Press Release
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Amniotics Phase Ib study of PulmoStem™ to include broader patient population

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announced that the company has received approval from the regulatory authorities in the UK and Sweden for a protocol amendment to expand the clinical indications in its Phase Ib study of PulmoStem™ to also include patients with severe lower respiratory tract infections caused by other viruses than SARS-CoV-2 (COVID-19).

"We now are able to investigate the clinical potential of PulmoStem™ in a much wider range of difficult pathogens. Airborne viruses such as SARS-CoV-2 and Influenza A cause diseases with high morbidity and mortality, and new tools to combat such diseases are needed. This approval opens up a wider clinical spectrum in the continued development of PulmoStem™, to help patients with high clinical unmet needs," says Marcus Larsson, CEO at Amniotics.

The study is conducted in the UK and Sweden and the clinical sites are activated and ready to start recruitment.

The Phase Ib clinical study is an adaptive, dose-escalation trial including 9-18 hospitalized patients. The primary objective is to evaluate the safety and tolerability of intravenous (IV) dosing of PulmoStem™ in patients with moderate to severe COVID-19 or other viral lower respiratory tract infections such as Influenza A, Metapneumovirus and Respiratory Syncytial Virus (RSV). The study will also include secondary and explorative endpoints related to lung regeneration indicators, biomarkers of inflammatory response and other clinical efficacy outcomes. Results from the study are expected in the second half of 2023. See clinicaltrials.gov (identifier: NCT05348772) for more details.

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 lower respiratory tract infections due to COVID-19, Influenza A, Metapneumovirus, Respiratory Syncytial Virus (RSV) and other causes, which can cause Acute Respiratory Distress Syndrome (ARDS). PulmoStem™ is also being investigated for lung transplantation treatment and chronic lung-disease such as 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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