

Kainova Therapeutics Announces Positive Phase I Results for DT-9081, an Oral EP4 Receptor Antagonist, in Advanced Solid Tumors

- *Phase I results demonstrate favorable safety, sustained target engagement, and early signs of anti-tumor activity*
- *Reinforce EP4 receptor antagonism as a validated, high-value strategy to overcome immunotherapy resistance*

Montreal, Canada – Strasbourg, France – Boston, United States, March 10, 2026:

Kainova Therapeutics (“the Company”), a key player for breakthrough treatments in immuno-oncology and inflammation, today announced positive topline results from its Phase I EPRAD study evaluating DT-9081, a proprietary, oral small molecule EP4 receptor (EP4R) antagonist in patients with advanced, recurrent, and metastatic solid tumors.

The study, conducted across four sites in France and Belgium, met all primary objectives. Results demonstrated a favorable safety profile, robust pharmacokinetic (PK) and pharmacodynamic (PD) characteristics with dose-proportional exposure, and sustained EP4 receptor engagement across all tested doses, with early signs of anti-tumor activity.

No dose-limiting toxicities were reported at any dose level, confirming DT-9081's clinical tolerability and validating its mechanism of action. The Phase I findings further support DT-9081's potential to improve responses to immune checkpoint inhibitors (ICIs). Full Phase I study details are available on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05582850) under identifier [NCT05582850](https://clinicaltrials.gov/ct2/show/study/NCT05582850).

Professor Jean-Pascal Machiels, Principal Investigator of the EPRAD study, commented: *“The results of the study not only validate EP4 receptor antagonism as a powerful mechanism to counteract PGE2-driven immune suppression, but also demonstrate the clinical potential of DT-9081 across a range of tumor types. Since chemotherapy and other standard treatments often trigger PGE2 production by cancer cells, restoring competence through selective EP4 inhibition offers a rational and versatile strategy to overcome resistance. It was my honor to contribute to the advancement of DT-9081 through the clinic.”*

Dr Jean-Marie Cuillerot, Chief Medical Officer of Kainova Therapeutics, said:

“The Phase I EPRAD study generated a clear and coherent dataset that precisely characterizes DT-9081’s clinical profile. Across all dose levels, we observed consistent safety findings together with robust PK/PD readouts. The high-quality clinical and translational data obtained in this study are essential for understanding how EP4 antagonism behaves in patients with advanced solid tumors in a clinical setting.”

Sean A. MacDonald, Chief Executive Officer of Kainova Therapeutics, added:

“The successful completion of this Phase I study represents an important step for Kainova Therapeutics, highlighting the strength of our innovative approach to targeting the EP4 receptor to overcome tumor-induced immunosuppression. The favorable safety and early efficacy signals observed with DT-9081 provide meaningful insight into EP4 biology and its role in immuno-oncology. These findings reflect the depth of expertise within our team and reinforce the relevance of GPCR-modulating strategies in addressing complex immune pathways.”

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About Kainova Therapeutics

Kainova Therapeutics is a clinical-stage biopharmaceutical company, headquartered in Montreal, Canada, driving a robust pipeline of breakthrough therapies that precisely modulate G protein-coupled receptors (GPCRs) with a focus on immuno-oncology and inflammation. Kainova Therapeutics' key programs include a unique clinical-stage Treg-depleting anti-CCR8 antibody with differentiated competitive features and a first-in-modality pre-IND stage biased antagonist of PAR2.

By unlocking challenging and unexploited GPCR targets through its integrated discovery-to-clinic approach that integrates deep biological knowledge, Kainova Therapeutics delivers highly differentiated therapies grounded in rigorous science and designed to improve therapeutic efficacy. Recognized for a solid track record of collaborations with major pharma, physicians and KOLs worldwide, Kainova Therapeutics brings scientific excellence to the development of GPCR-modulating therapies.

Operating in North America, France, and Australia, Kainova Therapeutics applies smart trial designs, capital efficiency, and operational rigor across its programs. As GPCRs gain renewed attention as next-generation drug targets, Kainova Therapeutics is uniquely positioned to lead this evolving field. For more information, please visit www.kainovatx.com

About DT-9081

DT-9081 is a best-in-class oral EP4 receptor antagonist designed to reverse Prostaglandin E2 (PGE2)-mediated immunosuppression within the tumor microenvironment. Preclinical studies have shown significant anti-tumor effects in triple-negative breast cancer, sarcoma, and colorectal cancer models, both as a monotherapy and in combination with chemotherapy or immune checkpoint inhibitors. PGE2, produced by COX-2 positive tumors, promotes tumor progression. By selectively inhibiting EP4 receptor, DT-9081 aims at restoring an immunocompetent environment and supporting immune reactivation, with the goal of improving the effectiveness of anticancer treatments, including chemotherapy and certain ICIs. The candidate is supported by a comprehensive biomarker strategy, enabling precise monitoring of EP4 receptor engagement during treatment and helping inform clinical positioning, de-risk development, and ensure an efficient, informative clinical trial strategy.

About GPCRs

G Protein-Coupled Receptors (GPCRs) are at the top of complex signaling cascades and are responsible for translating extracellular messages into intracellular actions, making them critical for various biological processes and attractive for therapeutic intervention. Despite being the most validated drug target family, with 30-35% of all marketed drugs acting on them, they remain challenging to drug, with existing drugs targeting only 10% of the total potential GPCR targets. While most efforts in GPCR drug discovery and development have traditionally focused on central nervous system and cardio-metabolic disorders, Kainova Therapeutics recognizes the substantial untapped potential of GPCRs in immuno-oncology and inflammatory diseases, areas where GPCRs have not been as extensively explored.