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Kitov Pharmaceuticals' KIT-302 drug candidate meets primary efficacy endpoint in Phase III clinical trial

Published on December 15, 2015 at 8:10 AM

Kitov Pharmaceuticals (NASDAQ/TASE: KTOV), an innovative biopharmaceutical company focused on late-stage drug development, announced today that the Phase III, double-blind, placebo-controlled clinical trial for its leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the U.S. Food & Drug Administration (FDA). Data from the trial further revealed that KIT-302 was more efficacious at reducing hypertension than the widely used hypertension drug amlodipine besylate. Kitov plans to file its New Drug Application (NDA) for marketing approval of KIT-302 with the FDA in the second half of 2016. To view a webcast of the press conference discussing these results in Tel Aviv today, please visit: http//bit.ly/1Qi4WfU

A combination drug, KIT-302, simultaneously treats pain caused by osteoarthritis and treats hypertension, which is a common side effect of stand-alone drugs that treat osteoarthritis pain. KIT-302 is comprised of two FDA approved drugs, celecoxib (Celebrex®) for the treatment of pain caused by osteoarthritis and amlodipine besylate, a drug designed to treat hypertension.

The trial protocol, approved by the FDA through the Special Protocol Assessment process, was designed to quantify the decrease of hypertension in patients receiving KIT-302. The trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients, with a total of 152 patients. Each patient was treated over a total period of two weeks. Group One was treated with KIT-302, comprised of celecoxib and amlodipine besylate. Group Two was treated with amlodipine besylate only, one of the components of KIT-302. Group Three was treated with celecoxib only, the other component of KIT-302. Group Four was treated with a double placebo. The trial began in June 2014 and was completed in November 2015.

The primary efficacy end-point of the trial was to show that a combination of the two components of KIT-302, as demonstrated in Group One, lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients in Group Two, who were treated with amlodipine besylate only.

The trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results are final. These final results show that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

"We are very pleased with the successful and final outcome of our pivotal Phase III trial and we look forward to meeting with the FDA in the near future to finalize plans for our NDA submission. We believe we will be ready to submit the NDA for KIT-302 in the second half of 2016. Should the NDA meet with the FDA's approval, we would expect to receive marketing approval in 2017," stated Kitov CEO Isaac Israel.

"Data revealing that KIT-302 is more efficacious at reducing daytime systolic blood pressure than amlodipine besylate alone was particularly compelling. We are now conducting an in depth analysis of the robust data produced in this trial, and we look forward to sharing other findings that may be of interest to the medical community," commented Dr. J. Paul Waymack, Chairman of Kitov's Board and Chief Medical Officer.

"KIT-302 has the potential to address the multi-billion dollar market for the treatment of osteoarthritis pain and hypertension with one drug that reduces patients' risk of suffering a heart attack or stroke, while also reducing cost for payers. There is currently no single medication on the market that treats both osteoarthritis pain and hypertension and thus, KIT-302 will be the only NSAID indicated both to treat pain and to reduce the risk of heart attack, stroke and death."

Pain medications for osteoarthritis account for billions of dollars in annual sales globally. Most pain medications for osteoarthritis, including celecoxib which had global sales of $2.7 billion in 2014, are non-steroidal anti-inflammatory drugs (NSAIDs) which have the side effect of elevating blood pressure, and increasing the risk of heart attacks, strokes and death. Of the 27 million Americans who live with osteoarthritis, 13.5 million also suffer from hypertension, which also increases the risk of heart attack, stroke, and death.

Source:
Kitov