Press release 2018-12-06

DexTech Medical AB, 556664-6203

Report for DexTechs phase IIb-study for OsteoDex is ready

OsteoDex, the company´s phase 2b-project for treatment of advanced prostate cancer, mCRPC, is reported. The study is titled "A randomised, double-blind, dose-finding, repeat dose Phase II multicentre study of ODX for the treatment of patients with castration-resistant prostate cancer (CRPC) and skeletal metastases" and were done in Sweden Norrlands University hospital, Umeå, Södersjukhuset, Stockholm and Örebro University hospital), in Finland (Tampere University Hospital), in Estonia (East Tallin Central Hospital and Tartu University Hospital) and in Latvia (Riga East University Hospital and Daugavpils Regional Hospital).

Fifty one percent of the patients completed the treatment (5 months, 2 doses/month). Of these, 52 % had stable disease post therapy (improved/stable) regarding the bone metastases. Thirty-five % of the patients showed decreased tumor burden in the skeleton post therapy. The majority of these had received 2nd, 3rd and 4th line therapy before OsteoDex therapy (Docetaxel/Cabataxel/Extandi/Zytiga/Xofigo). This finding is of great importance for OsteoDex continued clinical development since this patient category represent a significant unmet need.

The results show that OsteoDex has a strong restraining effect on the vicious cycle, i.e. the biological process that progress the disease and shortens the survival. More than 50% of the patients showed significant decline of markers related to bone metabolism and an especially strong decline in 67% of the patients for marker associated with bone resorption. The efficacy on this bone marker and effects on the bone markers associated with bone metastases mirrors OsteoDex biological effect.
Tolerability was strikingly good with only few side effects. No patients had to stop treatment because of side effects and no OsteoDex related serious adverse events (SAE) were recorded. The three dose arms showed equal treatment effect. No efficacy difference between the three dose arms was recorded. The interpretation can be that even the lowest dose is sufficient to saturate the metastatic sites in the skeleton. The results fulfill the primary objectives of the study protocol. Parts of the results, that has been reported previously, were presented at the BioEurope conference in Copenhagen, 5-7th of November and were received with great interest.
The continuing clinical development of OsteoDex will be performed by a presumptive licensee.

"-We are very pleased with the results from the study. Two findings are considered especially important, first that the high tolerability is confirmed with absence of serious side effects, and second that OsteoDex could reduce the tumor burden in patients that have few or no additional treatment alternatives. The importance of this is reflected in the response we received at BioEurope, says ceo Anders R Holmberg".

For additional information:
Gösta Lundgren - CFO & Investor Relations
DexTech Medical AB
Telephone: +46 (0) 707104788
E-mail: gosta.lundgren@dextechmedical.com

This information is information that Dextech Medical 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 persons set out above, on December 6, 2018.

DexTech Medical AB *is a Swedish research company that based on its technology platform has developed four drug candidates that are protected by patents. The main candidate is OsteoDex for the treatment of castration-resistant prostate cancer (CRPC) with bone metastases. A successful Phase I / IIa study has been conducted with OsteoDex where the result shows high tolerability with mild side effects and the clear effect of the highest dose group. DexTechs goal is to last after phase II trial license the respective drug candidate. DexTech Medical AB is listed on Spotlight Stock Market.*