

Uppsala, 2023-03-27

DBP International AB: Full approval for SI-053 from The Ethics Commission of the Faculty of Medicine of Cologne University in Germany has been received

Double Bond Pharmaceutical International AB (publ) ("DBP") is very delighted to announce that the company has received for its product SI-053 full approval for starting clinical trials in Germany, in patients with glioblastoma.

Up to now, the SI-053 has obtained all approvals from the countries (Germany and the Netherlands) where the clinical trial is to be conducted.

"We are very excited to reach this crucial milestone. It is a result of lots of hard work done by our excellent colleagues, our preclinical and clinical partners, external consultants and KOLs, and all our investors who have supported us all the way. Now this competent and devoted team will proceed to work with the clinical trial, and eventually take our product all the way to the global market – and to all the patients in need of it around the world." - comments Igor Lokot, CEO of DBP.

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>

More about Glioblastoma: Glioblastoma, the most common and aggressive malignant form of all primary brain tumours, affects glial cells and accounts for 52 % of all brain tissue tumour cases and 20 % of all tumours inside the skull. Approximately 12,000 patients with glioblastomas are identified each year in the US and 250 000 globally.

The current standard of care is surgery followed by radiation and chemotherapy. Double Bond's Temodex®/SI-053 (Temozolomide) is a chemotherapy drug administered directly at the site of the tumour following surgical removal, in the form of a gel, thus ensuring that the therapeutic effect is felt precisely where it is needed. Temozolomide is a prodrug which destroys the tumour's DNA and triggers the death of tumour cells.

More about phase I of SI-053: A Dose Escalation Study to Estimate MTD, DLTs and Pharmacokinetics After a Single Intracranial Dose of SI-053 as an add-on to the Current Standard of Care, in Adult Patients With Newly Diagnosed GBM (TARGLIO) <https://clinicaltrials.gov/ct2/show/NCT04967690>

Information about Double Bond Pharmaceutical 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.



This information is information that Double Bond Pharmaceutical International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above at March 27, 2023.

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

Follow us on [LinkedIn](#) and [Twitter](#)!
