Uppsala, 2021-06-14

DBP International AB: The CTA for SI-053 has been sent - the tenth and the last milestone for the clinical trial of SI-053 has been completed

Double Bond Pharmaceutical International AB (publ) ("DBP") takes a final step towards the start of the phase 1 clinical trial of its front-line product SI-053 in patients with glioblastoma - Clinical Trial Application (CTA) for SI-053 has been submitted.

Double Bond Pharmaceutical reports that the CTA for SI-053 has been submitted to the competent National Regulatory Authorities, including the Ethics Committee. The process was carried out by DBP in cooperation with a company specializing in managing clinical trials located in the EU, on behalf of pharmaceutical companies. A CTA provides comprehensive information about the investigational medicinal product and planned trial, enabling regulatory authorities to assess the suitability and safety of conducting the study.

"It is very pleasing that our hard work with the development of SI-053 has yielded satisfying results. Moreover, we are extremely proud of the good cooperation between us and our CMO and we are happy to commence our highly anticipated clinical trial." - comments Sayeh Erfan, Director of Manufacturing Operations at DBP.

“In this first-in-human trial for SI-053, this novel TMZ-based formulation will be administered intracranially, as an add-on to Standard Of Care in subjects with newly diagnosed GBM. This is an important milestone in the clinical development of SI-053, our lead candidate. The main objective of this trial is to evaluate the safety and tolerability of SI-053 and, to establish the maximum tolerated dose and/or the recommended Phase 2 dose of SI-053. As part of our clinical development program, we aim to see if we can also obtain evidence for preliminary efficacy in those patients, thus providing a promising candidate for the treatment of this devastating disease.”- comments Breezy Lindqvist, CMO and Head of Clinical Development at DBP.

"We are very pleased to have succeeded to reach this important milestone in the development of SI-053 in order to satisfy the unmet medical needs of patients suffering from Glioblastoma." - comments Igor Lokot, CEO of DBP.

DOUBLE BOND Pharmaceutical

10 communicated milestones between Q3 2020 to Q2 2021 https://mb.cision.com/Main/12720/3191146/1304323.pdf		
Milestone	**Comments**	**Status**
Preclinical: Efficacy of SI-053 in subcutaneous tumor in mice	Finalized	✓
Preclinical: Biodistribution of SI053 after intracerebral administration in rats	Finalized	✓
Preclinical: Toxicity studies of SI-053 after intracerebral administration in rats	Finalized	✓
Clinical: Key Opinion Leader (KOL) meeting, an important milestone for SI-053 Phase 1 clinical study	Finalized	✓
Clinical: Feasibility studies for clinical site selection for Phase 1 SI-053 clinical study	Finalized	✓
CMC: Sterilization of SI-053 will be validated	Finalized	✓
CMC: Stability study for SI-053 has been started	Finalized	✓
CMC: The IMPD is completed	Finalized	✓
Financing phase 1	Finalized	✓
Regulatory: Clinical trial application (CTA) for Phase 1 SI-053 clinical study	**Finalized**	✓

More about Temodex/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 under the name SI-053 to pass through all the tests and trials required for registration within the EU and globally. **Video presentation**: https://youtu.be/iweOQPq316o

Information about 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.

Full Company Name: **Double Bond Pharmaceutical International AB (publ)**
Corporate identity: **556991-6082**
Stock short name: **DBP B**
Share ISIN code: **SE0007185525**

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