

Uppsala 2021-07-23

DBP International AB: clinical batch of SI-053 has been manufactured for the upcoming clinical trial phase 1

Double Bond Pharmaceutical International AB (publ) ("DBP") takes a step closer to the start of the Phase 1 clinical trial of its frontline product SI-053 in patients with glioblastoma - batch of SI-053 has been manufactured for the upcoming Phase 1 clinical trial of the EU GMP certified manufacturer.

This material will be used in the upcoming Phase 1 clinical trial which is an open dose escalation and dose expansion study to estimate maximum tolerated dose (MTD), identify dose limiting toxicities (DLT) and recommended phase 2 dose (RP2D) of SI-053.

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

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.

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>

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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