Press Release
05 April 2022 14:15:00 CEST

Amniotics receives approval for Phase I/II study of PulmoStem™ in hospitalized COVID-19 patients

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announced that it has received approval by regulatory authorities in UK and Sweden for its first clinical trial with PulmoStem™. The study is a first-in-human Phase I/II study in hospitalized COVID-19 patients aiming to investigate the safety and tolerability of different doses of PulmoStem™.

The study has been approved by the regulatory authorities in the UK, the Medicines & Healthcare products Regulatory Agency (MHRA) and in Sweden, the Medical Products Agency (MPA). The approval by the Swedish MPA is a conditioned to an amendment to the application. 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.

"Our team at Amniotics has worked diligently the past few years to be able to start this first-in-human trial. The authority approvals are a validation of the company and our manufacturing capabilities of advanced therapy medicinal products, and we are proud to reach this milestone," said Kåre Engkilde, CEO of Amniotics.

Amniotics is working with the clinical sites to prepare for initiation of recruitment and dosing of the patients.

About PulmoStem™
PulmoStem™ is a lung-specific stem cell product, derived from full-term amniotic fluid and intended for treatment of lung diseases with inflammatory components like Acute Respiratory Distress Syndrome (ARDS) due to COVID-19 and other causes. PulmoStem™ is also being investigated for treatment of chronic lung-disease Idiopathic Pulmonary Fibrosis (IPF) and in lung transplantation.

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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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