Press Release
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Amniotics announces first patient dosed in Phase Ib study with PulmoStem™ to treat severe viral lung disease

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

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 nine to eighteen hospitalized patients with COVID-19, which will be conducted across centers in Sweden and the UK. It is estimated to be completed in 2H 2023. See Clinicaltrials.gov (Identifier: NCT05348772) for more details.

“The initiation of this clinical trial is a major milestone for Amniotics. PulmoStem™ provides a novel approach for the treatment of severe and potentially fatal lung diseases, and our aim is to help patients that are in need of better treatments”, 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). PulmoStem™ is also being investigated for lung transplantation treatment and chronic lung-disease e.g. Idiopathic Pulmonary Fibrosis (IPF).

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About Amniotics

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 moving into clinical trials with the leading drug candidate, PulmoStem™ and 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.

Amniotics Certified Adviser on First North is Redeye AB, certifiedadviser@redeye.se

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

Learn more at www.amniotics.com.

Attachments

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