



Zura Bio Launches Global Phase 2 TibuSHIELD Study to Evaluate Tibulizumab in Adults with Hidradenitis Suppurativa

May 20, 2025 10:30 AM EDT

- *TibuSHIELD has launched with the activation of its first clinical site*
- *This study is the first to evaluate dual inhibition of B-cell activating factor (BAFF) and interleukin-17A (IL-17A) pathways in adults with moderate to severe hidradenitis suppurativa (HS)*
- *TibuSHIELD will assess tibulizumab over a 28-week study period, comprising a 16-week primary efficacy assessment and a 12-week safety follow-up, conducted at clinical sites across the United States, Canada, and Europe, with an optional open-label extension (OLE)*
- *Topline results for the primary efficacy endpoint at Week 16, along with key secondary and exploratory outcomes, are anticipated in the third quarter of 2026*

HENDERSON, Nev.--(BUSINESS WIRE)--May 20, 2025-- [Zura Bio Limited](#) (Nasdaq: ZURA) ("Zura Bio" or the "Company"), a clinical-stage, multi-asset immunology company dedicated to developing novel dual-pathway antibodies for a range of autoimmune and inflammatory diseases with unmet needs, today announced the launch of TibuSHIELD, a global Phase 2 clinical study evaluating tibulizumab in adults with moderate to severe HS.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20250520429104/en/>



Phase 2 TibuSHIELD study will evaluate tibulizumab in adults with hidradenitis suppurativa (HS).

"Hidradenitis suppurativa remains a difficult condition to manage, with many patients experiencing persistent disease activity despite currently available treatments," said Alexa B. Kimball, MD, MPH, Professor of Dermatology at Harvard Medical School, and President and CEO of Harvard Medical Faculty Physicians at Beth Israel

Deaconess Medical Center. "Studying tibulizumab represents an important opportunity to evaluate an investigational therapy designed to target multiple aspects of the inflammatory process in HS. We look forward to investigating this approach for individuals living with this challenging disease."

TibuSHIELD is designed to enroll approximately 180 adults with moderate to severe HS across the United States, Canada, and Europe. The study will evaluate tibulizumab over a 28-week period, comprising a 16-week primary efficacy assessment and a 12-week safety follow-up, with an optional OLE. Topline results for the primary efficacy endpoint at Week 16 are expected in the third quarter of 2026.

"The initiation of TibuSHIELD marks a key milestone in our mission to advance potentially differentiated therapies for patients with severe inflammatory diseases," said Kiran Nistala, MBBS, PhD, Chief Medical Officer and Head of Development at Zura Bio. "Tibulizumab's dual mechanism of action, targeting both BAFF and IL-17A, offers a novel approach for the potential treatment of hidradenitis suppurativa. We remain committed to advancing clinical development with investigators, clinical sites, and the HS community."

The launch of this HS study follows the December 2024 initiation of TibuSURE, a global Phase 2 study evaluating tibulizumab in adults with systemic sclerosis. Tibulizumab remains an investigational product and has not been approved by any regulatory authority. Its safety and efficacy have not yet been established.

ABOUT TibuSHIELD

TibuSHIELD is a global, Phase 2, randomized, double-blind, placebo-controlled clinical study evaluating the safety, tolerability, and efficacy of tibulizumab in approximately 180 adults with moderate to severe HS. Participants are randomized 1:1:1 to receive two different doses of tibulizumab or placebo. The study includes a 16-week efficacy assessment period followed by a 12-week safety follow-up and an optional OLE.

The primary endpoint of the study is the percent change from baseline in total abscess and nodule (AN) count at Week 16. Secondary endpoints include the proportion of participants achieving HiSCR50 or HiSCR75, defined as at least a 50% or 75% reduction in AN count without an increase in abscesses or draining fistulas at Week 16. Key safety assessments include the assessment of tolerability, and monitoring for adverse events.

ABOUT HIDRADENITIS SUPPURATIVA

Hidradenitis suppurativa (HS), also known as acne inversa, is a chronic, progressive, and debilitating inflammatory skin disease affecting approximately 1% of the global population. HS primarily involves follicular occlusion, rupture, and secondary inflammation of hair follicles, leading to painful nodules, abscesses, sinus tracts (also referred to as draining tunnels), and scarring. Lesions typically occur in areas where skin rubs together, such as the armpits, groin, and under the breasts.

HS is associated with several comorbidities, including inflammatory arthropathies, metabolic syndrome, increased cardiovascular risk, inflammatory disorders, lymphedema, squamous cell carcinoma, and depression. The chronic pain, visible scarring, and disease burden contribute significantly to physical disability, stigmatization, unemployment, and reduced quality of life.

Currently, there is no cure for HS. Despite its relatively high prevalence and disease burden, treatment options remain limited, and many patients fail to achieve adequate disease control.

