The preclinical development program of SI-053 is complete

The results of the two remaining preclinical studies are now available. The toxicological studies on SI 053 and its formulation showed expected results. The study on the excipient was a long-term study to confirm the safety of the hydrogel in the brain. Neither neurological side effects nor any effects on blood cells were noted.

There were no serious adverse events in the GLP-toxicity study of SI-053. The effects noted were due to the active pharmaceutical ingredient temozolomide, such as an effect on blood cells which was expected. Thus, the overall results of the GLP-tox study were expected, and a safe dose was established that will form the basis for the selection of a start dose in the upcoming Phase I Clinical trial. With these studies, Double Bond Pharmaceutical has completed the preclinical development of SI-053.

"The information we received is important for the understanding of the safety of SI-053," commented Igor Lokot, CEO of Double Bond. "I am pleased that the results we have received are in line with our expectations and that the preclinical development of SI-053 is completed according to time lines".

More about SI-053/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

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 below, at 4 of October 2018.

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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.