

Uppsala 2018-11-06

## DBP gets free Protocol Assistance from EMA for SI-053

Double Bond Pharmaceutical has submitted an application to EMA for scientific advice, known as Protocol Assistance, for SI-053. The assistance will be given during a pre-submission meeting, where DBP is able to get advice on issues and plans that exist for SI-053 before the more formal procedure starts. The assistance is free of charge since the product has orphan drug status, and is expected to be completed in March 2019. Double Bond Pharmaceuticals goal is to then start the clinical trial with SI-053 as soon as possible.

"The possibility to consult the agency to discuss the development of SI-053 and to get advice on the protocol for the Phase I study before the clinical application is submitted is valuable to us. - commented Igor Lokot CEO for DBP. "With the application to EMA, we have achieved an important interim target for the commercialization of our front line product SI-053 for the treatment of brain tumors. "

**More about Temodelex:** Temodelex, 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. Temodelex 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>

*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 November 2018.*

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

**Corporate identity:** 556991-6082

**Stock short name:** DBP B

**Share ISIN code:** SE0007185525



For more info, contact

Igor Lokot, CEO

Homepage: <http://www.doublebp.com/>

**E-mail: [info@doublebp.com](mailto:info@doublebp.com)**

Blog: <http://blog.doublebp.com>

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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.