Zura Bio Presents Data for the Tibulizumab (ZB-106) Program at EULAR 2024

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Tibulizumab (ZB-106) was well tolerated and neutralized IL-17A and BAFF in a Phase 1 study in patients with Sjogren's syndrome

Preclinical data demonstrating the potential of dual inhibition of IL-17A and BAFF in a rheumatoid arthritis animal model support clinical development

HENDERSON, Nev.--(BUSINESS WIRE)--Jun. 14, 2024-- Zura Bio Limited (Nasdaq: ZURA) ("Zura Bio"), a clinical-stage immunology company developing novel dual-pathway antibodies for autoimmune and inflammatory diseases, today shared supportive data from a Phase 1 study evaluating its lead candidate, tibulizumab (ZB-106), for the treatment of Sjogren's syndrome. These data, along with preclinical data supporting further development of tibulizumab in rheumatoid arthritis (RA), were presented at the Annual European Congress of Rheumatology (EULAR) 2024 in Vienna.

"Collectively, these data add to early-phase evidence demonstrating that dual-inhibition of both IL-17A and BAFF could be a breakthrough approach for autoimmune and inflammatory diseases in which single-pathway inhibition is the standard of care," stated Robert Lisicki, Chief Executive Officer. "The results in Sjogren's syndrome demonstrate that tibulizumab achieved robust target engagement, nearing maximum serum levels following single, well-tolerated subcutaneous doses at four-week intervals. Further, the preclinical results suggest dual-pathway inhibition may warrant clinical exploration in RA and other autoimmune diseases, adding to the breadth of potential we see with tibulizumab."

Key Findings from Phase 1 Study of Tibulizumab in Sjogren's Syndrome

The randomized, double-blind, placebo-controlled Phase 1 study evaluated four ascending doses of tibulizumab in 25 participants with Sjogren's syndrome. Twenty-one participants in the 12-week study received ≥1 dose of tibulizumab (30mg Q4W, 100mg Q4W, 300mg Q4W, 300mg Q2W), with four receiving placebo.

- Treatment with tibulizumab was generally well tolerated in patients with Sjogren's syndrome.
- Serum levels of total IL-17A and BAFF increased following tibulizumab administration, reflecting target engagement. At doses of 100 mg Q4W and higher, the total IL-17A and BAFF concentrations appeared to plateau, suggesting the targets were engaged nearly to maximum levels.
- Throughout the study, total B cell counts were dose-dependently reduced in all participants, while administration of tibulizumab was associated with lower levels of Th1 cells. Tibulizumab was also shown to modulate inflammatory mediators, including serum amyloid A, interleukins 5 and 10, as well as basic fibroblast growth factor. These reductions suggest tibulizumab has treatment potential for additional autoimmune conditions.

The poster is available in the News and Events section on the Zura Bio website and will be archived for at least 30 days following presentation.

Key Findings from Preclinical Study of Tibulizumab in an RA Model

The preclinical study was designed to evaluate the respective and combined benefits of inhibiting IL-17A and BAFF in a mouse model of RA. Mice received IL-17A antibodies and/or BAFF antibodies, or a control antibody.

- Cumulative clinical disease scores were significantly reduced in mice treated with the combination of anti-IL-17A and anti-BAFF compared to the isotype control ($p<0.001$); combined IL-17A and BAFF inhibition also resulted in less signs of disease compared to individually targeted treatment.
- Combined IL-17A and BAFF inhibition reduced inflammation significantly compared to the control ($p<0.05$).
- Combined IL-17A and BAFF inhibition was associated with a significant reduction of anti-collagen antibodies compared to the control ($p<0.01$).

The study abstract, which was accepted for publication only, is available on the EULAR website.

ABOUT TIBULIZUMAB

Tibulizumab, a humanized bispecific dual antagonist antibody, is a fusion of TALTZ® (ixekizumab) and tabalumab that has been engineered to bind to and neutralize both IL-17A and BAFF. Tibulizumab is expected to enter Phase 2 clinical development for the treatment of systemic sclerosis in Q4-2024 and hidradenitis suppurativa in Q2-2025. Completed tibulizumab studies include Phase 1/1b trials in Sjogren's syndrome and rheumatoid arthritis.

ABOUT ZURA BIO

Zura Bio is a clinical-stage, multi-asset immunology company developing novel dual-pathway antibodies for autoimmune and inflammatory diseases. Currently, Zura Bio is developing three assets which have completed Phase 1/1b studies and are Phase 2 ready. The company is developing a portfolio of therapeutic indications for tibulizumab (ZB-106), ZB-168, and torudokimab (ZB-880), with a goal of demonstrating their efficacy, safety, and dosing convenience in autoimmune and inflammatory diseases, including systemic sclerosis and other novel indications with unmet needs.

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" 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 Zura Bio's anticipated proceeds to be received in the proposed Private Placement, expected timing of closing of the proposed Private Placement and the size, completion and use of proceeds of the proposed Private Placement, the forecast of cash runway and the Company's expectations regarding funding, operating and working capital expenditures, business strategies and objectives, statements related to Zura Bio's abilities to achieve anticipated internal readouts and achieve them in expected time periods, Zura Bio's product candidates, clinical trials and the design and timing thereof, statements with respect to expected therapeutic potential and statements regarding Zura Bio's product candidates ability to proceed into Phase 2 clinical trials. 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 and the ability to consummate the proposed Private Placement and the timing and proceeds thereof; are difficult or impossible to predict and could differ materially from those expressed or implied in such forward-looking statements. You should carefully consider the risks and uncertainties described in the "Risk Factors" sections of Zura Bio's 10-K for the year ended December 31, 2023 and other filings with the SEC, including: Zura Bio's expectations regarding product candidates and their related benefits; Zura Bio's beliefs regarding potential benefits or limitations of competing products both in development and approved; information regarding Zura Bio's vision and strategy; anticipated timing of key events and initiation of Zura Bio's studies and release of clinical data; Zura Bio's expectations regarding the general acceptability and maintenance of our products by regulatory authorities, payors, physicians, and patients; Zura Bio's ability to attract and retain key personnel; the accuracy of Zura Bio's future operating expenses, capital requirements and needs for additional financing; Zura Bio's ability to obtain funding for operations, including funds that may be necessary to complete development of our product candidates; the fact that Zura Bio has not completed any clinical trials and has no products approved for commercial sale; the fact that Zura Bio has incurred significant losses since inception, and it expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future; Zura Bio's ability to renew existing contracts; Zura Bio's reliance on third-party contract development manufacturing organizations for the manufacture of clinical materials; Zura Bio's ability to obtain regulatory approval for our products, and any related restrictions or limitations of any approved products; Zura Bio's ability to effectively manage growth and competitive pressures from other companies worldwide in the therapies in which Zura Bio competes; and litigation and Zura Bio's ability to adequately protect intellectual property rights. These risks and uncertainties may be amplified by health epidemics or other unanticipated global disruption events, 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, including projections, 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 publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, or should circumstances change, except as otherwise required by securities and other applicable laws.

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