

SOTIO Initiates VIABLE, a Global Phase III Clinical Trial for Prostate Cancer Immunotherapy Treatment with DCVAC/PCa

Prague, May 22, 2014

SOTIO, a biotechnology company owned by the PPF Group, today announced that the first patient has enrolled in its VIABLE study, the global Phase III clinical trial for DCVAC/PCa, an active cellular immunotherapy treatment for prostate cancer patients

VIABLE is a randomized, double blind, multicenter, parallel-group, Phase III study to evaluate the efficacy and safety of DCVAC/PCa as an add-on therapy to 1st line standard of care chemotherapy in men with metastatic Castration Resistant Prostate Cancer (mCRPC), which is based on overall survival (OS) in mCRPC patients treated with DCVAC/PCa versus placebo with standard of care chemotherapy.

The first patient was enrolled into the study in Hungarian Army Medical Center (Magyar Honvédség Egészségügyi Központ), Department of Oncology. The VIABLE study will recruit patients through cooperation with medical centres in 20 countries: Belgium, Bulgaria, Croatia, the Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Spain, Sweden, Turkey, the United Kingdom and the United States. The initiations of individual countries have already started and the first patients will be enrolled in the coming weeks. SOTIO's aim is to enrol a total of about 1,170 prostate cancer patients in the study from Europe, Russia and the United States.

Radek Špíšek, Chief Scientific Officer of SOTIO said: *“We believe that in order to be successful in treating advanced stages of the disease it is essential to understand if cancer immunotherapy should be combined with existing treatment modalities, such as chemotherapy. In accordance with this strategy, we have designed a combined chemo-immunotherapy clinical trial that explores the combination of standard care chemotherapy and dendritic cell based immunotherapy treatment with DCVAC/PCa. Dendritic cells are separated from patients' monocytes and introduced to a prostate cancer cell line killed by high hydrostatic pressure. While the chemotherapy treatment decreases tumor cell load, the cancer immunotherapy treatment with DCVAC/PCa may induce an immune response directed against multiple tumor antigens and therefore control the growth of tumor cells. The VIABLE study will thus test the hypothesis that the combination of two treatment modalities synergizes and leads to the prolonged survival of treated patients.”*

Ladislav Bartoníček, CEO of SOTIO added: *“I am delighted to announce that SOTIO is the first company from the CEE region to initiate a Phase III clinical trial in the area of cellular immunotherapy. This milestone is due to all the hard work and the cooperation of Charles University and University Hospital in Motol in Prague as well as many years of research by a dedicated group of*

scientists and we are now focused on delivering the results of the trial in our efforts to further the treatment of prostate cancer on a global scale.”

About VIABLE:

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. Phase I and Phase II clinical trials, already involving several hundred patients with prostate cancer at various stages, indicate promising preliminary results to support further study.

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SOTIO

SOTIO is an international biotechnology company developing new medical therapies, focusing on the treatment of cancer and autoimmunity diseases. The company conducts research concerning the actual platform of active cellular immunotherapy on the basis of dendritic cells, with the goal of significantly improving this treatment and making it accessible to patients.

In SOTIO’s laboratory in Prague, equipped with state-of-the-art technology, leading scientists research the role of dendritic cells in the therapeutic activation of the immune system and work to verify its safety and efficacy through clinical trials. SOTIO has facilities in Europe, the United States, China and Russia. For more information about the company visit the website www.sotio.com.