ABOUT TIBULIZUMAB

Tibulizumab is an investigational, humanized, tetravalent dual-antagonist antibody engineered by fusing Taltz® (ixekizumab) and tabalumab to bind to and neutralize both IL-17A and BAFF. It is currently being evaluated in two Phase 2 clinical studies in adults with systemic sclerosis and hidradenitis suppurativa. Prior to in-licensing, Phase 1/1b studies were conducted in patients with Sjögren's syndrome and rheumatoid arthritis.

Tibulizumab is an investigational compound and has not been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

ABOUT ZURA BIO

Zura Bio is a clinical-stage, multi-asset immunology company dedicated to developing novel dual-pathway antibodies for a range of autoimmune and inflammatory diseases with unmet needs. The Company's pipeline includes dual-pathway product candidates designed to target key mechanisms of immune system imbalance, with the goal of improving efficacy, safety, and dosing convenience for patients.

Zura Bio's lead product candidate, tibulizumab (ZB-106), is currently being evaluated in two separate Phase 2 clinical studies in adults, including TibuSURE for systemic sclerosis and TibuSHIELD for hidradenitis suppurativa. Additional product candidates, crebankitug (ZB-168) and torudokimab (ZB-880), have completed Phase 1/1b studies and are being evaluated for their potential across a range of autoimmune and inflammatory conditions.

For more information, please visit www.zurabio.com.

FORWARD-LOOKING STATEMENTS

This communication includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believe," "predict," "potential," "continue," "strategy," "future," "opportunity," "would," "seem," "seek," "outlook," "goal," "mission," and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties that could cause the actual results to differ materially from the expected results. These statements are based on various assumptions, whether or not identified in this communication. These forward-looking statements in this release include, but are not limited to, statements regarding: the potential of tibulizumab's dual-pathway approach to better manage persistent disease activity and improve outcomes for patients affected by HS; the ability of tibulizumab to improve the lives of patients with HS; and expectations with respect to Zura Bio's development program, including its product candidates and the potential clinical benefits and commercial potential thereof, data readouts, regulatory matters, clinical trials and the design and timing thereof. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability.

Actual events are difficult or impossible to predict and could differ materially from those expressed or implied in such forward-looking statements, as a result of these risks and uncertainties, which include, but are not limited to: Zura Bio's expectations regarding its product candidates and their related clinical benefits, and Zura Bio's beliefs regarding competing product candidates and products both in development and approved, may not be achieved; Zura Bio's vision and strategy may not be successful; the timing of key events and initiation of Zura Bio's studies, regulatory matters and release of clinical data may take longer than anticipated or may not be achieved at all; the potential general acceptability and maintenance of Zura Bio's product candidates by regulatory authorities, payors, physicians, and patients may not be achieved; Zura Bio's ability to attract and retain key personnel; Zura Bio's expectations with respect to its future operating expenses, capital requirements and needs for additional financing may not be achieved; Zura Bio has not completed any clinical trials, and has no products approved for commercial sale; Zura Bio has incurred significant losses since inception, and expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future; Zura Bio requires substantial additional capital to finance its operations, and if it is unable to raise such capital when needed or on acceptable terms, Zura Bio may be forced to delay, reduce, and/or eliminate one or more of its development programs or future commercialization efforts; Zura Bio may be unable to renew existing contracts or enter into new contracts; Zura Bio relies on third-party contract development manufacturing organizations for the manufacture of clinical materials; Zura Bio relies on contract research organizations, clinical trial sites, and other third parties to conduct of its preclinical studies and clinical trials; Zura Bio may be unable to obtain regulatory approval for its product candidates, and there may be related restrictions or limitations of any approved products; Zura Bio may be unable to successfully respond to general economic and geopolitical conditions; Zura Bio may be unable to effectively manage growth; Zura Bio faces competitive pressures from other companies worldwide; Zura Bio may be unable to adequately protect its intellectual property rights; and other factors set forth in documents filed, or to be filed by Zura Bio, with the Securities and Exchange Commission (SEC), including the risks and uncertainties described in the "Risk Factors" section of Zura Bio's Annual Report on Form 10-K for the year ended December 31, 2024 and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, and other filings with the SEC. These risks and uncertainties may be amplified by health epidemics or other global disruption events, including the conflict between Russia and Ukraine and the Israel-Hamas war and sanctions related thereto, international trade policies, including tariffs, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems, which may continue to cause economic uncertainty. Zura Bio cautions that the foregoing list of factors is not exclusive or exhaustive and not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Zura Bio gives no assurance that it will achieve its expectations. Zura Bio does not undertake or accept any obligation to update any forward-looking statements, except as required by law.

Dr. Kimball is a paid consultant to Zura Bio.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250520429104/en/): <https://www.businesswire.com/news/home/20250520429104/en/>

Megan K. Weinshank
Head of Corporate Affairs

ir@zurabio.com

Source: Zura Bio Limited