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Double Bond Pharmaceutical International AB (publ) Qualifies New Swedish EU-GMP-Approved Supplier for Key Component of SI-053

Double Bond Pharmaceutical International AB (publ) ("DBP"), a clinical-stage biopharmaceutical company, today announced that it has successfully qualified a well-established, EU-GMP-approved pharmaceutical company based in Sweden as an additional potential supplier for dextran phosphate, a key component of SI-053. This internationally recognized partner has now been added to DBP's internal approved supplier list following a thorough qualification process. DBP chooses not to disclose the supplier's name to protect sensitive business information.

"This strategic addition significantly strengthens our supply chain by improving material availability, potentially reducing lead times, and enhancing process oversight. The inclusion of a local, compliant, and proven supplier contributes to increased manufacturing reliability and supports our commitment to maintaining the highest quality standards," says Sanaz Peyrovan, IMP Project Manager at Double Bond Pharmaceutical. *"Importantly, this development further reinforces the consistency of our investigational product, thereby supporting the generation of robust and reliable data in our ongoing Phase 1 clinical study."*

More about SI-053: SI-053, an enhanced reformulation of Temodex, is a locally acting formulation of temozolomide. SI-053 received Orphan Drug Designation from the European Medicines Agency in 2016 and received multiple Competent Authority and Ethics Committee approvals from 2021 to 2023 to initiate a Phase 1 clinical study. In a proof-of-concept study with human subjects conducted in 2015, SI-053 demonstrated significant overall survival benefit when added to the standard of care for glioblastoma. **Video presentation:** <https://youtu.be/iweQQPq316o>

More about phase I study 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>

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. SI-053 is a novel delivery format of temozolomide (gel format) directly administered at the site of the tumour following surgical removal, thus ensuring that the therapeutic effect is delivered precisely where it is needed and without the need to pass through the blood-brain barrier. Temozolomide is a prodrug which destroys the tumour's DNA and triggers the death of tumour cells.

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 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

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