

## Aspire Announces Filing of a Pre-IND Meeting Request with U.S. FDA and a Pre-CTA Meeting Request with Health Canada for its ACT-20 Cellular Therapy against COVID-19 Pneumonia

ORLANDO, Florida, March 31st, 2020 – Aspire Health Science, LLC (the “Company” or “Aspire”), an FDA registered manufacturing facility specialized in the development and manufacturing of cell-based therapies, is pleased to announce that it has filed its pre-IND (Investigational New Drug) meeting request with the U.S. FDA and Pre-CTA (Clinical Trial Application) with Health Canada. A complete briefing package accompanied the meeting requests. This initiates formal communications between Aspire and both the U.S. FDA and Health Canada regarding development of the Company’s cellular therapy, ACT-20 for the treatment of severe COVID-19 Pneumonia.

The decision to file the ACT-20 clinical study with the U.S. FDA and Health Canada, was made in light of the COVID-19 global pandemic that is of unprecedented proportions and the tremendous need to control the COVID-19 Pneumonia.

Aspire’s decision was supported by our scientific and clinical evaluation of the recent clinical study publications conducted by research and development teams in China, showing that MSCs (Mesenchymal Stem Cells) improves the outcome of patients with COVID-19 pneumonia by possibly controlling the cytokine storm.

### About ACT-20

Aspire’s ACT-20 is an allogeneic cryopreserved cell preparation of human Mesenchymal Stem Cells (MSCs) that are *ex-vivo* culture expanded from human umbilical cord tissue, and the conditioned media (MSC-CM) produced from the culture of the umbilical cord derived MSCs.

“The team has worked tirelessly to find some way to use our experience to develop a therapy to battle this pandemic. We have extensive experience in the area of cell-derived therapies and specialized treatments for use in human trials, and I can tell you now we are extremely excited at the potential of this product to save lives” says Kyle Makofka, CEO of Aspire Health Science.

MSCs have been previously used in clinical studies for immune modulation of inflammatory diseases such as graft-versus-host disease (GVHD) and systemic lupus erythematosus (SLE). Further, Conditioned Media from MSCs contains metabolites, growth factors, and extracellular matrix proteins secreted by the cultured cells. Published preclinical studies have reported that treatment with MSC conditioned media reduced inflammatory influx, improved alveolar structure, reduced neutrophil influx, and reduced pro-inflammatory cytokines in acute lung injury models.

## About Aspire Health Science, LLC

Aspire health Science, LLC is an FDA registered manufacturing facility specialized in development and manufacturing of cell-based therapies.

Kingsman Scientific Management provides both strategic and high level project management to support and accelerate development of novel technologies.

### **CONTACT INFORMATION**

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