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DexTech Medical AB, 556664-6203

DexTech Medical's myeloma study fully recruited, preliminary results very positive

The study was conducted at Karolinska University Hospital Huddinge and at Uddevalla Hospital. The treatment has lasted for a total of 14 weeks with 2 doses per month. Three dose levels of OsteoDex (ODX) have been studied, 3mg/kg body weight, 6mg/kg, and 9mg/kg. The Principal Investigator (PI) is Dr Katarina Uttervall, MD, PhD, Department of Hematology/HERM, Karolinska University Hospital Huddinge. Dr Dorota Knut is the principal investigator at the Department of Hematology at Uddevalla Hospital. Analysis of biomarkers takes place at the Central Laboratory, Karolinska University Hospital Solna, NKS. Adult myeloma patients with, according to IMWG (International Myeloma Working Group) criteria, *progressive treatment-resistant disease*, who had previously received 1–5 lines of treatment were included in the study. The primary objective is to confirm ODX safety and tolerability and with a secondary objective to demonstrate indications of treatment response.

The last patient in dose group 2 (6mg/kg) was fully treated week 50, 2025 (7 doses). The patient continued to have stable, i.e. non-progressive, disease just over 5 months after the end of treatment and before new progress resumed. All patients in dose group 3 (9mg/kg) had achieved stable (non-progressive) disease after discontinuation of treatment at the end of February. The patients have continued to maintain non-progressive disease at the end of May. No significant ODX-related adverse events have been noted. Thus, no induced toxicity on organ systems, such as kidneys, liver, or bone marrow.
Primary endpoint has been met, with the absence of significant ODX-related toxicity. The results also show that all patients responded positively to ODX treatment, with a transition from progressive (according to IMWG criteria) to non-progressive disease during ODX treatment. More than 70% of the patients maintained their achieved stable, non-progressive, disease even after the ODX treatment was discontinued. This is consistent with the mechanism of action, i.e. significant enrichment of ODX in the myeloma areas of the skeleton.
The patients in dose group 3 are now being followed continuously (>June) until new disease progression, which is why the completion of the CSR (clinical study report) is postponed until all results from the extended follow-up are available.

The company has analyzed all clinical data, including the prostate cancer studies (mCRPC), and finds the effects of the same mode of action (MOA) in both mCRPC and multiple myeloma. Simply described, ODX rapidly changes/modifies the tumor cells' microenvironment and thereby impairs their breeding ground and the conditions for continued growth (progression). The mechanism is unique to ODX as an anticancer drug and has very interesting implications for the treatment of other cancers with bone involvement, e.g. breast cancer. The absence of ODX-related toxicity opens up great opportunities for combination therapies (very common in modern cancer treatment) without adding toxicity.

"- We are now compiling strong data to present to our stakeholders as soon as the remaining long-term follow-up data is available. We feel very optimistic in light of study data and a unique MOA," says CEO Anders R Holmberg.

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***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 lead candidate is OsteoDex for the treatment of castration-resistant prostate cancer (CRPC) with bone metastases. A successful clinical phase II study has been conducted with OsteoDex where the results show high tolerability with mild side effects and treatment effect on patients who fail existing drugs. DexTech's goal is to out-license each drug candidate no later than after completion of the phase II study. DexTech Medical AB is listed on the Spotlight Stock Market.*