February 14, 2024

Carrick Therapeutics Announces First Patient Dosed in Phase 1b/2 Clinical Trial of Samuraciclib in Combination with Vepdegestrant in Patients with Advanced Breast Cancer

BOSTON, Feb. 14, 2024 (GLOBE NEWSWIRE) -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today announced that the first patient has been dosed in its Phase 1b/2 clinical trial evaluating the combination of samuraciclib (CT7001), an investigational oral and first-in-class inhibitor of CDK7, and vepdegestrant (ARV-471), an investigational oral PROTAC® (PROteolysis TArgeting Chimera) estrogen receptor (ER) degrader, being jointly developed by Arvinas (Nasdaq: ARVN) and Pfizer (NYSE: PFE) in women with ER+, HER2- metastatic breast cancer who have previously received a CDK4/6 inhibitor.

“We’re excited to expand clinical development of samuraciclib with our Phase 1b/2 clinical trial evaluating the combination of samuraciclib and vepdegestrant, another step forward in addressing an important need for patients with advanced breast cancer,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “We believe there is great potential for this combination treatment, based on the encouraging initial clinical trial data for vepdegestrant and Pfizer’s deep expertise in developing treatments for breast cancer.”

The Phase 1b/2 clinical trial has two parts. In Phase 1b, escalating doses of samuraciclib and vepdegestrant will be tested to determine appropriate doses of each therapy to be used in combination. In Phase 2, additional patients will be enrolled to further explore the safety and efficacy of the selected doses.

This clinical trial evaluating the novel combination of samuraciclib and vepdegestrant is being conducted as part of the TACTIVE-U study in collaboration with Arvinas and Pfizer under a clinical trial collaboration and supply agreement. Clinical trial details can also be found on www.clinicaltrials.gov under study ID: NCT06125522. For additional information on the clinical trial, please contact hello@carricktherapeutics.com.

About Vepdegestrant (ARV-471)
Vepdegestrant is an investigational, orally bioavailable PROTAC protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with ER positive (ER+)/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed increased anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in

combination with a CDK4/6 inhibitor. In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits. Ongoing and planned clinical trials will continue to monitor and evaluate the safety and anti-tumor activity of vepdegestrant.

About Samuraciclib (CT7001)
Samuraciclib is the most advanced CDK7 inhibitor in clinical development. Inhibiting CDK7 is a promising therapeutic strategy in cancer as CDK7 regulates the transcription of cancer-causing genes, promotes uncontrolled cell cycle progression and promotes resistance to anti-hormone therapy. Samuraciclib has demonstrated a favorable safety profile and encouraging efficacy in early clinical studies. In addition to the above studies, samuraciclib has further potential in prostate, pancreatic, ovarian and colorectal cancers. Samuraciclib has been granted Fast Track designation from the U.S. Food and Drug Administration (FDA) for use in combination with fulvestrant for the treatment of CDK4/6i resistant HR+, HER2- advanced breast cancer. Carrick is collaborating with Roche, Menarini Group and Arvinas/Pfizer to evaluate novel combinations of samuraciclib with Roche's oral SERD giredestrant, Menarini Group's oral SERD elacestrant, and Arvinas/Pfizer's proteolysis targeting chimera (PROTAC) Estrogen Receptor degrader vepdegestrant (ARV-471) in late-stage CDK4/6i resistant HR+, HER2- metastatic breast cancer.

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 mid-2024.

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

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