

Therabron Therapeutics Receives Orphan Drug Designation in the European Union for CG367, Indicated for the Treatment of Bronchiolitis Obliterans Syndrome

ROCKVILLE, MD, January 23, 2017 -- Therabron Therapeutics, Inc., a clinical-stage biotechnology company dedicated to advancing a new standard in respiratory care, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products has granted Orphan Drug Designation for Therabron's CG367 program, indicated for the treatment of Bronchiolitis Obliterans Syndrome (BOS).

"We are pleased to have received Orphan Drug Designation from the EMA to treat patients diagnosed with BOS following lung transplantation. This is an extremely serious and potentially deadly complication of lung transplantation, which generally manifests between 18 months to four years after the procedure. The condition is, unfortunately, refractory to most forms of interventions and therefore represents the most common cause of death for this patient population. We believe that CG367 holds promise as a potentially important therapeutic option and we look forward to working with the EMA as we progress clinical development for this indication," stated Vinzenz Ploerer, Chief Executive Officer of Therabron.

In addition to CG367, Therabron's lead product candidate, CG100, in development for the prevention of chronic respiratory morbidity (CRM) in premature infants, has also been granted Orphan Drug Designation by both the U.S. Food & Drug Administration and the EMA.

About Bronchiolitis Obliterans Syndrome (BOS): BOS is a distinct complication following lung transplantation. It leads to fibrosis of airways in transplanted lungs, followed by significant functional loss, obliteration of the terminal airways and, eventually, death. Diagnosis of BOS is one of exclusion. It is made after other potentially treatable causes of obstructive lung disease have been ruled out, such as infection or acute graft rejection. In BOS, the terminal airways become increasingly obstructed, eventually being destroyed and lost. The onset of BOS varies from months to years, post-transplant, with most patients developing the condition between 18 months and four years after the procedure. Regardless, the outcome remains universally grim. The latest International Society of Heart and Lung Transplantation (ISHLT) statistics reflect the lack of meaningful advancement in the survival outcomes for those undergoing lung transplantation, with an estimated five-year survival of only 50%, making it one of the poorest survival outcomes among all solid organ transplantations performed, worldwide. Today, BOS remains the most common cause of death in lung transplant recipients who survive beyond the initial post-transplant period. Slowing the loss of lung function associated with advancing BOS could ultimately impact survival time in these patients.



About European Union (EU) Orphan Drug Designation: The European Commission grants Orphan Drug Designation status to provide incentives to develop medicinal products to treat, prevent or diagnose diseases or conditions that affect no more than five in 10,000 persons in the European Union. The Orphan Drug Designation provides Therabron with potential incentives and benefits in the EU, including protocol assistance, reduced fees and protection from market competition once CG367 is approved for BOS patients, post lung transplantation.

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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