Press Release
07 November 2022 15:20:00 CET

Affibody's partner Rallybio Announces Positive Phase 1 Results for RLYB116

Solna, Sweden, November 7, 2022. Affibody's licensee Rallybio Corporation (Nasdaq: RLYB), has announced positive topline results from a Phase 1 single ascending dose (SAD) study in healthy participants of RLYB116.

• A single 100 mg subcutaneous dose demonstrated a reduction of >99% in free C5 and was generally well-tolerated.
• Phase 1 Multiple Ascending Dose (MAD) study expected to commence in Q1, 2023.

In the ongoing Phase 1 study, all study participants that were administered a single 1 mL subcutaneous injection of 100 mg of RLYB116 (n=6) demonstrated a reduction in free C5 greater than 99% within 24 hours of dosing. The terminal elimination half-life of RLYB116 was greater than 300 hours.

Subcutaneously administered RLYB116 was observed to be generally well-tolerated at the 100 mg dose, with mild or moderate adverse events and no drug-related serious adverse events reported.

About the RLYB116 Phase 1 Study
The ongoing RLYB116 single-blind, placebo-controlled (3:1) dose escalation study was initiated in February 2022 and is designed to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of single subcutaneous dose RLYB116 in healthy participants and includes five dose cohorts (2, 10, 30, 100, 300 mg RLYB116) with each enrolling 8 participants. Post-treatment / study follow-up is expected to continue for 10 weeks.

About RLYB116
RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) and generalized Myasthenia Gravis (gMG). RLYB116 is an Affibody® molecule that has the potential to drive the rapid, complete, and sustained inhibition of C5 with a subcutaneous injection. The molecule was initially developed by Affibody under a collaboration with Sobi.

About RallyBio
Rallybio is a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases. Since its launch in January 2018, Rallybio has built a portfolio of promising product candidates, which are now in development to address rare diseases in the areas of hematology, immuno-inflammation, maternal fetal health, and metabolic disorders. The Company's mission is being advanced by a team of highly experienced biopharma industry leaders with extensive research, development, and rare disease expertise. Rallybio is headquartered in New Haven, Connecticut, with an additional facility at the University of Connecticut's Technology Incubation Program in Farmington, Connecticut.

Further information can be found at: www.rallybio.com.

Disclaimer
This press release contains forward-looking statements. While Affibody AB 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 Investor Contact
Alexandra Roy, aroy@soleburytrout.com

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

About Affibody

Affibody is a clinical-stage biopharmaceutical company with a broad product pipeline focused on developing innovative bi- and multi-specific next generation biopharmaceuticals based on its unique proprietary technology platforms: Affibody® molecules and Albumod®.

Affibody is a holding of Patricia Industries.

For more information, please visit www.affibody.com

Attachments

Affibody's partner Rallybio Announces Positive Phase 1 Results for RLYB116