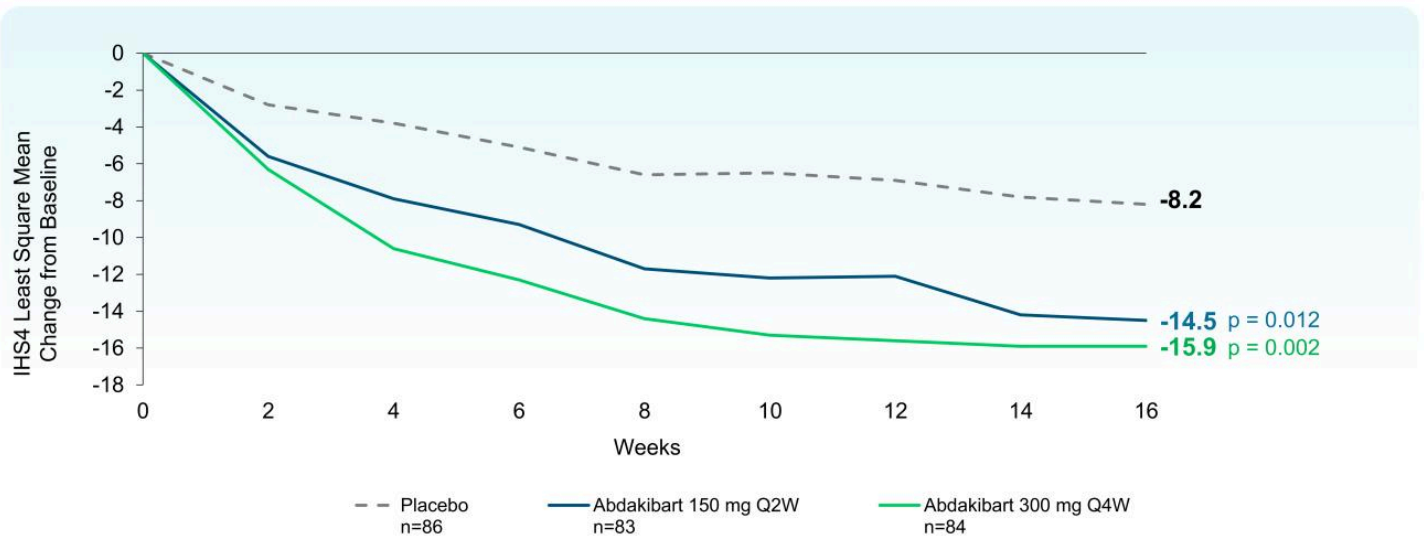
Difference in responder rate and p-value are obtained using a Mantel-Haenszel (MH) test stratified by the randomization stratification factors.

HiSCR75 Responses were Similar in Patients with and without Prior Biologic Exposure



*Prior biologic use refers to treatment with adalimumab, secukinumab, and/or bimekizumab for the treatment of HS; NRI: Non-response Imputation; Q2W, every 2 weeks; Q4W, every 4 weeks.
 Subjects who experience an intercurrent event using the composite strategy (i.e., use of rescue antibiotics or steroids before Week 16, discontinuation of study treatment due to an adverse event or lack of efficacy) are treated as non-responders following the intercurrent event. Subjects with missing data are imputed as non-responders.
 Difference in responder rate and p-value are obtained using a Mantel-Haenszel (MH) test stratified by the randomization stratification factors.

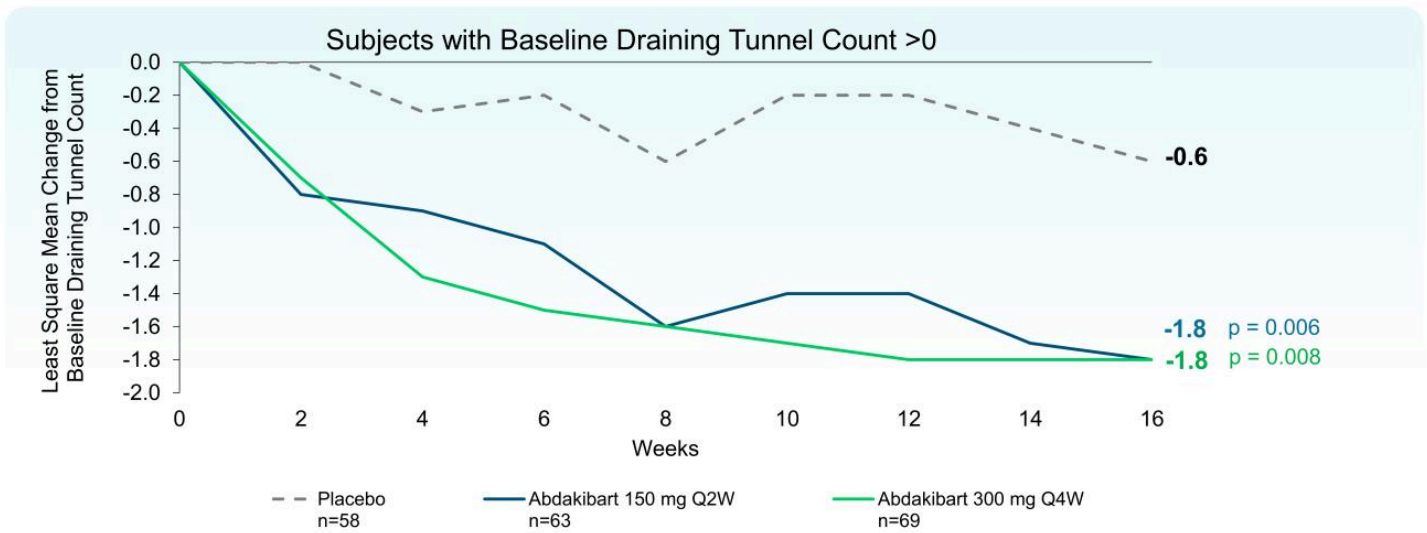
Early and Sustained Decreases in IHS4 were Seen in Both Treatment Groups



