The status of FDA studies conducted by BHI Therapeutic Sciences

In June 2018 BHI Therapeutic Sciences (BHITS) received FDA endorsement of Investigator-led Investigational New Drug (IND) application for initiation of a clinical study of FDA-approved cell therapy (HPC, cord blood) for treatment of acute ischemic stroke. The study is further approved by an Institutional Review Board (IRB) and registered on the clinicaltrials.gov database (NCT03735277).

BHITS plans to submit an IND application for the initiation of a clinical study of FDA-approved cell therapy (HPC, cord blood) for the treatment of knee osteoarthritis associated pain.
Many studies have shown that MSCs have immunomodulatory, antimicrobial, anti-inflammatory and tissue repair functions, being a great potential for the prevention and treatment of viral diseases. The rationale for BHITS new study is the further characterization of the safety and efficacy of human umbilical cord Mesenchymal Stem Cells (hUC-MSCs), delivered via an intravenous route of administration, for the indication of novel coronavirus causing severe pneumonia.

In March 2020, the study entitled "Retrospective Case Series Study of Umbilical Cord Mesenchymal Stem Cell Therapy in Previously Treated Subjects with Pneumonia Caused by 2019 Novel Coronavirus" was approved by Institute of Regenerative and Cellular Medicine IRB.

In April 2020, two clinical study proposals for hUC-MSCs in the Treatment of Hospitalized Subjects with Severe COVID-19 Pneumonia and Continued Respiratory Disability after Acute COVID-19 Infection were submitted to medicalcountermeasures.gov to request the U.S. government Coronawatch Meeting. The study is currently under review.

In April 2020, two clinical study proposals for hUC-MSCs in the Treatment of Hospitalized Subjects with Severe COVID-19 Pneumonia and Continued Respiratory Disability after Acute COVID-19 Infection were submitted to a special emergency program created by FDA - Coronavirus Treatment Acceleration Program (CTAP). The study is currently under review.

In May 2020, two clinical study proposals for hUC-MSCs in the Treatment of Hospitalized Subjects with Severe COVID-19 Pneumonia and Continued Respiratory Disability after Acute COVID-19 Infection were submitted to the Federal Ministry of Education and Research (Germany).

In collaboration with DataRevive USA LLC, BHITS is developing Pre-IND package for hUC-MSCs treatment of COVID-19 Pneumonia. Results of our previous clinical studies and nonclinical studies will be used to support our IND application.