



XTL to hire lupus-experienced CRO for a Phase II trial with peptide candidate – CEO

May require CMC to prepare additional lower, 0.25mg dose

Taking advantage of new lupus guidelines, intend to use BILAG responder endpoint

XTL Biopharmaceuticals (NASDAQ:XTLB) will select a CRO to run a Phase II trial in systemic lupus erythematosus (SLE) for its recently licensed peptide candidate hCDR1, according to CEO Joshua Levine. The firm may also require a CMO for chemistry, manufacturing and controls (CMC) work to formulate an additional lower dose to test in the Phase II trial, he said.

The company hopes to start a Phase II trial towards YE14 or early 2015 and will likely conduct it in the US, western Europe and Israel, with some additional sites in Asia and South America, Levine said. XTL is thus looking for a CRO with a global presence and experience in lupus trials, he noted.

The firm has not yet powered the trials, but the CEO expects a study in the 200 plus patient range. Levine expects the study to cost USD 12m15m.

XTL licensed hCDR1 in January 2014 from Rehovot, Israel based Yeda Research and Development, the technology transfer company of the Weizmann Institute of Science, according to a 7 January press release. Teva Pharmaceutical Industries (NYSE:TEVA) previously licensed the drug from Yeda and trialed it in Phase I and II trials, he explained. Teva returned the rights for the SLE candidate to Yeda in 2009, he added.

The firm has brought on a consultant who previously worked with hCDR1 at Teva who will start mapping out CROs, CMC and other aspects to get the trial going, the CEO said.

XTL believes it can learn lessons from Teva's studies with hCDR1 and take advantage of accepted endpoints, which has changed since the drug failed in Phase II, Levine explained. hCDR1 failed to meet its SLE disease activity index (SLEDAI) primary endpoint, but it had promising results at a secondary endpoint, the British Isles lupus assessment group (BILAG) index, he said.

In 2010, the FDA published guidelines for BILAG to be an acceptable primary endpoint, Levine explained. GlaxoSmithKline's (LON:GSK) Benlysta (belimumab), the only SLE biologic, approved in March 2011, also benefited from the new guidelines using SLE responder index (SRI) as its primary endpoint in Phase III, he said. hCDR1 is a 19 amino acid peptide that has an upstream

immunomodulation effect on the generation of regulatory T cells, according to a company presentation.

hCDR1 also had its most encouraging results at its lowest formulation; 0.5mg, 1mg and 2.5mg (weekly) were tested, the CEO said. The results were not dose dependent, but hCDR1's mechanism of action is as an immune system modulator rather than having an inhibitory role, he explained. Because of this, XTL will try the lower 0.5mg dose and will test a 0.25mg dose too, he added.

The company has already received excitement from two of the researchers who had been on the previous trials for the drug and agreed to participate on XTL's trial, he noted.

The company believes that with a proper Phase II trial using appropriate endpoints and without cutting corners, hCDR1 has an excellent chance of producing positive Phase II results, at which point potential pharma partners would be interested, Levine noted.

The firm will meet with regulators as it plans the Phase II trial, he added. Regulators have been "snakebitten" by its previous insistence on the SLEDAI endpoint and as a result, lupus approvals are slim, Levine said. Because of this, regulators will give leeway and are more willing to negotiate endpoints that may better suit a drug, he noted.

XTL's market cap is USD 41.3m.

by Casey McDonald in New York

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