Press Release
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Affibody's licensee Rallybio Announces Positive Data for RLYB116 Phase 1 Study Demonstrating Complete and Sustained Inhibition of Terminal Complement

Stockholm, Sweden, February 17, 2026. Affibody's licensee Rallybio Corporation (Rallybio) has today announced positive results from its Phase 1 confirmatory pharmacokinetic /pharmacodynamic (PK/PD) clinical study evaluating RLYB116, an innovative, once-weekly, small volume, subcutaneously injected complement factor 5 (C5) inhibitor, based on the Affibody® platform. Rallybio is developing RLYB116 for patients with complement-mediated diseases with its initial focus on immune platelet transfusion refractoriness (PTR) and refractory antiphospholipid syndrome (APS).

The data announced by Rallybio demonstrated the following:

- A 300 mg once-a-week dose of subcutaneously administered RLYB116 achieved complete and sustained inhibition of terminal complement.
- Complete and sustained inhibition of ex-vivo hemolytic activity demonstrates clinically effective blockade of terminal complement.
- RLYB116 administered as a 150 mg and 300 mg once-a-week dose was well tolerated with no gastrointestinal side effects reported among participants. The most common adverse events in both cohorts were mild-to-moderate injection site reactions, consistent with other subcutaneously administered biologics. None were severe or caused discontinuation of study drug. These results further validate the manufacturing process enhancements designed to improve the tolerability profile of RLYB116.

"We are very pleased with the highly encouraging results demonstrating complete and sustained inhibition of terminal complement by RLYB116 using a convenient, small volume, once-weekly subcutaneous dosing," said David Bejker, CEO of Affibody. "These data further illustrate the potential of the Affibody® platform to deliver best-in-class therapies."

The single-blind multiple ascending dose Phase 1 confirmatory PK/PD study of RLYB116 (NCT06797375) was designed to demonstrate complete and sustained complement inhibition with favorable tolerability in healthy volunteers. The study evaluated a 4-week treatment duration that included two cohorts of eight participants each, randomized 3-to-1 to receive either RLYB116 or placebo once weekly. Cohort 1 evaluated dosing of 150 mg and Cohort 2 evaluated dosing of 300 mg. The study included a 10-week follow-up period after the conclusion of treatment.

Rallybio is currently planning to initiate a Phase 2 clinical study with RLYB116 in PTR in H2 2026 with potential for topline data in 2027.

About Rallybio's RLYB116

RLYB116 is an innovative, long-acting, subcutaneously injected inhibitor of complement factor 5 (C5), based on the Affibody® platform, in development for the treatment of patients with complement-mediated diseases.

The molecule was initially discovered by Affibody under a collaboration with Swedish Orphan Biovitrum AB (Sobi).

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 benefit both as tumor-targeting moieties and as efficacious disease modifying agents in autoimmune indications by utilizing the inherent differentiated properties of the platform.

About Affibody

Affibody is a clinical stage radiopharmaceutical company developing next generation Radioligand Therapies (RLTs) designed to deliver highly selective tumor targeting across a wide range of cancers. Leveraging decades of innovation in Affibody® molecule discovery and engineering, together with deep understanding of the RLT field, the company is advancing a novel pipeline focused on oncology indications with high unmet medical need. Affibody's lead RLT candidate, ABY-271, is currently being evaluated in a first-in-human clinical study in HER2 positive metastatic breast cancer.

The Affibody® platform has also demonstrated clinical value in immunology and inflammation, with multiple programs being advanced through strategic partnerships.

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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