Press Release
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Positive 52-week Phase 2b/3 Data of Izokibep in Psoriatic Arthritis to be Presented at ACR Convergence 2025

Solna, Sweden, October 24, 2025. Affibody AB ("Affibody") today announced that positive 52-week data from a global Phase 2b/3 study of izokibep in psoriatic arthritis (PsA) will be presented as a late breaking poster presentation at the American College of Rheumatology (ACR) Convergence 2025, taking place October 24-29 in Chicago.

As previously announced, the pivotal Phase 2b/3 study of izokibep in PsA met the primary endpoint of ACR50 at 16 weeks with high statistical significance, as well as several secondary endpoints including PASI90, minimal disease activity (MDA) and quality-of-life measures.

At week 16, patients originally randomized to izokibep kept receiving izokibep per their original dose and schedule, while patients receiving placebo were switched to izokibep 160 mg once weekly (QW) up to week 52.

Continued improvement after week 16 was seen for patients randomized to either of the izokibep groups (160 mg once every two weeks (Q2W) or 160 mg QW), and rapid improvement was observed in patients following crossover from placebo to izokibep treatment. By week 52, approximately half of all patients achieved ACR50 (izokibep Q2W: 50%, izokibep QW: 57%, placebo-izokibep QW: 51%).

Substantial percentages of patients in all groups also achieved the high-hurdle endpoints of ACR70 (izokibep Q2W: 36%, izokibep QW: 42%, placebo-izokibep QW: 42%), PASI90 (izokibep Q2W: 63%, izokibep QW: 69%, placebo-izokibep QW: 65%), PASI100 (izokibep Q2W: 55%, izokibep QW: 64%, placebo-izokibep QW: 58%), and MDA (izokibep Q2W: 47%, izokibep QW: 52%, placebo-izokibep QW: 47%) at week 52. Improvements in quality-of-life measures were also observed across groups.

Izokibep was well-tolerated with a favorable safety profile consistent with previous studies.

"Even with current therapies, psoriatic arthritis remains difficult to manage," said Professor Philip Mease, M.D., Rheumatology Research, Providence Swedish Medical Center and University of Washington School of Medicine, Seattle, WA, USA. "The durable improvements observed with izokibep are highly encouraging and offer real promise for long-term disease control and higher quality of life for patients."

Professor Philip Mease, investigator in the study, will present the week 52 study results in a late breaking poster presentation at ACR Convergence 2025 on Tuesday, October 28.

The presentation details are as follows:
Title: Efficacy and Safety of Izokibep, a Novel IL-17A Inhibitor, in Patients with Active Psoriatic Arthritis: Week 52 Results from a Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase 2b/3 Study.

Date/Time: Tuesday, October 28, 2025 at 10:30 AM – 12:30 PM CT
Presenter: Professor Philip Mease, M.D., Rheumatology Research, Providence Swedish Medical Center and University of Washington School of Medicine, Seattle, WA, USA.
Abstract number: LB08

Additional information is available at: https://acrabstracts.org/abstract/efficacy-and-safety-of-izokibep-a-novel-il-17a-inhibitor-in-patients-with-active-psoriatic-arthritis-week-52-results-from-a-randomized-double-blind-placebo-controlled-multicenter-phase-2b-3-stu/.

About izokibep

Izokibep is an Affibody® molecule designed to inhibit IL-17AA with high potency through tight binding affinity, the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody, and an albumin binding domain that results in improved pharmacokinetic (PK) properties. Clinical trial data support the hypothesis that these unique characteristics of izokibep may provide clinically meaningful and differentiated benefits for patients, including resolution of key manifestations of disease. Izokibep has been administered to more than a thousand patients, some of whom have been dosed for more than three years.

Late-stage trials of izokibep in hidradenitis suppurativa (HS) and psoriatic arthritis (PsA) have demonstrated levels of clinical response comparable with next generation approaches to IL-17 inhibition. These data also demonstrate that targeting IL-17A alone with greater potency can achieve the same or better clinical responses than agents targeting IL-17 subunits more broadly than IL-17A, without their associated safety liabilities.

About the Phase 2b/3 Psoriatic Arthritis clinical trial

The Phase 2b/3 clinical trial (NCT05623345) is a global, multi center, randomized double-blind, placebo-controlled trial evaluating the safety and efficacy of izokibep dosed subcutaneously 160 mg every week (QW) or every two weeks (Q2W) versus placebo. 343 adult patients with active PsA were enrolled across 96 sites in the United States, Canada and Europe. At week 16, patients originally randomized to izokibep kept receiving izokibep per their original dose and schedule, while patients receiving placebo were switched to izokibep 160 mg once weekly (QW) up to week 52.

For more information about the Phase 2b/3 PsA clinical trial, please visit www.clinicaltrials.gov.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic immune-mediated inflammatory disease characterized by multiple manifestations including joint inflammation, skin lesions (psoriasis), and enthesitis (painful inflammation of the tissues that connect ligament and tendons to bone), all contributing to reduced quality of life and the risk of permanent disability. The pathology is dominated by pro-inflammatory T-helper (Th-17) cells that lead to over expression of IL-17, IL-23, and TNF cytokines. It is estimated that approximately 30% of people currently living with psoriasis will develop PsA over time. There remains a large unmet need for more effective therapies to treat PsA across all disease manifestations.

About Affibody® molecules

Affibody® molecules are a novel drug class of small therapeutic proteins with characteristics surpassing monoclonal antibodies (mAbs) and antibody fragments. The Company has created a large library consisting of more than ten billion Affibody® molecules, all with unique binding sites, from which binders to given targets are selected. Affibody® molecules are only 6 kDa in size.

They have demonstrated clinical utilities both as tumor-targeting moieties through their small size and as efficacious disease blocking agents in autoimmune indications by utilizing the inherent properties that allow multi-specific formats.

About Affibody

Affibody is a clinical stage integrated biopharmaceutical company with a broad product pipeline focused on developing innovative bi- and multi-specific next generation biopharmaceutical drugs based on its unique proprietary technology platform, Affibody® molecules.

Through its validated business model, the company has a proven capability of identifying and prioritizing strategic projects in a timely and de-risked way. Affibody has established several partnerships for the development and commercialization of its innovations with international pharmaceutical companies.

Affibody's main shareholder Patricia Industries is a part of Investor AB.

Further information can be found at: www.affibody.com.

Disclaimer

This press release contains forward-looking statements. While Affibody consider the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by several hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements.

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Attachments

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