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In-use stability for SI-053 is ensured

Double Bond Pharmaceutical reports that a European GMP-certified contract manufacturer has examined the highest dose of the SI-053 formulation, the results show that the formulation is stable over time (8 hours).

"Formulation stability is quite often a challenge in drug delivery system products and we are happy for this success" - commented Sayeh Erfan, CMC, Operations & Quality Specialist at DBP.

"With this study, we have now technically shown a product stability during use in a Phase 1 clinical trial, which is one of the most important milestones in product development" - commented Igor Lokot, CEO of DBP. Clinical trials will start during 2019 as planned.

More about SI-053: 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. The product has a working name SI-053 in DBP pipeline.

More about our products: www.doublebp.com

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 31 of August 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.