Press Release
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Positive Phase 3 Results in Hidradenitis Suppurativa Further Strengthen Competitive Profile of Izokibep

• Phase 3 trial of izokibep in patients with hidradenitis suppurativa met primary endpoint of HiSCR75 at week 12, as well as the key secondary endpoints of HiSCR90 and HiSCR100.
• Data from two-thirds of trial participants who have completed week 16 demonstrate deepening of responses over time.
• No new safety signals were identified, and the favorable safety profile demonstrated in previous trials was confirmed.

Stockholm, Sweden, August 13, 2024. Affibody's partner ACELYRIN, INC. today announced that the Phase 3 trial of the Affibody® molecule izokibep in patients with hidradenitis suppurativa (HS) achieved its primary endpoint of HiSCR75 at 12 weeks, as well as the key secondary endpoints of HiSCR90 and HiSCR100.

"We are delighted that the Phase 3 HS trial of izokibep was successful, again confirming the strength of the Affibody® platform in immunology and inflammation. Today's positive HS data and previously announced psoriatic arthritis (PsA) data support a path to approval for izokibep," said David Bejker, Chief Executive Officer of Affibody. "Our partner ACELYRIN has determined that a program of this breadth and size is best brought to market by a larger organization with the resources and existing footprint in these indications. Given our continuing confidence in izokibep's best-in-class potential, underpinned by the breadth of efficacy and safety data generated across multiple indications, we will work with ACELYRIN to bring izokibep to patients in need of novel treatments."

In addition to the positive Phase 3 HS results, ACELYRIN today announced that they will complete the ongoing HS and PsA trials but will not initiate the planned additional Phase 3 studies of izokibep in these indications. Top-line data from the ongoing Phase 2b/3 trial of izokibep in uveitis are expected in the fourth quarter of 2024.

The global Phase 3 trial in HS confirmed statistically significant responses across multiple efficacy endpoints at 12 weeks. 33% of patients receiving izokibep 160 mg weekly (QW) achieved HiSCR75, the primary endpoint, compared to 21% of patients receiving placebo ($p = 0.0294$). In higher order endpoints, 25% of patients on izokibep achieved HiSCR90, compared to 9% on placebo ($p = 0.0009$), and 22% of patients on izokibep achieved HiSCR100, compared to 8% on placebo ($p = 0.001$).

The primary endpoint was measured at 12 weeks and the study continued dosing patients in a placebo-controlled manner through week 16. Preliminary data from two-thirds of the trial participants who have completed week 16 further demonstrate deepening of responses with izokibep over time, where 40% of patients receiving izokibep 160 mg QW achieved HiSCR75, compared to 20% of patients receiving placebo ($p<0.05$). Additionally, in higher order endpoints 27% of patients on izokibep achieved HiSCR90, compared to 13% on placebo ($p<0.05$), and 25% of patients on izokibep achieved HiSCR100, compared to 10% on placebo ($p<0.05$).

Izokibep was well-tolerated with a favorable safety profile consistent with previous izokibep experience and the IL-17A class and no new safety signals were identified. Notably, there were no cases of candida infection, liver toxicity or suicidal ideation/behavior in the izokibep treatment arm.

“We are pleased that the Phase 3 HS trial of izokibep met its primary endpoint and provided clinically meaningful responses as early as week 12 in this devastating disease. Importantly, we are further encouraged by the deepening responses seen at week 16, with a quarter of the patients achieving HiSCR100. Past experience tells us these responses will deepen even further with continued treatment,” said Nikolai Brun, Chief Medical Officer of Affibody. “These results demonstrate that targeting IL-17A alone with greater potency can achieve the same or greater clinical responses than agents targeting IL-17 subunits more broadly, without their associated safety liabilities.”

Additional information about the results can be found at ACELYRIN.com.

About the Phase 3 Hidradenitis Suppurativa clinical trial
The Phase 3 clinical trial (NCT05905783) 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) versus placebo. The trial has enrolled 258 patients with moderate-to-severe hidradenitis suppurativa. The primary endpoint is the proportion of patients achieving HiSCR75 at week 12. Further endpoints include HiSCR90 and HiSCR100 as well as later timepoints. At week 16, patients who received placebo are switched to izokibep 160 mg QW.

For more information about the Phase 3 hidradenitis suppurativa clinical trial, please visit www.clinicaltrials.gov.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease causing scarring, abscesses, malodor, and severe pain. HS typically occurs in areas with high concentrations of sweat glands and is typically accompanied by pain, malodor, drainage, and disfigurement that contribute to disability and a devastating impact on quality of life. Patients with 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 orders such as HiSCR90, and HiSCR100 indicate 90%, and 100% reduction respectively.

About izokibep

Izokibep is small protein Affibody® therapeutic 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.

Izokibep is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa, psoriatic arthritis, and uveitis. Top-line data from the ongoing Phase 2b/3 trial of izokibep in uveitis is expected in the fourth quarter of 2024.

Affibody has licensed izokibep, to ACELYRIN, INC. and Inmagene Biopharmaceuticals Co. Ltd., while retaining an option to commercialize in the Nordic region.

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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