TPS2701 **Poster Session**

EXPAND-1, a phase I/II study with ANV600, a novel PD-1 targeted IL-2R-βγ agonist, in monotherapy and in combination with pembrolizumab, in patients with advanced solid tumors.

Iphigenie Korakis, Martina Imbimbo, Emiliano Calvo, Sebastian Ochsenreither, Ignacio Ortego, Pascale Tomasini, Kaïssa Ouali, Alexander Desuki, Daniela Di Blasi, Eduard Gasal, Markus Joerger; Inst University Du Cancer De Toulouse, Toulouse, France; Iosi Oncology Institute of Southern Switzerland, Bellinzona, Switzerland; START Madrid-CIOCC, Centro Integral Oncológico Clara Campal, Madrid, Spain; Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Department of Hematology, Oncology and Cancer Immunology; Charité Comprehensive Cancer Center; German Cancer Consortium (DKTK), Berlin, Germany; Clínica U. Navarra, Pamplona, Spain; CEPCM, Hôpital de la Timone, APHM, Marseille, France; Gustave Roussy, Drug Development Department (DITEP), Villejuif, France; University Hospital Mainz, Mainz, Germany; ANAVEON AG, Basel, Switzerland; Division of Medical Oncology, Kantonsspital St. Gallen, St. Gallen, Switzerland

Background: ANV600 is a novel PD-1 targeted, interleukin-2 receptor beta/gamma (IL-2Rβ/γ) selective agonist. This bispecific agent comprises two functionally distinct arms: a PD-1 targeting arm consisting of an anti-PD-1 antibody binding to an epitope that does not overlap with pembrolizumab or other PD-1 checkpoint inhibitors and an IL-2 receptor (IL-2R) agonistic arm, composed of an interleukin-2 (IL-2)/anti-IL-2 antibody fusion protein which selectively signals through IL-2Rβ/γ. ANV600 is expected to promote anti-tumor activity by preferentially stimulating and expanding antigen-experienced PD-1$^+$ CD8$^+$ T cells and be combinable with existing anti-PD-1 clinical therapies. ANV600 will be studied as single agent and in combination with pembrolizumab for the treatment of advanced solid tumors. **Methods:** Study ANV600-001 (EXPAND-1) is a global, multicenter, open-label, first-in-human Phase I/II study to characterize the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity and antitumor activity of ANV600 administered as a single agent or in combination with pembrolizumab in patients with advanced solid tumors. The Phase I will determine the maximum tolerated dose (MTD) and/or recommended phase 2 dose (RP2D) of ANV600 administered intravenously every 2 weeks (Q2W) either as single agent or in combination with pembrolizumab in previously treated advanced solid tumors. A Bayesian Optimal Interval (BOIN) design will guide the dose escalation to determine the MTD and/or RP2D. Once the RP2D has been determined, ANV600 will be further evaluated as monotherapy and in combination with pembrolizumab in the Phase II part of the study for efficacy and safety in PD-1 experienced patients with advanced melanoma, NSCLC and HNSCC. Additional cohorts may be selected based on emerging data. Tumor response will be assessed using RECIST v1.1. Enrolment began in June 2024, with 10 patients enrolled in the monotherapy arm and 4 in the combination arm. Up to 240 participants will be enrolled in 7 countries: Belgium, France, Germany, the Netherlands, Spain, Switzerland and the USA. Research Sponsor: ANAVEON AG. Clinical trial information: NCT06470763. Research Sponsor: None.