

Renewed GMP certification

Amniotics AB (publ) (Nasdaq Stockholm: AMNI) today announces the company has received a renewed certificate of GMP compliance of a manufacturer and permit by the Swedish Medical Products Agency to manufacture investigational medicinal products based on mesenchymal stem cells isolated from amniotic fluid and for aseptic reconstitution of cell therapy products. The permit is valid until 2028-08-24.

“We are happy that our quality work and continuous improvement work has paid off in the form of a renewed permit from the Swedish Medical Products Agency. We are looking forward to our next clinical trial, in the treatment area of lung transplantation, with advanced therapy investigational medicinal products manufactured in our own GMP facility,” says Ass. Prof. Jan Talts, PhD, COO Amniotics AB and Qualified Person (QP).

“Today, there are only 5 manufacturing sites in Sweden with the know-how and permits to aseptically prepare and certify cell therapy products for use in clinical trials. I am proud that Amniotics is one of these. Our GMP facility is where our R&D is transformed into production of pharmacy grade investigational cell therapeutics and a critical component for establishing commercial contracts with cell therapy developers in need of GMP expertise and facilities.” says Marcus Larsson, CEO, Amniotics AB.

For more information please contact

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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, e post: certifiedadviser@redeye.se.

Learn more at www.amniotics.com.

Press Release
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Attachments

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