

Double Bond Pharmaceutical joins hands with SMS-oncology for clinical development of SI-053

Uppsala, Sweden and Schiphol, the Netherlands (09 Oct 2019) - Double Bond Pharmaceutical AS (“DBP”) announces today that Specialized Medical Services-oncology BV (“SMS-oncology”) has been chosen for providing consultancy services to support the transition of their lead candidate, SI-053 from the preclinical phase to the clinical phase.

DBP’s strategy is to develop new medicines, thereby combining already known efficient approaches with their innovative first-in-class technologies to provide new therapeutic possibilities for treatment of life-threatening diseases. Its lead compound SI-053 is a novel temozolomide (TMZ) formulation intended to be used in combination with the current standard of care (SoC) for newly diagnosed glioblastoma (GBM). SI-053 has received orphan drug designation (ODD) from EMA.

DBP is planning to initiate a European multicentre phase I trial with SI-053 in GBM and aims to reach the first patient in (FPI) milestone by the end of 2020. An consultancy agreement is now signed with the oncology specialized CRO SMS-oncology to support the development of the protocol and setting up a scientific advisory board with key opinion leaders (KOLs) as trivial initial steps.

“As complimentary preclinical studies are underway, and we prepare for the upcoming phase I trial of intracerebrally administered SI-053, we are very pleased and excited to join work forces with SMS-oncology, when clinical development is of utmost importance”, says Dr. Breezy Lindqvist, CMO of Double Bond Pharmaceutical. “We have been in contact for a while and the advice and recommendations of SMS-oncology’s experts given so far have been extremely valid for our clinical development planning. We look forward to our continued collaboration.”

Dr. Raymond Hoffmans, CBDO of SMS-oncology: *“We are pleased to support DBP in this next step in clinical development of SI-053. GBM has an unfavorable prognosis mainly due to its high probability for tumor recurrence. We are excited to support the preparations of moving DBP’s novel local TMZ formulation to clinic, as well as to see the results once trial conduct commences.”*

About Double Bond Pharmaceutical AS (DBP): DBP is a Swedish pharmaceutical company established in 2014, for the development and commercialization of innovative products and approaches for treatment of cancer, infection, autoimmune disease and other disorders. The company is specialized in brain cancer, liver cancer and pneumonia. Their lead product is SI-053 (Temodex), a locally acting form of temozolomide (TMZ) to be used in combination with the current SoC for the treatment of glioblastoma. Temodex is already on the market in Belarus.

About SMS-oncology: SMS-oncology is one of the few full-service contract research organizations (CROs) in the world solely dedicated to oncology. With our unique business model of integrating oncology drug development affairs and clinical operations, we cover the whole value chain from trial design to the setup, management and completion of phase I to IV oncology trials. We specialize in early phase, pediatric and immuno-oncology trials.

About Temodex: 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 to pass through all the tests and trials required for registration within the EU and globally. **Video presentation:** <https://youtu.be/iweQQPq316o>

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