



Therabron Therapeutics Receives from FDA Rare Pediatric Disease Designation for Lead Phase 2 Program in Preterm Infants

ROCKVILLE, MD, June 2, 2016 — Therabron Therapeutics, Inc., a clinical-stage biotechnology company dedicated to advancing a new standard in respiratory care, today announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to rhCC10 (recombinant human Club Cell 10 kDa Protein), the company's lead product candidate, for the prevention of bronchopulmonary dysplasia and chronic respiratory morbidity (CRM) in preterm infants. The Rare Pediatric Disease Designation supplements the Fast Track Designation recently granted by the FDA for rhCC10. This program has also previously been granted Orphan Status by both the US and EU Health Authorities.

Thomas F. Miller, PhD, MBA, President and Chief Executive Officer of Therabron, noted, "We are extremely pleased that the FDA, in support of drug development for rare pediatric diseases, has granted rhCC10 this designation for conditions where there are no available treatment options and several unmet medical needs persist."

Last week, the Company announced it has completed enrollment of its phase 2 clinical trial evaluating its lead product candidate, CG100, for the prevention of CRM in premature infants. CG100 is based on Therabron's recombinant rhCC10 protein. The Company plans to unblind the trial dataset mid-next year and continue its work to advance this product candidate toward phase 3 development. This phase 2 trial has been supported, in part, by a grant from the U.S. FDA Office of Orphan Product Development.

The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the United States, primarily aged from birth to 18 years. Under the FDA's Rare Pediatric Disease Priority Review Voucher Program, a sponsor who receives an approval of a new drug application (NDA) or biologic license application (BLA) for a rare pediatric disease, may be eligible for a voucher which can be redeemed to obtain priority review for any subsequent marketing application for a different product. If obtained, the priority review voucher may be sold or transferred to another sponsor.

About Chronic Respiratory Morbidity

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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