

Uppsala, 2021-01-22

DBP International AB: The sterilization of SI-053 has been validated - five out of ten milestones for the clinical trial of SI-053 have been completed

Double Bond Pharmaceutical International AB (publ) ("DBP") reports that the sterilization of SI-053 has been validated and completed. The process was carried out by a company specializing in sterilization services located in the EU, in close collaboration with a contracted partner that manufactures SI-053 for the upcoming Phase 1 clinical trial.

"This is an important part of the product development, which means that we will provide patients with a sterile and safe product, according to EU requirements" - comments Igor Lokot, CEO of DBP.

10 communicated milestones between Q3 2020 to Q1 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	Q1 2021	
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	Q4 2020	
CMC: Sterilization of SI-053 will be validated	Finalized	✓
CMC: Stability study for SI-053 has been started	Finalized	✓
CMC: The IMPD is completed	Q1 2021	
Regulatory: Clinical trial application (CTA) for Phase 1 SI-053 clinical study	Q1 2021	
Financing phase 1	Q1 2021	

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/iweQQPq316o>

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

For more info, contact
Igor Lokot, CEO
Homepage: <http://www.doublebp.com/>
E-mail: info@doublebp.com

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