IHS4: International Hidradenitis Suppurativa Severity Score System; Q2W, every 2 weeks; Q4W, every 4 weeks.

Data after an intercurrent event using the composite strategy (both missing and observed) are not used in the analysis. All other missing data are left as missing. Least square means are based on a mixed effects model for repeated measures (MMRM).

Early and Sustained Decreases in Draining Tunnel Count were seen in Both Treatment Groups



Q2W, every 2 weeks; Q4W, every 4 weeks.

Data after an intercurrent event using the composite strategy (both missing and observed) are not used in the analysis. All other missing data are left as missing. Least square means are based on a mixed effects model for repeated measures (MMRM).

Rates of TEAEs, Including SAEs were Similar to Placebo



| # of Subjects (%) | Placebo | Abdakibart | |
|---|-----------|--------------------|--------------------|
| | N=86 | 150 mg Q2W N=83 | 300 mg Q4W N=83 |
| Any TEAE* | 46 (53.5) | 43 (51.8) | 46 (55.4) |
| Any TESAE | 2 (2.3) | 2 (2.4) | 1 (1.2) |
| Non-cardiac chest pain | 0 | 0 | 1 (1.2) |
| Major depressive disorder | 0 | 1 (1.2) | 0 |
| Hidradenitis | 2 (2.3) | 1 (1.2) | 0 |
| Any TEAE leading to study drug discontinuation | 2 (2.3) | 2 (2.4) | 1 (1.2) |
| Deaths | 0 | 0 | 0 |

TEAE: Treatment Emergent Adverse Event; TESAE: Treatment Emergent Serious Adverse Event; SAE: Serious Adverse Event; Q2W, every 2 weeks; Q4W, every 4 weeks.

*The most common TEAEs reported in both abdakibart arms were headache and nausea. One subject randomized to abdakibart 300 mg Q4W did not receive study drug and therefore is not included in safety population.

Few Adverse Events of Special Interest



| # of Subjects (%) | Placebo | Abdakibart | |
|----------------------------------|---------|--------------------|--------------------|
| | N=86 | 150 mg Q2W N=83 | 300 mg Q4W N=83 |
| Hypersensitivity Reaction | 0 | 0 | 0 |
| Injection Site Reaction | 4 (4.7) | 3 (3.6) | 5 (6.0) |
| Leukopenia | 0 | 0 | 0 |
| Neutropenia | 0 | 0 | 0 |
| Serious Infections | 0 | 0 | 0 |
| MACE | 0 | 0 | 0 |
| Malignancy | 0 | 0 | 0 |
| Opportunistic Infections | 0 | 0 | 0 |
| Tuberculosis | 0 | 0 | 0 |

Building a New Standard in HS



Abdakibart
(AVTX-009)
highly potent,
specific inhibitor
of IL-1 β

Compelling Efficacy

- **42.5% (p=0.004) combined HiSCR75 and 61.7% (p=0.0009) combined HiSCR50**, the highest absolute response rates observed in a study of this size or larger

Consistent Response

- All secondary endpoints were statistically significant or numerically favorable
- Response rates similar across doses and regardless of prior biologic exposure

Favorable Safety

- Abdakibart was well-tolerated. No adverse events related to neutropenia, serious or opportunistic infections

Simple Monthly Dosing

- Potential for differentiated and patient friendly monthly dosing regimen starting at treatment initiation

