

Uppsala 2024-06-24

Double Bond Pharmaceutical Re-engages Global CRO Allucent to Accelerate Phase 1 Clinical Trial for Glioblastoma Candidate SI-053

Double Bond Pharmaceutical International AB (publ) ("DBP"), a clinical-stage biopharmaceutical company focused on oncology with a strong emphasis on innovative drug delivery for hard-to-treat cancers, including brain tumors, today announced a renewed contract with global clinical service provider Allucent. This extended agreement will further support the robust execution of DBP's upcoming Phase 1 clinical trial for SI-053, an investigational therapy targeting glioblastoma.

The renewed contract strengthens the ongoing collaboration on critical clinical trial activities, including preparation, initiation, and early-phase execution. This continued partnership is essential for ensuring operational continuity and maintaining alignment with strict regulatory timelines as SI-053 advances into human clinical trials.

"We're honored to expand our collaboration with Double Bond Pharmaceutical as SI-053 progresses toward first-in-human studies," said Paula Brown Stafford, CEO of Allucent. "Our deep expertise in early-phase development and our tailored, cross-functional approach are designed to meet the unique needs of innovative biotech companies like DBP. Together, we're advancing a shared mission to deliver impactful therapies to patients facing some of the most difficult-to-treat cancers."

"Our partnership with Allucent has been instrumental in refining and advancing our development strategy for SI-053," said Igor Lokot, CEO of Double Bond Pharmaceutical. "Extending and re-designing this agreement with such an experienced and dedicated CRO like Allucent positions us to maintain critical momentum and ensure seamless operational efficiency as we enter this pivotal clinical phase of development for SI-053. This collaboration is key to our mission of bringing new hope to glioblastoma patients."

More about Allucent: Allucent is a leading full-service contract research organization (CRO) with a global footprint spanning over 60 countries. Known for its strategic partnerships with small and mid-sized biotech innovators, Allucent leverages a nimble, cross-functional A-Team approach to streamline drug development from early-phase studies through post-marketing support.

<https://www.allucent.com/>

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/iweQQPg316o>

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

For more info, contact

Igor Lokot, CEO

Homepage: <http://www.doublebp.com/>

E-mail: info@doublebp.com

Follow us on [LinkedIn](#)