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DBP International AB: the SI-053 efficacy was successfully proven in *in vivo* study in mice

Double Bond Pharmaceutical International AB (publ) (“DBP”, “Double Bond” or “Double Bond Pharmaceutical”) reports today that the *in vivo* proof-of-concept study of SI-053 was successfully finished. The *in vivo* study of the efficacy of SI-053, Double Bond’s front-line product for local treatment of primary malignancies in the brain, was designed and set up in accordance with recommendations from the European Agency of Medicines (EMA). It consisted of using an immunodeficient nude mouse with an injection of human glioblastoma cells to mimic the brain tumor in a subcutaneous model. The efficacy was evaluated by the single intratumoral injection of SI-053 (either low, middle or high dose) combined with a standard of care (SoC), which is equivalently adapted from patient to mouse.

The main results obtained from this study which have demonstrated the efficacy of SI-053 showed that:

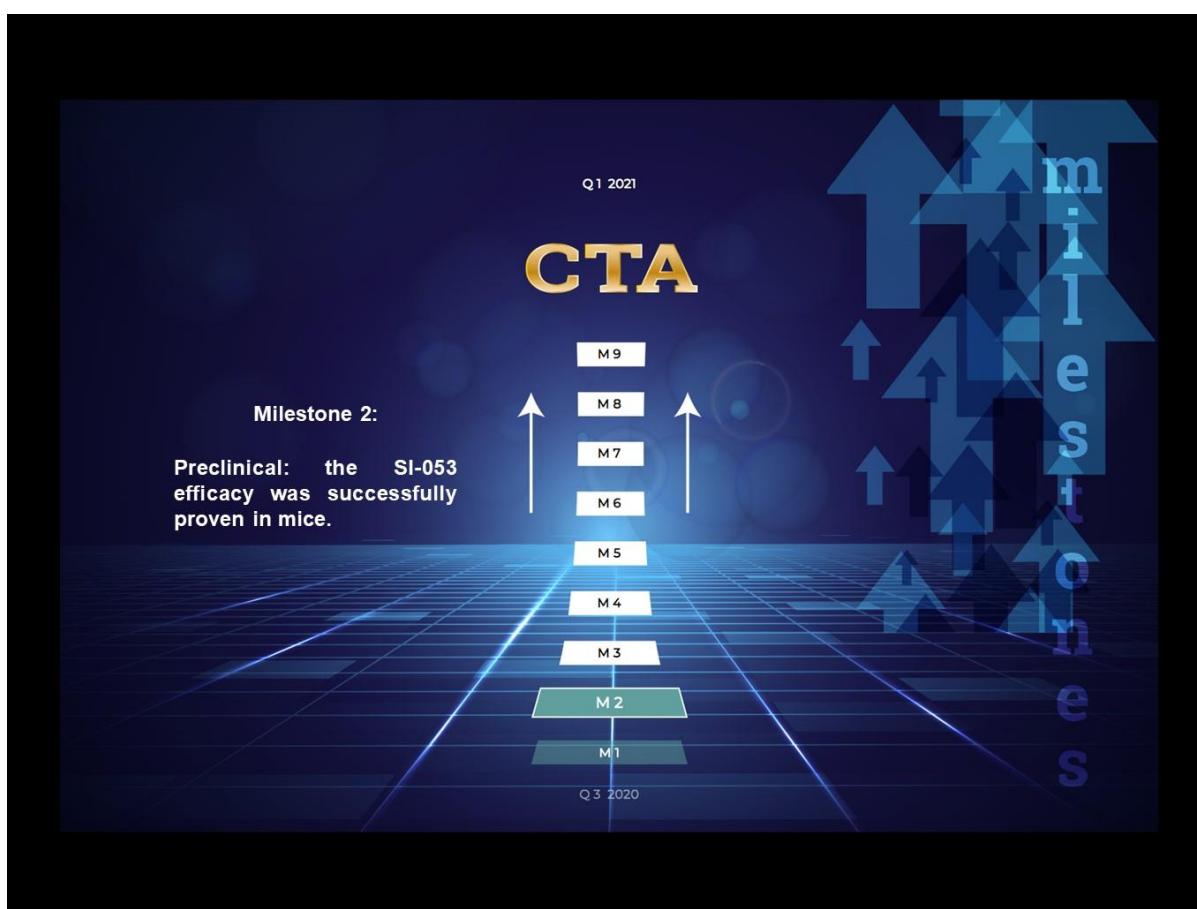
- The animals tolerated the SoC and showed reduced tumor volume when compared to non-treated animals;
- All SI-053 doses showed statistically significant superiority in reducing the tumor volume even before starting the SoC;
- The effect of SI-053 was potentiated when combined with the SoC, resulting in 34% of the tumor growth inhibition;

“The study was carefully designed to imitate the clinical conditions and well-performed which resulted in a robust proof of concept”, says Dr. Carolina Araújo, Preclinical Development Director at Double Bond Pharmaceutical.

“This is the second important milestone which is reached by our team in order to start clinical development of SI-053”, - comments Igor Lokot, CEO of Double Bond Pharmaceutical.

10 communicated milestones between Q3 2020 to Q1 2021		
Milestone	Comments	Status
Preclinical: Efficacy of SI-053 in subcutaneous tumor in mice	Report in preparation	✓
Preclinical: Biodistribution of SI053 after intracerebral administration in rats	Waiting for finalization in Q4 2020	

Preclinical: Toxicity studies of SI-053 effects after intracerebral administration 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 finalized 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 AB (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>

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