

Uppsala 2025-02-19

## **DBP International AB Optimizes Manufacturing Process for SI-053 Ahead of Phase 1 Clinical Trial in Glioblastoma**

**Double Bond Pharmaceutical International AB (publ) ("DBP" or "The Company", org. No. 556991-6082) has taken a significant step toward initiating the Phase 1 clinical trial of its lead product, SI-053, for glioblastoma patients. DBP has successfully completed improvements to the manufacturing process of SI-053, ensuring readiness for the upcoming trial.**

A key enhancement focuses on securing the quality of dextran phosphate, a critical excipient that forms SI-053's hydrogel with unique physical and chemical properties. The entire supply chain and manufacturing process comply with EU-cGMP standards and are fully localized within EU countries.

With this advancement, DBP is now prepared to commence manufacturing the material for the Phase 1 clinical trial. The study is designed as an open-label dose escalation and dose expansion trial to determine the maximum tolerated dose (MTD), identify dose-limiting toxicities (DLT), and establish the recommended Phase 2 dose (RP2D) of SI-053.

*"This marks an important milestone in the development of SI-053, ensuring that we deliver a safe and high-quality product to patients, fully aligned with EU regulatory requirements,"* said Sanaz Peyrovan, Project Manager IMP of DBP.

**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>

---

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



For more info, contact  
Igor Lokot, CEO  
Homepage: <http://www.doublebp.com/>  
**E-mail: [info@doublebp.com](mailto:info@doublebp.com)**

Follow us on [LinkedIn](#)

---

#### **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.