Press Release
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Amniotics Phase I/II study of PulmoStem™ in hospitalized COVID-19 patients ready to start

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announced that several batches of PulmoStem™ have been certified by the company's Qualified Person (QP) and that clinical sites in the UK and Sweden are set to start the enrollment of subjects in the first-in-human Phase I/II study of hospitalized COVID-19 patients.

"During the summer we have worked intensely on completing the preparations at the trial sites and preparing for the release of PulmoStem™ for our first clinical trial. We are therefore very pleased to announce that Amniotics' QP has released several batches of PulmoStem™ to the clinical sites, which means that we are set for the start of the trial. We expect to have the first patients enrolled shortly and to be able to present results from the study in the second half of 2023," says Kåre Engkilde, CEO at Amniotics.

The study is an adaptive, dose-escalation trial including 9-18 hospitalized patients with COVID-19. The primary objective is to evaluate the safety and tolerability of intravenous (IV) dosing of PulmoStem™ in patients with moderate to severe COVID-19. The study will also include secondary and explorative endpoints related to lung regeneration indicators, biomarkers of inflammatory response and other clinical efficacy outcomes. See Clinicaltrials.gov (Identifier: NCT05348772) for more details.

The study has previously been approved by the regulatory authorities in the UK, the Medicines & Healthcare products Regulatory Agency (MHRA) and in Sweden, the Medical Products Agency (MPA).

For more information please contact

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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, telephone: +46 (0) 8 121 576 90.

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

Learn more at www.amniotics.com.

Attachments

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