BioLineRX stem cell leukemia drug meets goals in early trial

  March 25, 2015 7:57 AM

JERUSALEM (Reuters) - Israeli biopharmaceutical company BioLineRX Ltd said on Wednesday an early stage trial for a drug that uses stem cells to treat leukemia and other blood cancers met all safety and efficacy goals.

Current stem cell treatments require four or five days of injections of material from a donor to get into the bloodstream, but BioLineRX said its treatment, currently called BL-8040, needed just one.

"The results support BL-8040 as a one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care," the company said.

It noted it planned to present the full set of results from the Phase 1 study at a hematology conference in Vienna in June.

"The results exceeded our expectations, and validate BL-8040 as a highly differentiated stand-alone treatment for stem-cell collection," said Kinneret Savitsky, BioLineRx's chief executive.

She said the company planned to meet with the U.S. Food and Drug Administration as soon as practicable to discuss the results of this study and obtain more clarity on the next steps in the clinical development program for this treatment.

In addition to stem-cell mobilization, the BL-8040 platform is also undergoing a Phase 2 study for treating relapsed and refractory acute myeloid leukemia patients, results of which are expected in the second half of 2015, Savitsky said.

BioLineRX also expects to start clinical trials for three additional indications for BL-8040 in the second quarter of 2015.

Drugs normally have to pass three phases of testing in humans before being considered for approval by regulators.

Shares in BioLineRX were up 5.7 percent in early afternoon trade in Tel Aviv. Its Nasdaq-listed shares were 7 percent higher at $2.44 in pre-market trading.

In December, Swiss drugmaker Novartis bought a 12.8 percent stake in BioLineRX as part of a multi-year collaboration deal.