NEXT STEPS

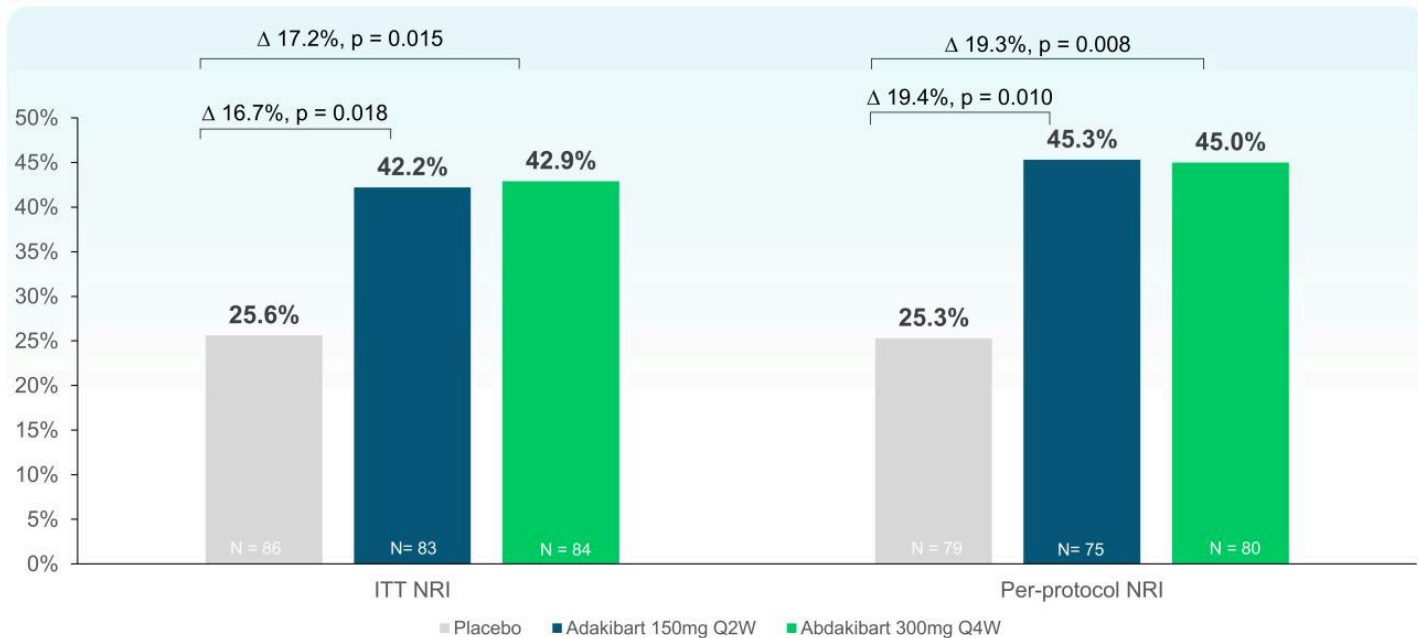
Avalo plans to initiate a Phase 3 registrational program in HS



Appendix



HiSCR75 Responders ITT and Per Protocol at Week 16 (NRI)



Key Secondary Endpoints were Statistically Significant or Numerically Improved Compared to Placebo



| Secondary Endpoints | Placebo | Abdakibart | |
|---|--------------|--------------------------------------|--------------------------------------|
| | N=86 | 150 mg Q2W N=83 | 300 mg Q4W N=84 |
| Flare Rate (NRI)¹ | 37.2% | 24.1% Δ -13.3 p = 0.058 | 21.4% Δ -15.8 p = 0.021 |
| AN change from Baseline (LS mean)² | -5.8 | -7.8 Δ -1.9 p = 0.111 | -9.1 Δ -3.2 p = 0.008 |
| HiSCR90 Responder Rate (NRI)³ | 14.0% | 22.9% Δ 9.2% p = 0.116 | 23.8% Δ 9.7% p = 0.100 |
| PGA Skin Pain NRS30 Responder Rate (NRI)^{3,4} | 23.9% | 27.0% Δ 4.1% p = 0.586 | 37.3% Δ 13.7% p = 0.076 |

Δ Difference between treatment arm and placebo; Q2W, every 2 weeks; Q4W, every 4 weeks; NRI, Non-Response Imputation; NRS, Numerical Rating Scale; AN, Abscess and Inflammatory Nodule.

1. Flare Rate at any visit up to and including Week 16. Flare defined as at least a 25% increase in the total AN count, plus an increase of ≥ 2 in AN count compared to baseline. Subjects who experience intercurrent events using the composite strategy (i.e., use of rescue antibiotics or steroids before Week 16, discontinuation of study treatment due to an adverse event or lack of efficacy) are treated as experiencing a flare following the intercurrent event. Subjects with missing Week 16 data are imputed as experiencing a flare.

2. Data after an intercurrent event using the composite strategy (both missing and observed) are not used in the analysis. All other missing data are left as missing. For the analysis at Week 16, placebo, N=67; abdakibart 150 mg Q2W, N=72; abdakibart 300 mg Q4W N=74.

3. Subjects who experience an intercurrent event using the composite strategy are treated as a non-responder following the intercurrent event. Subjects with missing data are imputed as a non-responder.

4. Among subjects with Baseline Pain NRS ≥ 3 , placebo, N=71; abdakibart 150 mg Q2W, N=63; abdakibart 300 mg Q4W, N=67. The score is derived from the weekly average of daily responses, defined as the sum of the scored item over the course of the study week divided by the number of days in which the item was completed, relative to each respective visit date. Response criteria are met if there is at least a 30% reduction and at least a 1 unit reduction from Baseline.

Difference in rate and p-value are obtained using a Mantel-Haenszel (MH) test stratified by the randomization stratification factors (Baseline weight [< 90 kg, > 90 kg] and Baseline Hurley Stage [II, III]). LS mean, difference in LS mean, and p-value are based on a mixed effects model for repeated measures (MMRM).

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