INTRATUMORALLY ADMINISTERED CV8102 IN PATIENTS WITH ADVANCED SOLID TUMORS: PRELIMINARY RESULTS FROM ONGOING EXPANSION PART IN STUDY 008

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Background CV8102 is a non-coding, non-capped RNA complexed with a carrier peptide activating the innate (via TLR7/8, RIG-I) and adaptive immune system. An ongoing phase I trial (CV-8102-008) is investigating intratumoral administration of CV8102 either as a single agent or in combination with systemic anti-PD-1 antibodies in patients with advanced cutaneous melanoma (cMEL), squamous cell carcinoma of the skin (cSCC) or head and neck (hnSCC) and adenoid cystic carcinoma (ACC). Recruitment of the expansion part in melanoma patients is completed and preliminary results from this part are reported here.

Methods Study CV-8102-008 is an open-label, cohort-based, dose escalation and expansion phase I study. Eight intratumoral injections of CV8102 are being administered initially over a 12-week period. The trial consists of two parts, a dose escalation part and an expansion part. Primary objective of the expansion part is to obtain additional safety data as well as initial estimates of efficacy in patients with advanced melanoma in a single agent cohort and patients with advanced melanoma patients refractory to anti-PD-1 therapy receiving CV8102 in combination with anti-PD-1 antibodies. In the expansion part, CV8102 was administered at a dose level of 600μg which has been determined as recommended phase 2 dose during the dose escalation part.

Results As of January 2022 10 patients have been treated with CV8102 as a single agent and 30 patients have received CV8102 in combination with anti-PD-1 antibodies within the expansion part. Most frequent treatment emergent adverse events were mild to moderate fever, chills and asthenia. Regression of injected and distant noninjected lesions was observed (including 4 PR per RECIST 1.1. in the combination cohort). Preliminary safety and efficacy as well as selected biomarker results from the expansion cohorts will be presented.

Conclusions The acceptable safety profile already observed during the dose escalation part could be confirmed in the expansion part. Preliminary evidence of clinical efficacy in the expansion cohorts was seen in combination with anti-PD-1 antibodies.

Trial Registration NCT03291002

Ethics Approval The study was approved by central or local ethics committees depending on the country.

In Germany: Central Ethics Committees in Tuebingen, Germany under 785/2016AMG1.


In Spain: CEC COMITÉ DE ÉTICA DE INVESTIGACIÓN CLÍNICA CON MEDICAMENTOS del Hospital Universitari Vall d’Hebron, Barcelona, approval date 28-Nov-2019 under the EUdraCT number.

In Austria: Central Ethics Committee in Graz under 31-426 ex 18/19 approved on 19-Sep-2019.

In the Russian Federation: ETHICS COMMITTEE AT FSBI "NMRC OF ONCOLOGY n.a. N.N. BLOKHIN" OF THE MINISTRY OF HEALTHCARE OF THE RUSSIAN FEDERATION, INTERDISCIPLINARY ETHICS COMMITTEE of Omsk Region, Local Ethics Committee at FSAEI HE "I.M. Sechenov First MSMU" of the Ministry of Healthcare of Russia (Sechenov University, Extract from Minutes № 03-21 of the scheduled meeting of the Local Ethics Committee dated 03 February 2021), BIOMEDICAL ETHICS COMMITTEE at N.I. PIROGOV CLINIC OF HIGH MEDICAL TECHNOLOGIES (IN-PATIENT AND OUTPATIENT FACILITIES), ST. PETERSBURG STATE UNIVERSITY (EXTRACT FROM MINUTES № 02/21 of the meeting of the Biomedical Ethics Committee), Ethics Committee at Federal State Budgetary Institution “National Medical Research Center of Oncology named after N. N. Petrov” of the Ministry of Health of the Russian Federation (Extract No. 5/130 from the Minutes of the scheduled meeting of the Ethics Committee dated 03 February 2021),