Press Release
14 December 2023 11:20:00 CET

Amniotics receives orphan designation for PulmoStem® from the European Commission for the Treatment of Primary Graft Dysfunction following Lung Transplantation

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announced that the European Commission has granted PulmoStem (AmnioPul-02) designation as orphan medicinal product for the treatment of Primary Graft Dysfunction (PGD) following lung transplantation.

PulmoStem is an advanced therapy medicinal product (ATMP), consisting of allogeneic mesenchymal stem cells (MSC) extracted from term amniotic fluid and selected with antibodies against a lung-relevant cell surface marker, developed for the treatment of PGD following lung transplantation. Amniotics expects to start a clinical study evaluating PulmoStem in this indication during 2024.

Marcus Larsson, CEO, Amniotics AB, commented**:** "This is excellent news. To have been granted Orphan Designation for our lead project PulmoStem in lung transplantation strengthens our clinical program offering and the commercial potential. I view this as a validation of the quality and versatility of our cell therapeutics platform".

PGD after lung transplantation represents a multifactorial parenchymal injury and dysfunction to the transplanted lung that develops in the first 72 hours after transplantation in the absence of identifiable secondary causes. PGD of the lung occurs in approximately 20% to 30% of lung transplant recipients and is characterized by poor oxygenation, low pulmonary compliance and is a significant risk factor for death in short and long term. There is no current treatment for PGD except for prolonged hospitalization and advanced intensive care. Per the opinion of European Medicines Agency (EMA) there is a need for more efficacious treatment options. Amniotics background data indicate that PulmoStem has the potential to significantly reduce lung damage and increase survival in this patient population.

In the EU, orphan drug status is given to products that treat, prevent, or diagnose a disease which is life-threatening or chronically debilitating and affects less than 5 in 10,000 people across the EU. Sponsors who obtain orphan designation in the EU benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, waivers or reductions of certain fees as well as a ten-year market exclusivity once the medicine is on the market. The European Commission grants orphan designation based on the opinion from EMA. For more information about orphan designation in the EU, please see www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview

For more information please contact

Marcus Larsson
CEO, Amniotics AB
Phone: +46 (0) 763 08 40 91
Email: ml@amniotics.com

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 2023-12-14 11:20 CET.

Attachments

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