Fraunhofer ITMP Celebrates Milestone as Rallybio Releases Preliminary Data for RLYB212 Phase 1 Study

Novel Multiple Dose Cohort Demonstrates Promising Results for FNAIT Prevention. Completion of Maternal-Fetal Toxicology Program Bolsters Confidence for Phase-2 and Phase-3 Studies

Frankfurt/Main, Nov. 28, 2023. Rallybio Corporation’s preliminary data show promising results for the recently completed multiple-dose cohort of the Phase-1 safety and pharmacokinetic (PK) study of RLYB212. This landmark study, initiated in the first quarter of 2023 and conducted in our Clinical Research Department, was designed to evaluate the safety and PK of subcutaneously administered RLYB212 for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT). This groundbreaking study, initiated in the first quarter of 2023 and conducted at our Clinical Research department, aimed to evaluate the safety and PK of subcutaneous RLYB212 for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT).

In collaboration with the German Red Cross, the Fraunhofer ITMP played a crucial role in advancing this research, focusing on HPA-1a negative healthy participants. The preliminary data presented by Rallybio highlights the consistency in multiple dose PK within and between subjects, supporting a once-monthly dosing regimen for the planned Phase-2 study. We are particularly pleased to note that RLYB212 was generally well tolerated, with no reports of injection site reactions or serious adverse events.

In Rallybio’s announcement vom November 28, 2023, Róisín Armstrong, Ph.D., Rallybio’s RLYB212 Program Lead, expressed gratitude, stating, “These data support our belief in the potential use of subcutaneous RLYB212 as a prophylactic therapeutic for the prevention of HPA-1a alloimmunization and FNAIT.”

Significantly, Rallybio’s completion of the RLYB212 toxicology package, including the maternal-fetal toxicology program, is a testament to the success of our collaboration and a key milestone for the future Phase-2 and Phase-3 studies, especially in pregnant women.

The Fraunhofer ITMP continues to promote innovative research projects and thus contributes to the development of therapeutic options for serious and rare diseases.