Press Release
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Amniotics submits CTA for Phase I/II trial in COVID-19 patients with PulmoStem™

Amniotics AB (publ) (Nasdaq Stockholm: AMNI), a developer of novel cell therapy products, today announced that it has submitted a CTA (Clinical Trial Application) to relevant regulatory authorities in Europe to start a Phase I/II study of its lung-specific candidate drug PulmoStem™ in hospitalized COVID-19 patients.

Amniotics has filed its Clinical Trial Application (CTA) for its planned Phase I/II study with its lead candidate drug in lung specific mesenchymal stem cells PulmoStem™. It is the first clinical trial in humans with the primary aim of demonstrating that the candidate drug is safe and well tolerated. In addition, the planned study may provide an indication of the effectiveness in patient populations with relevant lung diseases and opens for investigations of PulmoStem™ in other respiratory indications pursued by Amniotics. Pending the COVID-19 situation, an approval to initiate the patient recruitment and dosing is expected sometime during H1 2022.

“We are working intensively at Amniotics with the preparations for our first clinical trial in COVID-19 patients and I’m pleased that we have submitted this application to the regulatory authorities. Due to the ongoing development of the pandemic, with new variants and increasing infection numbers, we find it important to consider alternative treatments that are not focused on antiviral drugs, such as stem cell therapies. But, at the same time, the development of the pandemic can prolong regulatory interactions and the ability for clinical sites to conduct clinical studies including recruitment of patients,” says Amniotics’ CEO Kåre Engkilde.

For further 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 HospitalUniversity 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 also has also an, by Läkemedelsverket (Swedish MPA in Sweden), approved GMP (Good Manufacturing Practice (GMP) manufacturing facility to produce Advanced therapy Therapy medicinal Medicinal products 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.

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

Learn more at www.amniotics.com.

Attachments

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