



Therabron Therapeutics Receives FDA Fast Track Designation for rhCC10 for the Prevention of Chronic Lung Disease Related to Premature Birth

ROCKVILLE, MD, April 28, 2016 — Therabron Therapeutics, Inc., a clinical-stage biotechnology company dedicated to advancing a new standard in respiratory care, announced today that it has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for rhCC10 (recombinant human Club Cell 10 kDa Protein), specifically for the prevention of chronic lung disease related to premature birth.

Therabron Therapeutics' lead biopharmaceutical product candidate is a proprietary preparation of recombinant human CC10 protein which has potential clinical applications, based on its potent anti-inflammatory properties, in a variety of respiratory diseases. CG100, the company's lead compound based on rhCC10 and intended to prevent chronic lung disease in neonates, is currently in a Phase 2 clinical trial enrolling 88 preterm infants. This ongoing Phase 2 study is supported, in part, by a grant from the U.S. FDA Office of Orphan Product Development.

"The receipt of Fast Track Designation signifies further recognition by the FDA of the merits of this program, and allows the company to submit completed portions of the Biologics License Application (BLA) on a rolling basis, thereby expediting the FDA review process," stated Dr. Thomas F. Miller, President and Chief Executive Officer of Therabron Therapeutics. "As such, we look forward to working closely with the FDA and other Global Health Authorities to advance this program and eventually bring CG100 to market." rhCC10 was previously granted Orphan Drug Designation by the FDA.

The Fast Track program was created by FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track Designation may qualify for priority review to expedite the FDA review process, if relevant criteria are met.

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 secretoglobulin 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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