Press Release
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Amniotics AB receives positive information about safety data for PulmoStem™ in clinical study

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) announces today that safety has been established in the second cohort of the completed Phase Ib clinical trial investigating the lung-specific stem cell therapy PulmoStem™ in hospitalized patients with severe respiratory infections caused by COVID-19, RSV or other viral infections.

The study dose escalation committee has announced that no dose-limiting safety findings were noted in the second dose level of two million cells per kilogram of body weight. The company has previously announced that the study ended after the second dose level and that the study report is expected to be ready in the third quarter of 2023.

"*An exciting and at the same time expected result. That the dose escalation committee's review shows safety at the dose of two million cells per kilogram is positive for the continued development of PulmoStem and we are now looking forward to the data from the final report,"* says Amniotics CEO Marcus Larsson.

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 phase Ib study with PulmoStem™ in 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 (Identifier: NCT05348772) for further details.

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

Attachments

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