Press Release
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Positive 16-week Phase 3 Data of Izokibep in Hidradenitis Suppurativa Presented at EADV 2025

Solna, Sweden, September 19, 2025. Affibody AB ("Affibody") today announced positive 16-week data from a global Phase 3 study of izokibep in hidradenitis suppurativa (HS) that was presented at a late breaking session of the 2025 European Academy of Dermatology & Venereology Congress (EADV) in Paris.

The Phase 3 study of izokibep in HS met the primary endpoint of HiSCR75 at week 12, as well as several key secondary endpoints including HiSCR90 and HiSCR100.

Data from week 16 demonstrate deepening of responses over time with statistically significant improvement across multiple efficacy endpoints. 37% of patients treated with 160 mg izokibep weekly (QW) achieved HiSCR75 compared to 20% of patients receiving placebo ($p<0.01$).

In higher order endpoints, 24% of patients treated with izokibep achieved HiSCR90, compared to 12% with placebo ($p<0.05$), and 21% of patients treated with izokibep achieved HiSCR100, compared to 9% with placebo ($p<0.01$).

"Hidradenitis suppurativa is a painful, chronic disease that profoundly affects patients' physical and emotional well-being, underscoring the urgent need for better treatments to improve outcomes and quality of life," said presenter and principal investigator Kim Papp, M.D., Ph.D., Probity Medical Research, Inc. and Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Canada. "The statistically significant and clinically relevant responses demonstrated for izokibep across multiple efficacy endpoints, especially in higher-order responses with over 1 in 5 izokibep-treated patients achieving HiSCR100, are very encouraging and can mean a real difference for the significant number of patients debilitated by HS".

Significant improvement was also demonstrated in patient reported outcomes. Among patients treated with izokibep and with a baseline pain numeric rating scale (NRS) ≥4, 38% achieved a ≥3-point reduction in pain NRS compared to 17% of patients receiving placebo ($p<0.01$). In addition, significant improvements were seen with izokibep in Dermatology Life Quality Index, for which patients treated with izokibep had a least squares mean change from baseline of −4.4 (standard error: 0.6) compared to −2.9 (standard error: 0.5) for patients receiving placebo ($p<0.05$).

Izokibep was generally well-tolerated with a favorable safety profile consistent with previous studies. There were no reports of Candida infection, inflammatory bowel disease, or suicidal ideation with izokibep.

"We are very pleased with the izokibep 16-week data in HS demonstrating deepening of responses with time and significant improvement in hard-to-reach endpoints," said David Bejker, Chief Executive Officer of Affibody. "With its strong Phase 3 results, clear path to approval, and compelling product profile, we believe izokibep can become a game-changing drug bringing new hope to patients."

About the Phase 3 Hidradenitis Suppurativa clinical study

The Phase 3 clinical study (NCT05905783) was a global, multicenter, randomized double-blind, placebo-controlled trial evaluating the safety and efficacy of izokibep dosed subcutaneously 160 mg every week (QW) versus placebo. The study included 258 randomized patients with moderate-to-severe HS. The primary endpoint was the proportion of patients achieving HiSCR75 at week 12. Further endpoints included HiSCR90 and HiSCR100 as well as later timepoints. At week 16, patients who received placebo were switched to izokibep 160 mg QW.

For more information about the Phase 3 HS clinical study, please visit www.clinicaltrials.gov.

About Hidradenitis Suppurativa

HS is a chronic inflammatory skin disease which typically manifests in areas with high concentrations of sweat glands causing inflammatory nodules, abscesses, draining fistulas, malodor, scarring, and severe pain. HS is a highly burdensome condition that profoundly impairs patients' quality of life. Patients suffering from HS miss a greater number of days of work and have increased disability compared to the average population.

HiSCR measures response to treatment in HS with HiSCR75 indicating at least a 75% reduction in total abscess and inflammatory nodule count (AN count), with no increase in abscess count, and no increase in draining fistula count relative to baseline. Higher order measures such as HiSCR90, and HiSCR100 indicate 90%, and 100% reduction respectively.

About izokibep

Izokibep is an Affibody® molecule designed to inhibit IL-17A 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 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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