Press Release
19 December 2022 14:20:00 CET

Amniotics AB receives positive safety data from PulmoStem™ clinical study

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announced that safety has been established in the first cohort in its Phase Ib clinical study evaluating the lung-specific stem cell therapy PulmoStem™ in hospitalized patients with severe respiratory infections, including COVID-19, RSV, and other causes.

The Dose Escalation Committee of the study has concluded that no dose limiting toxicity was found in the one million cells per kilogram cohort, and that dose escalation to two million cells per kilogram may proceed. Patients with Covid-19 as well as Respiratory Syncytial Virus (RSV) were treated in the first cohort.

The primary objective of the study is to evaluate the safety and tolerability of intravenous (IV) dosing of PulmoStem in patients with severe lower respiratory tract infections, including COVID-19, Influenza A, Metapneumovirus and Respiratory Syncytial Virus (RSV). The study also includes secondary and explorative endpoints related to lung regeneration indicators, biomarkers of inflammatory response and other clinical efficacy outcome measures.

The study is an adaptive, dose-escalation trial including hospitalized patients with COVID-19 and other lower respiratory tract infections. The recruitment is estimated to be completed in Q1 2023. See clinicaltrials.gov (Identifier: NCT05348772) for more details.

“I am very happy about the positive safety data. In addition, we have successfully included both Covid-19 as well as RSV patients in the study, which opens up for new opportunies for PulmoStem and for Amniotics. These airborne viruses are affecting many people globally and is a huge burden on the health care system and PulmoStem provides a novel approach for the treatment of these severe and potentially fatal lung diseases”, says Marcus Larsson, CEO at Amniotics.

About PulmoStem™

PulmoStem™ is a lung-specific stem cell product, derived from full-term amniotic fluid. PulmoStem™ is expected to be efficacious in various acute and chronic diseases of the lung through modulation of the immune response and anti-fibrotic capabilities. The first-in-human clinical study with PulmoStem™, is targeting hospitalized patients suffering from severe lower respiratory tract infections due to COVID-19, Influenza A, Metapneumovirus, Respiratory Syncytial Virus (RSV) and other causes, which can lead to Acute Respiratory Distress Syndrome (ARDS).

Press Release
19 December 2022 14:20:00 CET

For more information please contact

Marcus Larsson
CEO, Amniotics AB
Phone: +46 (0) 763 0840 91
Email: ml@amniotics.com

or
Johny Humaloja
CFO, Amniotics AB
Phone: +46 (0) 735 0668 56
Email: jh@amniotics.com

About Amnioitics

Amniotics is a biopharma company focusing on mesenchymal stem cells (MSC) from amniotic fluid. The company was born out of the discovery of a novel source of stem cells in full-term amniotic fluid. Based on a decade of research at the internationally recognized Lund University Stem Cell Centre and the Skåne University Hospital of Lund, the company is pioneering the harvesting and propagation of tissue specific neonatal quality mesenchymal stem cells (MSC). These stem cells have unique properties for applications in regenerative medicine. Amniotics has also an, by Läkemedelsverket (Swedish MPA), approved Good Manufacturing Practice (GMP) facility to produce Advanced Therapy Medicinal Products (ATMPs). With the GMP facilities operational since 2020, Amniotics is now a company in clinical phase with the leading drug candidate PulmoStem™. The company is looking to establish strategic partnerships with researchers and companies that are interested in developing stem-cell-based therapies targeting diseases with high unmet needs.
Amniotics (publ) has it´s headquarter in Lund, Sweden.

The company is listed at Nasdaq First North Growth Market in Stockholm.

Learn more at www.amniotics.com.

Attachments

Amniotics AB receives positive safety data from PulmoStem™ clinical study