Zura Bio Provides Clinical Update on Phase 2 TibuSHIELD Study of Tibulizumab (ZB-106) in Hidradenitis Suppurativa

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- *Study did not meet primary endpoint of percentage change from baseline in total abscess and inflammatory nodule (AN) count at Week 16*
- *Key secondary endpoints, including HiSCR50 and HiSCR75, were not met*
- *Both doses of tibulizumab were well tolerated; observed safety was consistent with established safety profiles for both IL-17 and BAFF inhibition*
- *The ongoing TibuSURE trial in systemic sclerosis (SSc) and the planned NEXUS-PMR trial in polymyalgia rheumatica (PMR) will continue, with data expected in H1 2027 and Q4 2028, respectively; Zura is discontinuing development in hidradenitis suppurativa*

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 9, 2026-- Zura Bio Limited (Nasdaq: ZURA) ("Zura"), a clinical-stage biotechnology company developing novel and differentiated medicines to meaningfully improve the lives of patients with serious and debilitating autoimmune and inflammatory diseases, today announced that its Phase 2 TibuSHIELD study, which evaluated tibulizumab (ZB-106) in adults with moderate-to-severe hidradenitis suppurativa (HS), did not meet its primary endpoint of percentage change from baseline in total abscess and inflammatory nodule (AN) count at Week 16 in either the 300 mg or 150 mg treatment arm. Key secondary endpoints, including HiSCR50 and HiSCR75, were also not met.

TibuSHIELD was a global, randomized, double-blind, placebo-controlled Phase 2 trial evaluating the safety, tolerability, and efficacy of tibulizumab in adults with moderate-to-severe HS. The trial enrolled 247 participants randomized 1:1:1 to receive one of two tibulizumab dose regimens or placebo. The study included a 16-week efficacy assessment period, followed by an optional 16-week open-label extension (OLE), with a 12-week safety follow-up period.

At Week 16, study participants experienced 56.0% and 58.1% reductions from baseline in AN count in the tibulizumab 300 mg and 150 mg arms, respectively, compared with a 52.5% reduction in the placebo arm. HiSCR50 response rates were 48.0% and 52.7% for the tibulizumab 300 mg and 150 mg arms, respectively, versus 45.5% for placebo. HiSCR75 response rates were 35.3% and 34.0% for the tibulizumab 300 mg and 150 mg arms, respectively, versus 28.1% for placebo. Results are shown in Table 1 below.

"We are disappointed to report that the TibuSHIELD study was unable to deliver a positive outcome for patients. Despite TibuSHIELD being a large and well-controlled study, these results highlight the challenges of developing medicines in hidradenitis suppurativa, including the high variability of placebo responses. We are conducting a full analysis of the data to understand what it tells us about the biology of HS, the impact of tibulizumab, and the roles of IL-17 and BAFF. We are grateful to the patients, caregivers, and investigators whose participation and commitment made this study possible," said Sandeep Kulkarni, MD, Chief Executive Officer of Zura. "We remain committed to exploring the effect of dual IL-17 and BAFF inhibition in SSc and PMR, two indications with distinct and uncorrelated pathobiologies and clinical presentations from those of HS. We are looking forward to reporting topline results from our TibuSURE study in systemic sclerosis in the first half of 2027 and starting the NEXUS-PMR study by the end of this year."

Based on these results, Zura is discontinuing development of tibulizumab in HS. Additional analyses are ongoing, including pharmacokinetic/pharmacodynamic assessments, exposure-response relationships, and the impact of HS-specific factors. Zura continues to advance tibulizumab in SSc and PMR, which have biology distinct from HS. Hidradenitis suppurativa is a deep-tissue disease in which the pharmacology of biologic therapies is known to differ from that in systemic autoimmune conditions. Systemic sclerosis and polymyalgia rheumatica are driven by distinct immune mechanisms, in which B-cell and IL-17 pathways are each independently implicated.

Table 1: Results on key efficacy endpoints

Endpoint, Week 16	Tibulizumab 300 mg (N=82)	Tibulizumab 150 mg (N=82)	Placebo (N=82)
% change in AN count (primary)	56.0	58.1	52.5
HiSCR50, %	48.0	52.7	45.5
HiSCR75, %	35.3	34.0	28.1
Discontinuation rate, %	11.0	12.2	14.6

% change in AN count = reductions from baseline in total abscess and inflammatory nodule (AN) count.
HiSCR50 = ≥50% reduction from baseline in total abscess and inflammatory nodule count, with no increase in abscess or draining tunnel count.

