DOUBLE BOND Pharmaceutical

Uppsala 2023-09-17

DBP International AB and Vivo Biopharma LLC Enter into Asset Purchase and Collaboration agreements to Develop and Commercialize a novel Glioblastoma Treatment

Double Bond Pharmaceutical International AB (publ) ("DBP") and Vivo Biopharma LLC ("Vivo"), a wholly owned subsidiary of Sauvie Inc. ("Sauvie") today announced that they have entered into an asset purchase, collaboration and transition agreements for DBP's SI-053 development product and related assets. SI-053 is a locally acting formulation of temozolomide for the treatment of glioblastoma and it received Orphan Drug Designation from the European Medicines Agency in 2016. Recently, SI-053 received both Competent Authority and Ethics Committee approvals to initiate a Phase 1 clinical trial in two Western European countries.

"This transaction is a natural fit with our mission to discover and develop therapies for markets with high unmet need utilizing unique delivery systems with proven active ingredients which can accelerate development and get critical therapies to patients quickly. Both companies are now uniquely positioned to revolutionize glioblastoma therapy by enabling temozolomide, a proven glioblastoma treatment, to be applied locally in conjunction with surgery. With the signing of the agreements DBP will validate its business approach and begin a new chapter in the company's history." said Igor Lokot, Chief Executive Officer and a founder of DBP.

"We are excited to sign these agreements with DBP to provide hope for patients suffering with glioblastoma. Through Vivo's focused efforts to develop and commercialize SI-053, Sauvie continues to realize its mission of developing and delivering highly novel therapies that target proven disease pathways to get back life for patients suffering from cancer," said Ken Suh, Chief Executive Officer of Sauvie Inc.

Upon the close of the transaction, Vivo will acquire SI-053 and related assets to advance the clinical program with DBP's collaboration to support Vivo's efforts. Based on SI-053 achieving certain clinical, regulatory and commercial milestones, DBP is entitled to receive more than $150 million of milestone and royalty payments from Vivo. The closing is conditioned by Vivo completing financing. Both parties anticipate closing the transaction by Q1, 2024.

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/iweOQPq316o

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.

Information about Sauvie Inc. and Vivo Biopharma, LLC:

Vivo, a wholly owned subsidiary of Sauvie Inc.: https://sauvieinc.com , is focused on developing and commercializing SI-053 and supporting Sauvie Inc.'s mission to develop and deliver novel therapies that target proven disease pathways to get back life for patients suffering from cancer. Sauvie Inc. is a private biopharma organization and currently advancing a novel immuno-oncology technology, a bispecific camelid nanobody platform for multiple cancer indications through its subsidiary Sauvie BiKE, LLC.

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 September 17, 2023.

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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