Press Release
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Amniotics receives positive topline results from clinical phase Ib study with PulmoStem

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announces positive safety results from the first-in-human, phase Ib, clinical study with PulmoStem, completed in hospitalized patients with severe viral respiratory infections. The study also shows signals of efficacy and target engagement in a hyperinflammatory patient sub-group.

The primary objective of the study was to evaluate the safety and tolerability of intravenous dosing of PulmoStem in patients with severe lower respiratory infections such as Covid-19, influenza A, and RS virus. The study also included secondary and exploratory endpoints related to lung regeneration, biomarkers of inflammatory response, and other clinical endpoints. The study was an adaptive and dose-escalating study that included 6 hospitalized patients with Covid-19 or other respiratory tract infections and was conducted at a clinic in Sweden.

No dose-limiting toxicity were noted in the first or second dose cohorts, which was the primary endpoint of the study. In-depth review of the safety data confirms no other safety signals and reinforces the strong safety profile of PulmoStem.

The study patients were followed for 22 days after administration of PulmoStem. At Day 22, all 6 patients were alive, i.e. 100% survival rate and no pre-defined study events had occurred. The median time until discharge from the hospital following PulmoStem administration was 6.5 days. One subgroup of patients with high baseline inflammation, assessed by the clinically used biomarker procalcitonin, displayed better clinical response and shorter time to hospital discharge.

- The confirmation of the safety profile and event-free survival will be a cornerstone for further development of PulmoStem in lung transplantation and for our other closely related cell therapeutic candidates, says Marcus Larsson, Amniotics' CEO.

The full analysis of the biomarker data will guide the ongoing PulmoStem development. The work to finalise the full Clinical Study Report (CSR) is ongoing and is expected to be completed during quarter 3, 2023.

About PulmoStem™

PulmoStem is a neonatal lung-specific mesenchymal stem cell product. PulmoStem is expected to be efficacious in various acute and chronic lung diseases through modulation of the immune response and anti-fibrotic capabilities. The first-in-human clinical study with PulmoStem was completed in hospitalized patients suffering from severe lower respiratory tract infection due to COVID-19, Influenza A, and Respiratory Syncytial Virus (RSV), 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 AB (publ) is a clinical stage biotech company, developing innovative therapies, based on amniotic fluid derived stem cells. The company develops therapies to treat diseases where effective treatments are currently lacking.
Amniotics has an established GMP-facility, approved and licensed by the Swedish Medical Products Agency. The company has capabilities as a Contract Development and Manufacturing Organization (CDMO) for other biotech companies.
Amniotics is headquartered in Lund, Sweden.
The company is listed at Nasdaq First North Growth Market in Stockholm. Amniotics Certified Adviser at First North is Redeye AB.
Learn more at www.amniotics.com.

This information is information that Amniotics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-25 15:03 CEST.

Attachments

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