SOTIO Receives VHP approval to start Phase III Clinical Trial

February 04, 2014
SOTIO a.s., Prague, announced today that it received from the EU Heads of Medicines Agencies (HMA) a positive decision on a substantial amendment to its Phase III VIABLE Clinical Trial of DCVAC/PCa – an active cellular immunotherapy for the treatment of prostate cancer. The HMA originally approved SOTIO’s submission for the VIABLE Phase III clinical trial in March 2013. This amendment was submitted by SOTIO as part of the European Voluntary Harmonisation Procedure (VHP), based on feedback received from US Food and Drug Administration (FDA). Amendment was developed to ensure unification of the protocol design for EU and US. SOTIO plans to start recruiting patients in the trial beginning in March 2014.

The Phase III VIABLE clinical trial will assess the safety and efficacy of DCVAC/PCa as an add-on therapy to 1st line standard of care chemotherapy in men with metastatic Castration Resistant Prostate Cancer (mCRPC), based on overall survival (OS) in mCRPC patients treated with DCVAC/PCa versus placebo with standard of care chemotherapy.

After approvals by national regulatory authority and ethics committees in the following European countries: Belgium, Bulgaria, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Portugal, Spain, Sweden, and the UK (via the national VHP process) and in Croatia, Poland, Romania, Slovakia, Russia, Serbia, and Turkey (via the country specific process) the VIABLE study will enroll patients through cooperating medical centres. After obtaining all necessary regulatory approvals, SOTIO plans to enroll US patients in the trial as well.

SOTIO expects enrolment of the first patients to initiate the trial in March 2014. Altogether 1,170 prostate cancer patients from Europe and the US will be enrolled into the trial.

Description of the clinical trial
SP005 VIABLE (Eudra CT: 2012-002814-38; IND: 015255): A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy.

About DCVAC/PCa
DCVAC/PCa was the first SOTIO product candidate to enter clinical evaluations. DCVAC/PCa is an active cellular immunotherapy treatment for prostate cancer patients being evaluated in clinical studies; DCVAC/PCa is produced individually for each patient; it uses a patient’s dendritic cells (that are part of the immune system), to induce an immune reaction against presented tumor antigens.