

## PRESS RELEASE

May 30, 2025

### Phase I/II study of vorbipirant combined with anti-PD-1 immunotherapy results in metastatic gastrointestinal non-colorectal cancers presented at ASCO 2025

*Monza (Italy)* – Rottapharm Biotech announces that results from the phase I/II study of the EP4 antagonist vorbipirant (CR6086) with an anti-PD-1 antibody (balstilimab, Agenus Inc, Nasdaq: AGEN) in metastatic gastrointestinal non-colorectal cancers, will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 02, 2025.

The study was conducted at the National Cancer Institute (Istituto Nazionale Tumori) in Milan, Italy, by the Gastroenterological Oncology Unit led by Dr. Filippo Pietrantonio, within the Department of Medical Oncology.

The trial was an extension of the phase Ib/IIa prospective, trial in colorectal cancer (CRC) and enrolled patients with non-colorectal metastatic gastrointestinal (GI) cancers. Patients were divided into 3 cohorts: gastric cancer (GC) with PD-L1 Combined Positive Score (CPS)  $\geq 5$  (cohort A), GC with PD-L1 CPS  $< 5$  (cohort B), and GI cancers other than CRC and GC (cohort C). Primary endpoints were safety and disease control rate, secondary endpoints included objective response rate, duration of response, progression-free and overall survival. Exploratory endpoints include tissue and blood biomarkers.

Vorbipirant combined with PD-1 blockade was well tolerated and showed signs of activity in non-colorectal GI cancers, thus confirming a broader spectrum of activity, on top of the results obtained in MSS mCRC. To further confirm preliminary positive results, a Phase II expansion in both MSS mCRC and GC patients is planned.

#### **Presentation Details**

**Title:** Phase I/II study of the EP4 antagonist vorbipirant combined with anti-PD-1 immunotherapy: safety and efficacy results in metastatic gastrointestinal non-colorectal cancers.

**Poster Number:** 2608

**Presenting Author:** Filippo Pietrantonio, MD, Department of Medical Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy



**Presentation Session Date and Time:** “Developmental Therapeutics—Immunotherapy”. Monday, June 02, 2025, 1:30 PM-4:30 PM CDT

**Board Number:** 255

The poster will be available to view in this website page following the ASCO congress.

### **About CR6086 (vorbipirant)**

CR6086 (vorbipirant) is a novel targeted immunomodulator acting as an antagonist at the prostaglandin E2 (PGE2) receptor EP4 subtype. EP4 receptors have an important role in the altered immune response observed in autoimmune diseases. PGE2-EP4 signalling plays a major immunosuppressive role in the tumour microenvironment, and as such it favours cancer immune escape and tumour progression. Consistently, experimental evidence suggests that EP4 receptor antagonists may improve the response to immune checkpoint inhibitors (ICIs).

A Phase I/II clinical trial to evaluate the safety and efficacy of CR6086 in combination with the PD-1 inhibitor balstilimab in patients with pretreated mismatch-repair-proficient and microsatellite stable metastatic colorectal cancer, and other metastatic GI cancers, provided promising results.

### **About Rottapharm Biotech**

Rottapharm Biotech is a research company dedicated to the discovery and development of innovative drugs, located in Monza (Italy). The company expertise in research and development includes medicinal/computational chemistry for small molecules, development of biologics and advanced therapies, new targets validation, pharmacological and pharmacokinetic characterization of new drug candidates, original formulations, and design of innovative clinical trials. The company strategy is to develop its own pipeline independently and then seek partnerships with pharmaceutical companies, as well as investing in alliances on innovative projects of other biotech companies or university spin-offs.

### **Rottapharm Biotech Contact**

Federica Girolami, Business Development Director

Tel. +39 346 4131428

[federica.girolami@rottapharmbiotech.com](mailto:federica.girolami@rottapharmbiotech.com)