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DBP International AB: transition of the SI053 clinical trials protocol to a new Clinical Trial Information System has been completed

Double Bond Pharmaceutical International AB (publ) ("DBP" or "The Company", org. No. 556991-6082) is pleased to announce the successful transition of its clinical study "An open-label dose escalation study to estimate the maximum tolerated dose (MTD), identify dose-limiting toxicities (DLTs), and study pharmacokinetics following a single dose of intracranially administered temozolomide-based SI-053 as an add-on to the current standard of care (SoC) in adult patients with newly diagnosed glioblastoma (GBM)," to a new Clinical Trial Information System (CTIS). Adoption to this on-line system will be mandatory by February 2025 and is implemented to streamline trial management across all involved member states and to ensure compliance to the Clinical Trials Regulation.

"This is a significant formal step in preparing for the initiation of clinical trials for SI053", comments Dr. Charlotta Grånäs Folkesson, CMO of DBP.

More about CTIS: <https://euclinicaltrials.eu/>

More about clinical trials of SI053: <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2024-515128-35-00,>
<https://clinicaltrials.gov/study/NCT04967690?term=Double%20Bond%20pharmaceutical&rank=5>

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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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.