Uppsala, 2021-12-16

DBP International AB: positive response for SI-053 from Ethical Committee in the Netherlands has been received

Double Bond Pharmaceutical International AB (publ) ("DBP") takes the final step towards the start of clinical trial phase 1 in the Netherlands of its front-line product SI-053 in patients with glioblastoma – positive response from Ethical Committee of the Netherlands (Medisch Ethische Toetsings Commissie) has been received.

"We are very pleased to have succeeded in reaching this important milestone in the development of SI-053 to satisfy the unmet medical needs of patients suffering from Glioblastoma." - comments Igor Lokot, CEO of DBP. "We are now very enthusiastic to find the most optimal dose of SI053 to deliver an even more efficient treatment compared to Temodex".

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

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.
The current standard of care is surgery followed by radiation and chemotherapy. Double Bond's Temodex®/SI53 (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.
DBP is managing an Early Access to Treatment program to raise awareness of the treatment's availability to physicians and patients across the globe:
https://mb.cision.com/Main/12720/3446924/1491329.pdf
For more information on how this product works, and how physicians can access this treatment, please go to www.GlioblastomaEarlyAccessProgram.com.

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 December 16, 2021.

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