Press Release
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Affibody's Licensee ACELYRIN Announces Top-line Results for Izokibep in Uveitis

Stockholm, Sweden, December 10, 2024. Affibody's licensee ACELYRIN, INC. today announced that the Phase 2b/3 trial of izokibep in non-infectious, non-anterior uveitis did not meet the primary endpoint. Izokibep was well-tolerated in the trial, with a favorable safety profile consistent with previous data and the IL-17A class.

The primary endpoint, treatment failure rate at 24 weeks, was 45.0% for izokibep and 50.7% for placebo (p-value: 0.4914). Additionally, no key secondary endpoints achieved statistical significance. While IL-17 inhibition is an extensively validated mechanism of action across a range of chronic inflammatory conditions, including hidradenitis suppurativa (HS) and psoriatic arthritis (PsA), it remains to be proven in uveitis.

"The outcome in the uveitis trial is in stark contrast to the best-in-class results from late-stage trials of izokibep in both HS and PsA that were recently presented at the EADV and EULAR conferences respectively," said David Bejker, Chief Executive Officer of Affibody. "While the positive HS and PsA data support a path to approval for izokibep, ACELYRIN has determined that a program of this breadth and size is best brought to market by a larger organization. Affibody continues to believe that izokibep can become a game-changing drug in the dermatology field, particularly for the significant number of patients debilitated by HS."

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.

Late-stage trials of izokibep in psoriatic arthritis (PsA) and hidradenitis suppurativa (HS) 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.

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.

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Attachments

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