



Plakous Therapeutics Receives Rare Pediatric Disease and Orphan Drug Designations for Protego-PD™ for the Prevention of Necrotizing Enterocolitis

WINSTON-SALEM, N.C., June 18, 2020—Plakous Therapeutics, Inc. has been granted orphan drug and rare pediatric disease designations for its human placental extract, Protego-PD™, for the prevention of necrotizing enterocolitis (NEC) in early preterm infants.

The FDA grants orphan drug and rare pediatric disease designations to encourage the development of new drugs and biologics for the treatment and prevention of serious and life-threatening diseases that occur in fewer than 200,000 persons in the United States and affect children under the age of 18. These designations include frequent interactions with the FDA and eligibility for priority review and development incentives.

“With no currently approved treatment for NEC, receiving these designations is a significant step forward to stop this devastating disease from affecting fragile, premature babies,” said Robert Boyce, Chief Executive Officer of Plakous Therapeutics. “The team is excited by this news and its important role in our commercialization strategy. In the meantime, we are focused on expanding our successful preclinical data and achieving the regulatory milestones to develop the first FDA-approved treatment for the prevention of NEC.”

About Necrotizing Enterocolitis

NEC is caused by inflammation and lack of development of the intestine and is observed in very low birth weight babies (VLBWB), those babies born weighing less than three pounds. Over 90% of NEC cases occur in VLBWB. NEC is a rare pediatric disease that affects 6,000 VLBWB annually in the United States and carries a 30% mortality rate. Managing NEC consumes 20% of the \$5 billion in annual NICU expenditures plus an estimated \$4 billion in hospital costs for subsequent treatments. Currently, NEC has no approved treatments or diagnostic tests.

About Plakous Therapeutics

Plakous Therapeutics is a patient-focused biotherapeutic company that is dedicated to researching and developing regenerative therapies to improve patient outcomes and reduce health care costs. Our first product, Protego-PD™, is an orally delivered acellular biotherapeutic developed from post-delivery placentas. For more information, please visit the company’s website at plakoustherapeutics.com.

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