XTL initiates regulatory talks to test recombinant human EPO in a Phase II multiple myeloma trial – CEO

CRO or clinical research associate will be used
In talks with commercial suppliers for rHuEPO
Process to raise funds in US has started

XTL Biopharmaceuticals (NASDAQ:XTLB) has started talks with regulatory groups regarding a Phase II trial testing recombinant human erythropoietin (rHuEPO) in multiple myeloma (MM), said CEO Joshua Levine. He declined to comment on timing for the Phase II trial but noted that plans are further along than those for the company's lupus candidate, which should be in the clinic around yearend 2014 or early 2015, Levine noted.

The firm may hire a CRO to run the Phase II trial in multiple myeloma or may hire a clinical research associate and manage the trial internally. The study could enroll close to 100 patients, he said. The trial would take place mostly in Israel and could have some US sites if the FDA wants a US presence, the CEO said.

XTL plans to buy rHuEPO for the study from a commercial source and is in discussions now with potential suppliers, Levine noted.

To support trials in MM and lupus, XTL expects to raise funds in the US, where timing looks good, the CEO noted. The company has started the process and details will be disclosed publicly at a later date, he said.

The thinking behind testing rHuEPO in MM is based on a clinical observation in endstage, bedridden MM patients who were given rHuEPO for anemia, Levine said. The patients were expected to live six months but lived three to six years longer than expected, he added. The company filed for a use patent, which it has received in the US, Europe, Israel and Canada and has also received orphan designation, he added.

The firm could benefit from black box warnings for rHuEPO treatments, which limit off label use, he said.

XTL's market cap is USD 41.2m.

by Casey McDonald in New York

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