Press Release
11 September 2025 09:30:00 CEST

Positive 16-week Phase 3 Data of Izokibep in Hidradenitis Suppurativa to be Presented at EADV 2025 Late Breaking Session

Solna, Sweden, September 11, 2025. Affibody AB ("Affibody") today announced that positive 16-week data from a global Phase 3 study of izokibep in hidradenitis suppurativa (HS) will be presented in a late breaking session of the 2025 European Academy of Dermatology & Venereology Congress (EADV) taking place September 17-20 in Paris.

As previously announced, 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 and confirm the favorable safety profile observed in previous studies.

Dr. Kim Papp, principal investigator in the study, will present the week 16 study results in a late breaking oral presentation at EADV on Wednesday, September 17, 2025. The presentation details are as follows:

Title: Efficacy and safety of izokibep, a novel interleukin-17A inhibitor, in moderate to severe hidradenitis suppurativa: Week 16 results from a randomised, double-blind, placebo-controlled, multicentre, phase 3 study.
Date/Time: Wednesday, September 17, 2025 at 3:00 – 3:15 PM CEST
Presenter: Kim Papp, M.D., Ph.D., Probity Medical Research, Inc. and Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Canada
Abstract ID: LBA-288

Additional information about EADV 2025 is available at: https://eadv.org/congress/.

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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