Therabron Therapeutics Secures New Orphan Designation for the Prevention of Bronchopulmonary Dysplasia

Company Expands Orphan Designations in Major Market for Lead Product Candidate CG100

ROCKVILLE, MD -- May 13, 2015 -- Therabron Therapeutics, Inc. (Therabron), a specialty biotechnology company focused on the advancement of respiratory therapeutics with disease-modifying potential, today announced that the European Medicines Agency (EMA) has granted the Company’s lead product candidate, CG100, an orphan drug designation for the prevention of bronchopulmonary dysplasia (BPD). An orphan drug designation allows products receiving a marketing authorization from the EMA to have up to ten years of market exclusivity in the European Union (EU). Therabron previously secured an orphan designation for the prevention of BPD from the US Food and Drug Administration (FDA).

“Orphan designations granted by regulatory bodies like the FDA and EMA are important because it encourages research and product development for underserved patient populations that can benefit from innovative solutions to otherwise overlooked healthcare conditions. We are proud to be recognized for our efforts to help physicians address BPD in premature infants,” stated Thomas F. Miller, President and Chief Operating Officer at Therabron. “The orphan designations granted by both the US and EU give significant meaning to the current CG100 phase 2 clinical trial currently underway as our experience to date suggests this product candidate has the potential to be a viable therapeutic option to prevent chronic respiratory morbidities that are common in preterm infants.”

The CG100 product candidate is a potentially transformative biologic drug that consists of a recombinant human club cell 10kD protein (rhCC10), a secretory protein that is believed to play an important protective role in the lung via maintenance of airway epithelia and through immunomodulatory mechanisms. Last year Therabron announced the initiation of its second clinical trial in preterm infants, which is a phase 2 study to evaluate CG100 for the prevention of chronic respiratory morbidities in premature infants. This phase 2 study is supported by a $1.6M grant from the FDA’s Office of Orphan Product Development.

About Therabron Therapeutics, Inc.

Therabron Therapeutics, Inc. is a clinical-stage biotechnology company, founded in 2007 and located in Rockville, MD. Therabron is focused on the advancement of respiratory therapeutics with disease-modifying potential. The company’s product candidates aim to restore the natural
immune balance in the lungs of respiratory patients through the administration of recombinant human CC10 proteins. The family of CC10 proteins, also known as secretoglobins, have the potential to change the course of acute and chronic respiratory diseases, representing large markets into which few truly novel drugs have been introduced. Therabron’s product candidates have the potential to be first-in-class, disease-modifying, breakthrough biologic therapeutics. For additional information, please visit www.therabron.com.

Source: Therabron Therapeutics, Inc.

For further information: Media Relations, Michael Parks, Pitch360: 484.356.7105 or michael@pitch360inc.com