BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Transgene receives FDA IND clearance for Ph1 trial of lead myvac

May 13, 2019 | News

Phase 1 clinical trial, expected to start in H2 2019, will be co-funded by Transgene and its collaboration partner NEC



Transgene, a biotech company that designs and develops virus-based immunotherapies for the treatment of solid tumors has announced that it has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to proceed with a Phase 1 clinical trial of its lead *myvac* candidate TG4050 as a potential treatment for ovarian cancer patients after first-line surgery and chemotherapy.

TG4050 is an individualized MVA-based immunotherapy derived from the *myvac* platform. It has been designed to stimulate and educate the immune system of patients to recognize and destroy tumor cells. Tumor cells accumulate mutations and each patient has a set of mutations that are unique to his tumor. TG4050 is designed to target a panel of patient specific mutations selected using a NEC's Neoantigen Prediction System

"We are very pleased to have been granted an IND for TG4050 by the FDA allowing us to commence the first trial with our lead myvac candidate in ovarian cancer patients who have already received first-line treatment" said Maud Brandely, Chief Medical Officer of Transgene. "We believe individualized vaccination is a promising solution with significant potential to transform treatment outcomes for a wide range of solid tumors. With TG4050, we are confident that we can show that this therapeutic modality will improve patient outcome. We look forward to updating you on the progress of this clinical trial, which is expected to start later this year."

The Phase 1 clinical trial will evaluate the safety and the tolerability of TG4050 in patients with ovarian, fallopian or peritoneal serous cell carcinoma. Antitumor activity will also be measured. This multi-center, one-arm trial will recruit patients in the United States and Europe.

The study, sponsored by Transgene, will be co-financed by Transgene and its partner NEC, which will also support the trial by contributing to the therapeutic vaccine design and the selection of target neoantigens (see press release dated March 5, 2019).

TG4050 is an immunotherapy designed to stimulate the immune system of patients in order to induce a response that is able to recognize and destroy tumor cells in a specific manner. This personalized immunotherapy is developed for each patient, on the basis of mutations identified through sequencing of tumor tissue, prioritized using NEC's Neoantigen Prediction System and delivered using the *myvac* technological platform which allows development and manufacture of a product that is specific to the patient within time frames compatible with clinical management.

myvac is a viral vector (MVA) based, individualized immunotherapy platform that has been developed by Transgene to target solid tumors. The myvac-derived products are designed to stimulate the patient's immune system, recognize and destroy tumors using the patient's own cancer specific genetic mutations. Transgene has set up an innovative network that combines bioengineering, digital transformation, established vectorization know-how and unique manufacturing capabilities. Transgene has been awarded an "Investments for the Future" funding from Bpifrance for the development of its platform myvac.