PRESS RELEASE

Transgene presents immunological data demonstrating that TG4001, a novel therapeutic cancer vaccine, can induce T-cell responses against HPV16 antigens in the ongoing Phase II trial at ASCO 2023

TG4001 can induce *de novo* immune responses against HPV16 antigens E6 and E7 in patients with advanced HPV16-positive anogenital cancers

Patients with complete objective response showed strong vaccine-induced immunoreactivity

Transgene is preparing for a potentially registrational study

Strasbourg, France, June 5, 2023, 7:30 a.m. CET – **Transgene (Euronext Paris: TNG),** a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, announced that **new data will be presented today on TG4001. These data confirm the ability of this novel investigational therapeutic cancer vaccine to induce immune responses against HPV16 antigens, that are associated with anti-tumor response. These results have been presented in a poster at the ongoing American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.**

TG4001 is an investigational viral vector based therapeutic cancer vaccine. It is being evaluated in a randomized controlled Phase II clinical study comparing TG4001 in combination with avelumab to avelumab alone in patients with HPV16-positive anogenital tumors (NCT: 03260023). The data presented at ASCO were generated from 46 patients included in both arms of the trial.

TG4001 induced the priming of adaptive immunity

58% of patients receiving TG4001 + avelumab showed an increase of immune responses against HPV antigens versus 9% in the avelumab arm. At baseline, immune responses against HPV antigens were limited to 4/46 patients. The occurrence of an immune response was detected at day 43 and tended to gain in intensity at day 85.

These data clearly demonstrate that **Transgene's TG4001 could induce a specific immune response against the antigens vectorized within this vaccine.**

11 of the 13 patients with an immune response had either stable disease, partial or complete tumor response according to RECIST criteria.

Remarkably, two case studies are presented, with **patients exhibiting a strong E6 and E7 immune response while showing a complete clinical response**.

Preparing for a planned potentially registrational trial in an HPV-positive indication

Transgene anticipates that the last patient will be randomized in the current Phase II clinical study in the first half of 2024. **Final results will be communicated in 2024**.

Transgene is working on the design of a potentially registrational trial to further confirm the benefit of this novel investigational therapeutic cancer vaccine.

Dr Alessandro Riva, MD, Chairman and CEO of Transgene, added: *"We are very excited by the immunological data that we are presenting at ASCO. These data further confirm that our therapeutic vaccine TG4001 can induce clinically meaningful immune responses, that are associated with antitumor response. We look forward to the final analysis of the ongoing randomized phase 2 study and the potential next steps for TG4001 in patients with HPV positive cancers".*

The abstract and poster can be accessed on the ASCO and Transgene websites.

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About TG4001

TG4001 is an investigational therapeutic vaccine based on a non-propagative, highly attenuated Vaccinia vector (MVA), which is engineered to express HPV16 antigens (E6 & E7) and an adjuvant (IL-2). TG4001 is designed to have a two-pronged antiviral approach: to alert the immune system specifically to cells presenting the HPV16 E6 and E7 antigens, that can be found in HPV16-related tumors, and to further stimulate the infection-clearing activity of the immune system through interleukin 2 (IL-2). TG4001 has been administered to more than 350 individuals, demonstrating good safety and promising efficacy results [1]. Its mechanism of action and good safety profile make TG4001 an excellent candidate for combinations with other therapies in HPV-mediated solid tumors.
It is currently evaluated in a multi-center, open label, randomized Phase II trial (NCT03260023) designed to compare the efficacy of the combination of TG4001 and avelumab versus avelumab alone in patients with advanced, recurrent and/or metastatic HPV16-positive anogenital cancers who have disease progression after a maximum of one line of systemic treatment, or who are not eligible for first-line chemotherapy.

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing cancer cells.
The Company's clinical-stage programs consist of a portfolio of therapeutic vaccines and oncolytic viruses:
TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform, TG4001 for the treatment of HPV-positive cancers, as well as TG6002, BT-001 and TG6050, three oncolytic viruses based on the Invir.IO® viral backbone.
With Transgene's *myvac*® platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The *myvac*® approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.
With its proprietary platform Invir.IO®, Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses.
Additional information about Transgene is available at: www.transgene.fr
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