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Carrick Therapeutics Announces U.S. FDA Clearance of IND for CT7439, a First-In-Class Inhibitor of CDK12/13

DUBLIN, Ireland and BOSTON, Sept. 07, 2023 (GLOBE NEWSWIRE) -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for CT7439, a novel cyclin dependent kinase 12/13 (CDK12/13) inhibitor. The Company plans to initiate the Phase 1 clinical trial in the first half of 2024 and intends to enroll patients with advanced solid tumors, including breast, ovarian and Ewing's Sarcoma.

"FDA clearance of our IND application for CT7439, Carrick's second therapeutic candidate, further strengthens our oncology pipeline and will allow us to evaluate how our promising preclinical data translate into clinical benefits in patients with solid tumors," said Tim Pearson, Chief Executive Officer of Carrick Therapeutics.

The Phase 1 clinical trial is a modular design, beginning with a dose escalation for the initial administration of CT7439 to patients. The initial clinical evaluation will be focused on safety and pharmacokinetics, with an opportunity for early Proof of Principle using a blood based pharmacodynamic assay of the homologous recombination repair (HRR) pathway.

About CT7439
CT7439 is an inhibitor of CDK12/13 as well as a 'glue degrader' of Cyclin-K, which is the obligate co-factor for CDK12/13, giving both first-in-class and best-in-class potential. This dual modality significantly increases the potency of the compound and leads to the inhibition of DNA repair at the transcriptional level. CDK12/13 regulates gene transcription through the activation of RNA Polymerase II. It has the potential to synergise with other agents targeting DDR such as the PARP inhibitors in multiple cancer types including breast, ovarian and Ewing's Sarcoma.

About Carrick Therapeutics
Carrick Therapeutics is an oncology-focused biopharmaceutical company developing highly differentiated novel therapies that address significant unmet needs. The Company's lead program, samuraciclib, is a novel CDK7 inhibitor currently in Phase 2 clinical trials for HR+ breast cancer. Additionally, Carrick is developing CT7439, a novel CDK12/13 inhibitor / Cyclin-K glue-degrader, which is expected to enter a Phase 1 clinical trial in the first half of 2024.

For more information about Carrick Therapeutics, please visitwww.carricktherapeutics.com

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