The Annual report for Orphan Drug Designation status for SA-033 received no remarks from EMA

Double Bond Pharmaceutical International AB (DBP) has the 20th of September submitted the Annual report for the drug candidate SA-033 to the European Medicines Agency (EMA), which is mandatory after obtaining Orphan Drug Designation status. The Annual report received no remarks or objections, which means that the development of the product is in line with EMA's requirements and expectations. The company was originally granted Orphan Drug Designation status in June 2015 by EMA for SA-033. The Designation applies to the treatment of hepatoblastoma, which is the most frequent type of liver cancer that affects children.

EMAs initial decision was based on SA-033 offering a significant benefit compared to existing treatment options. DBP is now planning to continue the development of the product by starting a clinical phase 1 study with SA-033 already during 2017 with the objective to include patients affected by hepatocellular carcinoma (HCC) which is a type of liver cancer.

- Our report shows that the company develops SA-033 in accordance with the demands that the agency has on pharmaceutical companies after granting Orphan Drug Designation, says Stellan Swedmark, Director of Preclinical Development/Regulatory Affairs at DBP. – We are at the moment investigating the therapeutic potential and safety of SA-033 before starting the first clinical trial, and our report is an important confirmation that we are developing the product in the right direction and at the right speed, says DBPs CEO Igor Lokot in a comment.

EMA grants Orphan Drug Designation status to drug candidates that intends to treat diseases where less than 200 000 people are affected in Europe. For DBP this means ten years of market exclusivity for the indication when the drug is registered and also that SA-033 will not have any direct generic competition during this period. EMA will also offer different kinds of support to facilitate and expedite the finalization of the development of the product.

Information about SA-033

SA-033 is the first drug candidate developed by DBP, and is based on the company's own innovative drug delivery technology, BeloGal®. The BeloGal® technology directs doxorubicin to the liver and thereby increases the concentration of the active substance in the targeted organ. That improves the efficiency and reduces the toxic side effects that are characteristic of systemic (whole body) chemotherapy.

Information about BeloGal®

BeloGal® is DBPs innovative drug delivery platform that directs the drug to the diseased target organ.

Information about hepatoblastoma

Hepatoblastoma (HB) is a primary malignant liver tumour and is the most frequent type of liver cancer affecting children. The etiology is unknown but HB is more common among children with low birthweight and has been associated with Beckwith-Wiedemanns syndrome and familial adenomatous polyposis. The five-year survival after diagnosis of hepatoblastoma is about 63% and there is a large demand for a more efficient and safe treatment for these children.

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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Information on Double Bond Pharmaceutical International 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. DBP acquired rights to Temodex, a drug registered in Belarus for treatment of brain tumours, in October 2015. The company was granted Orphan Drug Designation status by EMA for Temodex in July 2016.