DOUBLE BOND Pharmaceutical

Uppsala 2018-12-06

Pre-submission meeting with EMA has been completed

As previously announced, Double Bond Pharmaceutical has submitted an application to EMA for scientific advice, known as Protocol Assistance, for SI-053. The Protocol Assistance is given based on questions to EMA that the company prepares in advance regarding the clinical trial protocol for their product, and the quality of these questions is crucial for the outcome of the meeting in the form of value for the company and for product development.

Yesterday, Double Bond Pharmaceutical had therefore a pre-submission meeting with EMA and discussed the layout of these questions, before the more formal procedure starts. The scientific advice and all adjacent procedures are free of charge, because the product has the Orphan Drug Designation, and the advice from EMA on SI-053 clinical protocol is expected to be completed in March 2019. The enterprise's goal is to start the clinical trial for SI-053 as soon as possible thereafter.

"I am pleased that the development is proceeding according to plan and that we are able to get feedback from the authorities regarding our plans", - comments CEO Igor Lokot

More about Temodex: Temodex, which is a locally acting formulation of temozolomide developed by RI PCP in Minsk, Belarus, is registered for marketing as the first-line treatment of glioblastoma within Belarus since 2014. Temodex was acquired by DBP in autumn 2015 and is now being prepared to pass through all the tests and trials required for registration within the EU and globally. **Video presentation**: https://youtu.be/iweOQPq316o

More about Protocol Assistance meeting: http://mb.cision.com/Main/12720/2664607/939724.pdf

This information is information that Double Bond Pharmaceutical International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 6 of December 2018.

Full Company Name: Double Bond Pharmaceutical International AB (publ)

Corporate identity: 556991-6082

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Share ISIN code: **SE0007185525**

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Information on Double Bond Pharmaceutical International AB

DBP is a pharmaceutical company with the primary focus on development of therapies against cancer based on the company's own developed drug delivery technology BeloGal®. The company was granted Orphan Drug Designation status by European Medicines Agency (EMA) in June 2015 for its first product, SA-033, for treatment of hepatoblastoma. Double Bond Pharmaceutical acquired rights to Temodex, a drug registered in Belarus for treatment of brain tumours, in October 2015, and was granted Orphan Drug Designation status by EMA for in July 2016 for this formulation of temozolomide for the treatment of glioma. The formulation is now being further developed for registration in EU and globally and has a working name SI-053 in DBP pipeline.