PRESS RELEASE

Transgene Provides Update on Phase II Trial of Therapeutic Cancer Vaccine TG4001 in Recurrent or Metastatic HPV16-Positive Cervical and Anogenital Cancers

Top line data show that the randomized Phase II study of TG4001 in combination with avelumab versus avelumab alone in patients with recurrent or metastatic HPV16-positive cervical and anogenital tumors did not meet the primary objective of improvement in progression-free survival

Pre-planned subgroup analysis showed a positive efficacy trend in favor of the TG4001 containing regimen in patients with cervical cancer

Transgene will complete full analysis of the data before deciding on the best way forward for TG4001

Transgene will host a conference call today at 3:30 p.m. CET

Strasbourg, France, October 14, 2024, 7:30 a.m. CET – **Transgene (Euronext Paris: TNG)**, a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, announces that its randomized Phase II study to evaluate TG4001 in combination with avelumab versus avelumab alone in patients with recurrent or metastatic HPV16-positive cervical and anogenital tumors has not met the primary objective of the study (improvement in progression-free survival).

The pre-planned subgroup analysis showed a positive efficacy trend in favor of the TG4001 containing regimen in cervical cancer patients, which requires further confirmation through additional analyses, including by PD-L1 status. These patients account for approximately half of the patients enrolled in the study.

The treatment has been well tolerated. Adverse events are consistent with previous observations.

Transgene is currently evaluating the full study results in detail to determine the best way forward for this program and will communicate further once this is completed.

Dr. Alessandro Riva, Chairman and CEO of Transgene, said: *"Failure to meet the primary objective in our Phase II study with TG4001 is disappointing. Nevertheless, we are encouraged by the positive efficacy trend in favor of the combination regimen in cervical cancer patients. We plan to complete a full and rigorous analysis of the data before deciding on any path forward for this asset, in particular in cervical cancer, in the context of the evolving treatment landscape. The complete study results will be presented at an upcoming scientific conference. We would like to thank all the patients and caregivers who have taken part in this study for their important contribution. With a diversified portfolio of novel immunotherapies targeting solid tumors, our strategy remains focused on advancing our lead asset, TG4050, an individualized cancer vaccine for head and neck cancers for use following surgery and adjuvant therapy. We expect to report additional data on TG4050 from the 24-month median follow-up of Phase I patients in our head and neck cancer trial in November 2024 at the SITC conference."*

A conference call **in English** is scheduled today, October 14, 2024, at 3:30 p.m. CET (9:30 p.m. ET).

Webcast link to English language conference call:
https://edge.media-server.com/mmc/p/zh5cy2u9/

Please log in to the following link to obtain your personal telephone IDs.
https://register.vevent.com/register/BIec45dd6245524e73b35d874459dedd5e

A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.

***

Contacts

Transgene Contacts:
Media:
Caroline Tosch
Corporate Communications Manager
+33 (0)3 68 33 27 38
communication@transgene.fr

Lucie Larguier
Chief Financial Officer
Nadège Bartoli
IR Analyst & Financial Communications Officer
+33 (0)3 88 27 91 03 /00
investorrelations@transgene.fr

Transgene Media Contact:
MEDiSTRAVA
Frazer Hall/Sylvie Berrebi
+ 44 (0) 203 928 6900
transgene@medistrava.com

About TG4001

TG4001 (tipapkinogen sovacivec) 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-prolonged 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. Its mechanism of action and good safety profile make TG4001 an excellent candidate for combinations with other therapies in HPV-mediated solid tumors.

About the trial

TG4001 was 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 recurrent or metastatic HPV16-positive cervical and anogenital cancers who have disease progression after a maximum of one line of systemic treatment, or who are not eligible for first-line chemotherapy. The overall trial enrolled 100 patients.

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 BT-001 and TG6050, two 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
Follow us on social media: X (formerly Twitter): @TransgeneSA – LinkedIn: @Transgene

Transgene disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with

development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Universal Registration Document, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.