Double Bond Pharmaceutical concludes Key Opinion Leader (KOL) meeting, an important milestone for SI-053 Phase 1 clinical study

Uppsala, Sweden, 28 September 2020 - DBP has recently concluded KOL meeting with Professor Dr. Manfred Westphal (Department of neurosurgery, University Hospital Hamburg, Germany) and Professor Dr. Clemens M. F. Dirven (Department of Neurosurgery Erasmus Medical Center, The Netherlands), which has resulted in fine-tuning the Phase 1 clinical plan. This Phase 1 open-label dose escalation study is scheduled to begin in the first half of 2021. The aim of this study is to estimate the maximum tolerated dose (MTD) and safety of SI-053, when used as an add-on to standard of care in adult patients with newly diagnosed glioblastoma and will identify the recommended phase 2 dose (RP2D).

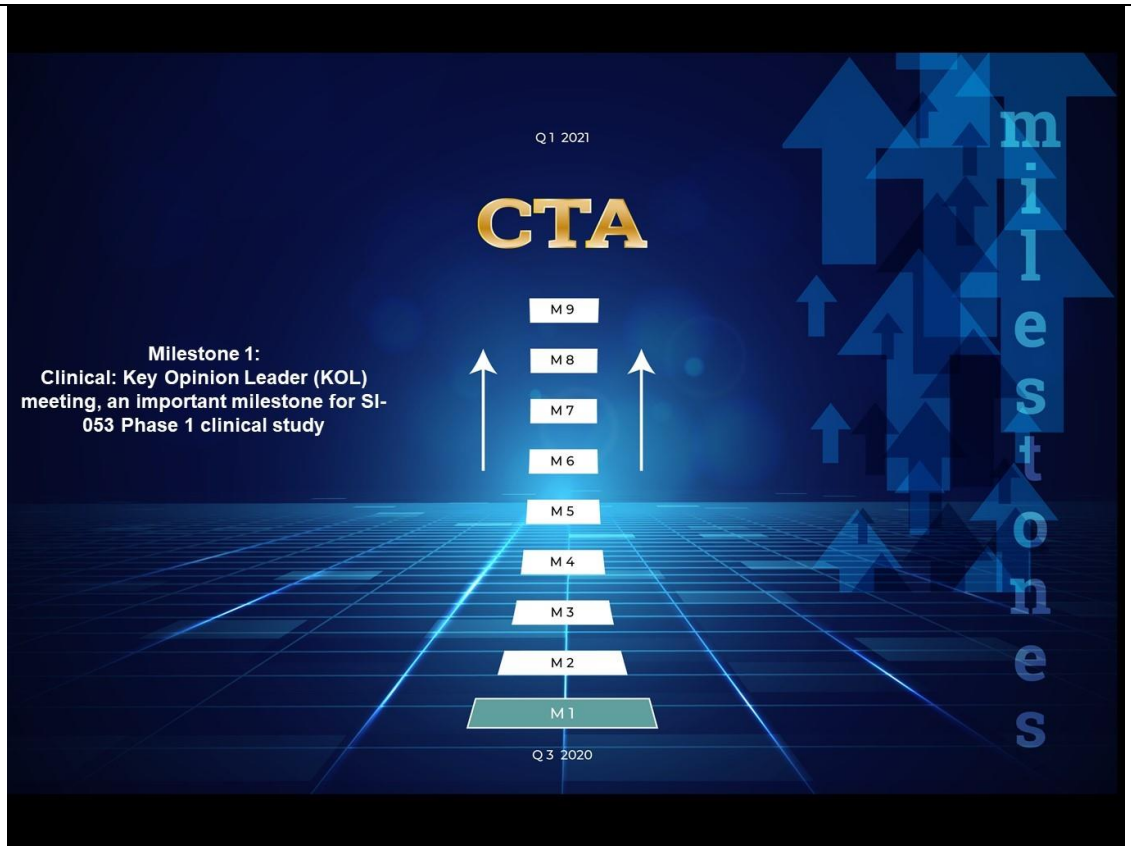
“As we are in the preparatory phase for the upcoming Phase 1 study, concluding KOL meeting with experts in the field is an important milestone. Their valuable opinion will help us to develop a well-designed study protocol, which is necessary for the efficient conduct of the planned Phase 1’’, says Dr. Breezy Lindqvist, CMO, Double Bond Pharmaceutical.

The clinical phase 1 study will be conducted in highly regarded sites in Germany and Netherlands. Currently feasibility studies for clinical site selection is ongoing, and is expected to be finalised in autumn 2020, to meet the Clinical trial application (CTA) milestone in Q1 2021.

Gliomas are the most common primary malignancies of the brain in adults and have a poor prognosis, with direct repercussion on cognition and quality of life. Glioblastoma is the most severe grade of gliomas, representing 55% of all glioma, with a 5-year relative survival of less than 5% and disease progression within 1 year in 70% of the patients. All therapies beyond radiation have limited efficacy because of poor penetrance into the brain across the blood brain barrier, and many are burdened with systemic toxicity or side effects. Therefore, therapies based on local delivery are continuously explored.

“We are excited to continue our successful collaboration with Double Bond Pharmaceutical in their clinical phase 1 study for SI-053 and their development program addressing such an important and unmet need. CATO SMS is committed to support Double Bond Pharmaceutical, utilizing our vast early phase oncology trials experience and dedicated experts team through our proven center of excellence in oncology”, says Philine van den Tol, President Clinical Trial Operations from CATO SMS, the CRO supporting the Swedish pharmaceutical company in this trial.

10 communicated milestones between Q3 2020 to Q1 2021 (more information, in swedish: https://mb.cision.com/Main/12720/3191146/1304323.pdf		
Milestone	**Comments**	**Status**
Preclinical: Efficacy of SI-053 in subcutaneous tumor in mice	Report in preparation	
Preclinical : Biodistribution of SI053 after intracerebral admnistration in rats	Waiting for finalization in Q4 2020	
Preclinical : Toxicity studies of SI-053 effects after intracerebral admnistration in rats	Waiting for finalization in Q4 2020	
Clinical: Key Opinion Leader (KOL) meeting, an important milestone for SI-053 Phase 1 clinical study	Release at Q3 2020	✓
Clinical : Feasibility studies for clinical site selection for Phase 1 SI-053 clinical study	Ongoing, to be finalised in Q4 2020	
CMC: Sterilization of SI-053 will be validated	Ongoing, to be finalized in Q4 2020	
CMC: Stability study for SI-053 has been started	Ongoing, to be finalized in Q4 2020	
CMC: The IMPD is completed	Ongoing, to be finalized in Q1 2021	
Regulatory: Clinical trial application (CTA) for Phase 1 SI-053 clinical study	Q1 2021	
Financing phase 1	Q4 2020	



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 the 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.

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

About CATO SMS: CATO SMS is a provider of specialized clinical research solutions that was formed in 2019 when Cato Research merged with SMS-oncology. With more than 30 years of experience focusing on the needs of small and emerging biopharmaceutical companies, CATO SMS effectively designs and executes studies — from strategy to approval — in complex indications and modalities across a variety of therapeutic areas with a proven center of excellence in oncology. CATO SMS' regulatory, therapeutic and operational expertise enables the company to meet goals and exceed expectations.
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