Press Release
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Affibody's Partner ACELYRIN Announces Top-Line Results from Placebo-Controlled Clinical Trial of Izokibep for Moderate-to-Severe Hidradenitis Suppurativa

• The primary endpoint of HiSCR75 at week 16 did not meet statistical significance in the Non-Responder Imputation (NRI) primary analysis.

• HiSCR75 did meet statistical significance at week 16 in a Last Observation Carried Forward sensitivity analysis.

• HiSCR response rates of izokibep 160mg weekly (QW) were consistent with Part A open label results, demonstrating early onset of HiSCR100 at week 4, increasing through week 12 to 38% of patients in the Independently Conducted Pre-Planned Interim Analysis.

• Response was dose ordered, and safety was consistent with prior izokibep experience and not dose-limiting.

• Izokibep appears to be demonstrating consistent early and high orders of response without safety or tolerability limitation.

Solna, Sweden, September 11, 2023. Affibody's partner ACELYRIN, INC. today announced top-line results from Part B of a Phase 2b/3 trial evaluating izokibep for the treatment of moderate-to-severe Hidradenitis Suppurativa (HS). The primary endpoint of HiSCR75 at week 16 did not meet statistical significance. However, response rates for izokibep showed early HiSCR100 responses, a clear dose-effect supported by both pharmacokinetic exposures and HiSCR responses favoring 160mg weekly dosing, and no evidence of safety or tolerability limitation.

"*Although the overall study did not meet statistical significance, as reported by our partner ACELYRIN, izokibep appears to be demonstrating high orders of response for patients suffering from hidradenitis suppurativa without safety or tolerability limitations*," said David Bejker, CEO of Affibody. "*The consistent and early achievement of HiSCR100, along with the prior izokibep experience in Psoriatic Arthritis (PsA), continues to demonstrate the potential of izokibep for resolution of disease, especially in difficult to treat tissues. Our partner continues to evaluate izokibep in additional ongoing late-stage trials in HS, PsA, and uveitis, with top-line data for the Phase 2b/3 trial in PsA expected in Q1, 2024.*"

The randomized double-blind, placebo-controlled, multi-center trial evaluated the safety and efficacy of izokibep dosed 160 mg weekly (QW) and every two weeks (Q2W), versus placebo, in 175 patients with moderate-to-severe HS (Hurley Stage II and III). The trial was conducted at 50 sites globally and assessed various efficacy endpoints, including the primary endpoint of HiSCR75 (Hidradenitis Suppurativa Clinical Response) at 16 weeks utilizing a non-responder imputation (NRI) analysis method.

In the primary NRI analysis of Part B, statistical significance was impacted by patients with HiSCR75-100 discontinuing as early as week 4 unrelated to adverse events. In addition, there was a marked increase in placebo rates during the course of the study. Applying a Last Observation Carried Forward (LOCF) sensitivity analysis of the full dataset highlighted the impact of responder discontinuations on the primary analysis and showed statistical significance of HiSCR75 at week 16.

Endpoint	Part B NRI Izokibep 160 mg QW (n=57)	Part B NRI Izokibep 160 mg Q2W (n=59)	Part B NRI Placebo (n=59)
HiSCR75 p-value	39% 0.3278	34% 0.5997	29%
HiSCR100 p-value	26% 0.0595	22% 0.1408	12%

Endpoint	Part B LOCF Izokibep 160 mg QW (n=54)	Part B LOCF Izokibep 160 mg Q2W (n=57)	Part B LOCF Placebo (n=57)
HiSCR75 p-value	51% 0.0423	36% 0.7451	32%
HiSCR100 p-value	30% 0.0751	22% 0.3558	15%

An independently conducted pre-planned interim analysis, to which the company remained blinded until the time of this primary analysis, occurred prior to a rise in placebo rates observed later in the trial. This dataset provides an opportunity to view the performance of izokibep prior to this increase. The table below shows the consistency of Part A open label results relative to the Part B placebo-controlled interim analysis, which was pre-specified to be an as observed analysis at week 12.

Endpoint	Part A Izokibep 160 mg QW (n=21)	Part B Interim Izokibep 160 mg QW (n=21)	Part B Interim Izokibep 160 mg Q2W (n=27)	Part B Interim Placebo (n=23)
HiSCR75 p-value	57%	52% 0.018	30% 0.435	17%
HiSCR100 p-value	33%	38% 0.009	11% 0.518	4%

Also, given the number of responders who discontinued in the QW arm – the majority unrelated to an adverse event – a modified-NRI (mNRI) approach showed a high level of statistical significance and highlighted the impact of discontinuations on magnitude and significance of response. This analysis demonstrates the performance of izokibep at this juncture in the study – in isolation from the placebo rate increases observed later in the trial – and provides an exploratory approach to analyzing responder discontinuations.

Endpoint	Part B Interim mNRI Izokibep 160 mg QW (n=31)	Part B Interim mNRI Izokibep 160 mg Q2W (n=28)	Part B Interim mNRI Placebo (n=27)
HiSCR75 p-value	45% 0.0062	25%	15%
HiSCR100 p-value	29% 0.0054	11%	4%

The safety profile for izokibep was consistent with prior studies and the anti-IL-17A class. There were no events of candida in the high dose 160mg QW arm and there were two discontinuations across the trial due to injection site reactions (3.5%).

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 HiSCR50 indicating at least a 50% 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 HiSCR75, HiSCR90, and HiSCR100 indicate 75%, 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 is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

Affibody has licensed izokibep, to ACELYRIN, INC. and Inmagene Biopharmaceuticals Co. Ltd., while retaining an option to co-promote 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.

Contacts

Affibody
David Bejker, CEO, +46 706 454 948
Camilla Danell, CFO, +46 761 148 910

Affibody Media Contact
Richard Hayhurst/Ola Bjorkman, RHApr, +44 7711 821 527, richard@rhacomms.eu

Attachments

Affibody's Partner ACELYRIN Announces Top-Line Results from Placebo-Controlled Clinical Trial of Izokibep for Moderate-to-Severe Hidradenitis Suppurativa