Prophylix AS Rare Disease Programs Acquired by Rallybio

Agreement consists of two orphan drug programs that target life-threatening bleeding disorder in newborns

TROMSØ, August 22, 2019 – Prophylix AS today announced that they have entered into a definitive agreement with Rallybio IPA LLC, a U.S.-based drug development company, under which Rallybio acquires two orphan drug programs from Prophylix AS, NAITgam and a follow-on therapy. NAITgam is a plasma-derived HPA-1a antibody in early clinical development for the treatment of fetal and neonatal alloimmune thrombocytopenia (FNAIT), a potentially disabling or life-threatening disorder in fetuses and newborns.

"I am incredibly proud of the achievements of the Prophylix team, and team of researchers who developed this technology, headed by Professor Bjørn Skogen at UiT – the Arctic University of Norway and at the National Unit for Platelet Immunology at the University Hospital of North Norway," said Søren Weis Dahl, CEO of Prophylix. "We are pleased with the progress we were able to make in advancing these two potential preventative therapies for FNAIT, and we believe that Rallybio's vast experience in developing therapies for the treatment of rare diseases will ensure that NAITgam is successfully brought to patients in need."

"We believe that NAITgam has the potential to eradicate FNAIT, saving babies from the debilitating and potentially catastrophic outcomes associated with this disease," said Martin Mackay, Chairman and CEO of Rallybio. "We thank the Prophylix team for putting a spotlight on this terrible disease and we look forward to using our expertise in rare disease drug development to bring NAITgam as rapidly as possible to pregnant women at risk for FNAIT."

NAITgam has received an Orphan Drug Designation (ODD) for the prevention of FNAIT from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and has been granted a Rare Pediatric Disease (RPD) designation by the U.S. FDA, which may qualify for a Priority Review Voucher (PRV).

Under the terms of the agreement, Prophylix will receive an undisclosed upfront payment, and is eligible for development milestones, a percentage of the value of a PRV, if granted, and single to low double digit tiered royalties on sales of NAITgam and the follow-on therapy. The Asset Purchase Agreement was signed and executed June 28, 2019, subject to customary closing conditions.

About Prophylix

Prophylix AS is a Scandinavian biotech company headquartered in Tromsø, Norway, and the owner of its U.S. subsidiary Prophylix Pharma Inc. Prophylix was established in 2008 by Norinnova Technology Transfer AS, the University Hospital of North Norway (UNN, Tromsø) and Oslo University Hospital, Ullevål. The scientific basis of this company is a collaborative research activity conducted by scientists at the universities and university hospitals in Oslo and Tromsø.

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