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Double Bond aims on adaptive design for SI-053 Phase I

Double Bond Pharmaceutical (DBP) has signed a service contract with Cytel Inc, a leading provider of clinical research services and software, to develop an adaptive model-based study design for upcoming Phase I clinical trial for SI-053.

"In our planned Phase I dose-escalation study we aim on using an adaptive model-based design to help identify the maximum tolerated dose (MTD) of SI-053, - says Dr Breezy Lindqvist, CMO of DBP. - This is considered to be much more effective than the traditional 3+3 model and is a crucial step in the clinical development of SI-053, as it also decides the recommended optimal dose of SI-053 for Phase II."

"Model-based designs are known to estimate optimum dose accurately and treat more patients at optimal dose. We are confident that this design will establish a better, i.e. more efficient and safe SI-053 dose, most likely with higher temozolomide content than Temodex, and hence further prolonged overall survival," – comments Igor Lokot, CEO of Double Bond Pharma.

The model will be based on the data already available for the product and on the software that Cytel has developed in-house and tested in multiple oncology studies. The report generated using this model will be submitted to regulatory authorities, as part of a Phase I clinical trial application for SI-053 in EU.

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. Find out more here.

More about Cytel: http://www.cytel.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 4 of May 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.