HiSCR75 = ≥75% reduction from baseline in total abscess and inflammatory nodule count, with no increase in abscess or draining tunnel count. For HiSCR50 and HiSCR75, missing data and intercurrent events were handled by modified non-responder imputation (mNRI).

Table 2: Safety up to Week 16 – adverse events

	Tibulizumab 300 mg (N=82)	Tibulizumab 150 mg (N=82)	Placebo (N=82)
Any treatment-emergent adverse events (TEAEs)	43 (52.4%)	43 (52.4%)	38 (46.3%)
Treatment-emergent serious AEs	5 (6.1%)	3 (3.7%)	1 (1.2%)
Treatment-related serious AEs	1 (1.2%)	0	0
TEAEs leading to discontinuation of study treatment	2 (2.4%)	3 (3.7%)	2 (2.4%)

The data show that tibulizumab was well tolerated and observed safety was consistent with established safety profiles for both IL-17 and BAFF inhibition. One death (cardiac arrest in a participant with multiple cardiovascular risk factors) was reported in the 300 mg tibulizumab arm during the study and was determined by the site investigator to be unrelated to study treatment. There was one adverse event of special interest (AESI): an exacerbation of pre-existing inflammatory bowel disease in a participant randomized to the 300 mg tibulizumab arm.

Anticipated upcoming milestones

The Company remains committed to the ongoing TibuSURE study of tibulizumab in systemic sclerosis, with topline data expected in H1 2027, and to the planned NEXUS-PMR study in polymyalgia rheumatica, with data expected in Q4 2028.

As of September 30, 2026, Zura had cash and cash equivalents of $187.7 million. Zura expects that its existing cash and cash equivalents are sufficient to support planned operations through at least the end of 2028.

About Zura

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

Zura's lead product candidate, tibulizumab (ZB-106), is being evaluated in TibuSURE, a Phase 2 study in systemic sclerosis (SSc). NEXUS-PMR, a Phase 2 study in polymyalgia rheumatica (PMR), is planned to be initiated by year-end 2026. Additional product candidates torudokimab (ZB-880) and crebankitug (ZB-168) 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.

About Tibulizumab

Tibulizumab is a bispecific dual-antagonist antibody engineered by the fusion of tabalumab with a single-chain variable fragment (scFv) derived from ixekizumab (Taltz®). Tibulizumab is designed to neutralize interleukin-17 and B-cell activating factor. It is being evaluated in Phase 2 clinical studies in adults with systemic sclerosis and hidradenitis suppurativa, with a Phase 2 study in PMR planned to be initiated by the end of 2026. Before Zura in-licensed tibulizumab, Lilly conducted Phase 1/1b studies 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.

FORWARD-LOOKING STATEMENTS

Any statements contained in this press release that do not describe historical facts may constitute "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "anticipate," "believe," "continue," "could," "designed to," "expect," "goal," "intend," "may," "outlook," "plan," "potential," "should," "will," and similar expressions, and are based on Zura's current beliefs and expectations. These forward-looking statements include, but are not limited to, statements regarding the development and potential therapeutic benefits of Zura's product candidates; the initiation, timing, progress, design and results of Zura's current and future clinical trials, including the reporting of data therefrom; the sufficiency of Zura's cash resources and projected cash runway; and other statements that are not historical facts. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. Risks and uncertainties that may cause actual results to differ materially include, but are not limited to: uncertainties inherent in the development of therapeutic product candidates, such as the risk that one or more of Zura's current or future product candidates may not be successfully developed or commercialized; the risk of delay or cessation of any planned or ongoing clinical trials of Zura's current or future product candidates; the risk that prior results, including signals of safety, activity or durability of effect observed in preclinical studies or clinical trials, may not be replicated or may not continue in ongoing or future studies or clinical trials; the risk that modeling data indicating therapeutic potential, or clinical evidence from other drug candidates, may not be predictive of results in Zura's current or future clinical trials; the risk that Zura's product candidates or procedures in connection with their administration may not have the safety or efficacy profiles anticipated; risks related to the accuracy of Zura's estimates of expenses, capital requirements and needs for additional financing; changes in expected or existing competition; changes in the regulatory environment; uncertainties related to the timing and outcome of the regulatory approval process; unexpected litigation or other disputes; the impact of macroeconomic conditions on Zura's business, clinical trials and financial position; and other risks and uncertainties described in Zura's Annual Report on Form 10-K for the year ended December 31, 2025, and other filings with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and are based on information available to Zura as of the date hereof. Zura assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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