Press Release
20 December 2023 15:30:00 CET

Affibody's Licensee Rallybio Announces Preliminary Phase 1 MAD Data for RLYB116

Solna, Sweden, December 20, 2023. Affibody's licensee Rallybio Corporation (Rallybio) today announced preliminary Phase 1 multiple ascending dose (MAD) data for RLYB116, an innovative, long-acting, low volume subcutaneously injected inhibitor of complement component 5 (C5), based on the Affibody® platform, in development for patients with complement-mediated diseases.

- 100 mg Results Demonstrated a Mean Reduction of Greater than 93% in Free C5 with Low Volume Weekly Subcutaneous Dosing
- Data Supports the Study of RLYB116 as a Differentiated Therapeutic for the Treatment of Generalized Myasthenia Gravis

"*We are pleased to see substantial reductions in free C5 with once weekly subcutaneous dosing of RLYB116*", said David Bejker, CEO of Affibody. "*This validates the Affibody® platform's inherent advantages to create potentially differentiated and attractive low volume subcutaneous alternatives for patients.*"

The Phase 1 MAD study for RLYB116 evaluated the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of subcutaneous RLYB116 in healthy participants with multiple dose administration. The MAD study utilized an adaptive design and included four cohorts of twelve (12) participants receiving doses of up to 200 mg per week of RLYB116 or placebo, with a four-week treatment duration and a 10-week follow-up period.

The preliminary results announced by Rallybio showed:

- A 100 mg low volume (1 mL) once-a-week dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at Day 29 with measurement prior to the last dose. The reduction in free C5 at 24 hours after the first dose of 100 mg was greater than 99%. Rallybio stated that these data and additional work conducted with RLYB116 reinforce their confidence that RLYB116 has the potential to be an effective treatment for patients with certain complement-mediated diseases, including generalized myasthenia gravis (gMG).
- RLYB116 also demonstrated low inter-subject variability and consistent increases in exposure relative to dose. The mean estimated elimination half-life for RLYB116 was >300 hours.
- In comparison to 100 mg weekly administration, higher concentrations of RLYB116 were observed in a cohort with 100 mg administered twice per week and were associated with a greater than 97% mean reduction in free C5.
- RLYB116 administered as a 100 mg once-a-week dose was observed to be generally well tolerated. The most common adverse event (AE) in the cohort was injection site reaction (ISR), which occurred in 60% of the participants in the cohort. All AEs during subcutaneous administration with the 100 mg weekly dose were mild in severity.

- The ISR rate for all participants in the four (4) cohorts was 59% and all were mild in severity. There were no serious AEs reported for participants receiving study treatment.
- A participant with a history of hepatitis A receiving the 150 mg dose experienced liver enzyme test elevation that resulted in discontinuation and a reduction in the dose for the 3rd cohort from 150 mg to 125 mg.
- The measurement of anti-drug antibody (ADA) formation in the study did not demonstrate an effect of ADA on PK or PD parameters and did not appear to be associated with an effect on AE incidence or severity.

As the next step, Rallybio stated that it will prioritize investments in the RLYB116 manufacturing process before proceeding to Phase 2. Rallybio stated that it expects that the additional manufacturing work will improve tolerability at higher doses with a low injection volume and infrequent subcutaneous administration. Rallybio believes such enhancements will enable higher exposure to RLYB116 and potentially increase C5 reduction, which can result in treating a broader range of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria and antiphospholipid syndrome.

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 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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