CBI Congratulates Meridigen Biotech Co., Ltd on their successful IND for their project!

"UMC119-01 (hUC-MSCs) for the treatment of Bronchopulmonary Dysplasia".

CBI and Meridigen Biotech Co., Ltd have collaborated together for the past 2 years developing and conducting IND enabling studies with their unique human umbilical stem cell therapy for the treatment of Bronchopulmonary Dysplasia in premature infants, who are born with underdeveloped lungs.

The Hyperoxygenated Rat Pup Model is the appropriate, but difficult, model for this indication. We worked with both normal and hyperoxygenated rats pups for dual efficacy and toxicologic assessments. The stem cells were surgically administered intratracheally to infant pups and toxicologic assessments followed. Importantly, we employed our novel, validated and proprietary Phase Contrast Analysis to assess the effects on the histopathology of the Bronchopulmonary Dysplasia which was key in both the toxicology and the efficacy determinations.

CBI specializes in the Hyperoxygenated Rat Pup Model as a preclinical and toxicologic model for Bronchopulmonary Dysplasia. The CBI model is validated and optimized for the purposes of both efficacy and GLP toxicology studies. For Meridigen, we conducted the preclinical studies and also interacted with the agencies to respond to their questions and comments resulting in a successful submission. It was a complete IND success!

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