Therabron Therapeutics Completes Enrollment of Phase 2 Clinical Trial for Lead Product Candidate CG100 for the Prevention of Chronic Lung Disease in Preterm Infants

ROCKVILLE, MD, May 25, 2016 — Therabron Therapeutics, Inc., a clinical-stage biotechnology company dedicated to advancing a new standard in respiratory care, today announced the Company has completed enrollment of its phase 2 clinical trial evaluating its lead product candidate, CG100, for the prevention of chronic respiratory morbidity (CRM) in premature infants. CG100, a potential product based on Therabron's recombinant human Club Cell 10 kDa Protein (rhCC10), recently received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the prevention of chronic lung disease related to premature birth and has been granted orphan designations by both the US and EU Health Authorities.

"Completion of enrollment in this phase 2 trial represents the achievement of a significant milestone for Therabron and an important step toward evolving the standard of care for preterm infants. To our knowledge, this is the first interventional phase 2 trial undertaken to address the issue of neonatal CRM, a condition for which there is substantial unmet medical need, considerable cost of care and currently no available therapeutic options. We look forward to completing patient follow-up, continued discussions with the FDA and other health agencies, and the prospect of advancing CG100 into phase 3 clinical development," stated Dr. Alan Cohen, SVP and Chief Medical Officer of Therabron Therapeutics.

The multi-center, randomized, double-blind, placebo-controlled, dose-escalation trial, has fully enrolled, as planned, with 88 preterm infants between 24-29 weeks gestational age who received positive pressure mechanical ventilation for the management of neonatal respiratory distress syndrome. The trial continues to assess the safety and efficacy of a single intratracheal dose of CG100. The primary endpoint of interest is infant survival without CRM through 12 months (corrected age), with specific objectives of the reduction in respiratory re-hospitalizations, signs and symptoms of respiratory disease, unscheduled doctor's visits and use of respiratory medications in CG100 treated infants vs. placebo. The planned un-blinding of the phase 2 trial dataset is expected to occur in mid-2017. This phase 2 trial was supported, in part, by a grant from the U.S. FDA Office of Orphan Product Development.

About CG100

CG100, Therabron's intratracheal dosage form of rhCC10, is a recombinant version of a naturally occurring and highly conserved secretory protein that is believed to play an important protective role in the lung via maintenance and repair of airway epithelia and modulation of inflammation in a large variety of respiratory diseases. CG100 has the potential to improve long-term clinical outcomes in preterm infants and significantly reduce the economic burden beyond the infant's in-patient stay in the Neonatal Intensive Care Unit (NICU).

About Chronic Respiratory Morbidities in Preterm Infants

More than four million infants are born in the U.S. each year. Of these annual live births, more than ten percent of newborns are delivered prematurely, or before 37 weeks of gestation. Many of these preterm infants require admission to the NICU and critical care management in the first weeks and months of life. Preterm infants that survive their NICU stay through discharge are at high risk for development of CRM through the first year of life post-discharge. These infants typically experience repeated hospitalizations for respiratory complications, have persistent coughing and wheezing with the need for numerous respiratory medications, and frequent doctor visits throughout their infancy and childhood. Additionally, these infants are predisposed to longer term, potentially life-threatening respiratory infections and airway disorders such as asthma. An estimated $26 billion is spent annually in the US on medical issues related to prematurity and the emotional cost to families impacted by having a preterm child is substantial.

About Therabron Therapeutics, Inc.

At Therabron Therapeutics, we are advancing a platform of novel therapeutic proteins in an effort to change how a variety of neglected and under-treated respiratory and fibrotic conditions are managed. We are a privately held, clinical-stage biopharmaceutical company, developing a new class of drugs based on the naturally occurring secretoglobin family of proteins, which includes the CC10 protein — a molecule with both anti-inflammatory and immunomodulatory mechanisms. Therabron's product candidates have the potential to become first-in-class biologic therapeutics. For additional information, please visit www.therabron.com.

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