

Amniotics completes phase Ib study of PulmoStem™

Amniotics AB (publ) today announced that the company has decided to close the phase Ib study of PulmoStem™ after completing the 2 million cell per kilo bodyweight cohort. Patients with Covid-19 as well as patients with Respiratory Syncytial Virus (RSV) have been successfully treated. The safety and tolerability of PulmoStem at two dose levels has been evaluated.

Given that the study has been completed earlier than planned the study report will be finalised already during the third quarter of 2023. The costs of study-related activities will therefore significantly decrease compared to previous forecasts. There are no safety concerns behind the decision to close the study.

"This is part of the strategic review we are conducting within Amniotics. The fact that we have dosed patients at these two dose levels will open new opportunities for Amniotics and the continued development of PulmoStem", says Marcus Larsson, CEO of Amniotics AB.

The study results will be integrated into the further development of PulmoStem™ in fibrotic and inflammatory lung diseases.

"We have shown that we can take the discovery of a hitherto unknown cell in amniotic fluid through basic research to our own production and into clinical trials in humans. We would like to take this opportunity to thank the patients and research team who participated and conducted the study", Marcus Larsson continues.

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).

About the phase Ib study with PulmoStem™ in patients with severe respiratory tract infections

The primary objective of the study is to evaluate the safety and tolerability of intravenous dosing of PulmoStem™ in patients with severe lower respiratory tract infections such as Covid-19, influenza A, metapneumovirus and RS virus. The study also includes secondary and exploratory endpoints related to lung regeneration, biomarkers of inflammatory response, and other clinical endpoints. The study is an adaptive and dose-escalating study that included 6 hospitalized patients with Covid-19 or other lower respiratory tract infections and was conducted at a clinic in Sweden. See [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05348772) (Identifier: NCT05348772) for further details.

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 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.

For more information please contact

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

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

Attachments

[Amniotics completes phase Ib study of PulmoStem™](#)