Press Release
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Affibody's Partner ACELYRIN Provides Update on Izokibep Clinical Development Program

Solna, Sweden, November 27, 2023. Affibody's partner ACELYRIN, INC. ("ACELYRIN") today provided an update on its izokibep clinical development program, including the ongoing global Phase 2b/3 trial in psoriatic arthritis ("PsA trial").

The ongoing PsA trial, initiated by ACELYRIN, is designed with four arms: 160mg dosed every week (QW), 160mg dosed every other week (Q2W), 80mg dosed every four weeks (Q4W) and placebo. ACELYRIN recently identified clinical trial execution errors involving its CRO and one of the vendors engaged by the CRO. ACELYRIN has confirmed that the protocol, which outlined dosing sequence, was correct. However, ACELYRIN's protocol was programmed incorrectly by the vendor, resulting in a sequencing error that went further unidentified through the providers' testing processes. As a result, some patients in the 160mg Q2W and 80mg Q4W arms received placebo and active treatment in random order rather than in an alternating pattern as intended. Importantly, there is no risk to patient safety resulting from the sequencing errors and no patient received more active treatment than was already included in the protocol for the most frequent 160mg QW dosing arm. The programming error has been addressed and the dosing sequence has been corrected.

ACELYRIN is working to determine the implications of the sequencing errors in the 160mg Q2W and 80mg Q4W arms. Based on ACELYRIN's review to date and the fact that the placebo and 160mg QW arms were designed for consistent weekly dosing, ACELYRIN has no reason to believe the 160mg QW and placebo arms are impacted.

ACELYRIN will contract with a third party-party to conduct an independent audit of the trials being conducted by the CRO for ACELYRIN. Pending completion of the evaluation from the third-party auditor, ACELYRIN plans to report top-line data from its PsA trial in the first quarter of 2024.

"We are disappointed by this information", said David Bejker, CEO of Affibody. *"We are, however, committed to fully understand these issues in the clinical development of izokibep and remain convinced that izokibep is a potentially very important treatment for multiple immunologic conditions with strong and differentiated Phase 2 data in PsA."*

Affibody announced in November 2020 the initiation of a Phase 2 trial of izokibep in PsA. This Phase 2 trial has generated differentiated 16- and 46-week data. Long-term efficacy results from the same trial presented recently at the American College of Rheumatology annual meeting showed that with longer duration of treatment, patients experienced durable and deepening resolution of disease.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory musculoskeletal condition affecting the peripheral joints, the skin (with psoriasis), the nails, and in approximately 30 percent of individuals, the spine. Left under-treated, PsA leads to chronic joint pain, swelling, and damage with a high potential for permanent disability. Psoriatic arthritis pathology is dominated by pro-inflammatory T-helper (Th-17) cells that lead to over expression of IL-17, IL-23, and TNF cytokines.

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

Attachments

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