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Carrick Therapeutics Announces First Patient Dosed in Phase 2 Clinical Trial of Samuraciclib in Combination with Elacestrant in Patients with Advanced Breast Cancer

BOSTON, Oct. 18, 2023 (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 2 clinical trial evaluating the novel combination of Carrick's samuraciclib (CT7001), an oral and first-in-class inhibitor of CDK7, and the Menarini Group's (Menarini) oral selective estrogen receptor degrader (SERD), elacestrant, in patients with CDK4/6i resistant HR+, HER2- metastatic breast cancer.

"Dosing the first patient in our Phase 2 clinical trial evaluating the combination of samuraciclib and elacestrant is an important milestone in our goal of improving outcomes for women fighting metastatic breast cancer," said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. "Our prior studies have validated the biology for elacestrant with CDK7, and we are eager to evaluate the potential synergistic benefit of this fully oral combination therapy in patients with advanced breast cancer."

The trial will initially evaluate the tolerability and pharmacokinetics of the combination then recruit an expansion cohort evaluating the longer-term progression free survival benefits. ctDNA analysis performed via liquid biopsy will form a critical component of the study to inform two key questions: (1) the level of benefit in patients without a detectable ESR1-mutation and (2) the patient selection biomarker potential of TP53-mutation status.

The Phase 2 clinical trial evaluating the novel combination of samuraciclib and elacestrant is being conducted in collaboration with Menarini, pursuant to a clinical trial collaboration and supply agreement for elacestrant. Clinical trial details can also be found on www.clinicaltrials.gov under study ID: NCT05963997. For additional information on the clinical trial, please contact hello@carricktherapeutics.com.

About ORSERDU® (elacestrant)

Indication
ORSERDU (elacestrant), 345 mg tablets, was approved in January 2023 for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

For more information, please see the full Prescribing Information for ORSERDUhere.

Important Safety Information
Warning and Precautions

Dyslipidemia: Hypercholesterolemia and hypertriglyceridemia occurred in patients taking ORSERDU at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking ORSERDU.

Embryo-Fetal Toxicity: Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the final dose.

Adverse Reactions
Serious adverse reactions occurred in 12% of patients who received ORSERDU. Serious adverse reactions in >1% of patients who received ORSERDU were musculoskeletal pain (1.7%) and nausea (1.3%). Fatal adverse reactions occurred in 1.7% of patients who received ORSERDU, including cardiac arrest, septic shock, diverticulitis, and unknown cause (one patient each).

The most common adverse reactions (>10%), including laboratory abnormalities, of ORSERDU were musculoskeletal pain (41%), nausea (35%), increased cholesterol (30%), increased AST (29%), increased triglycerides (27%), fatigue (26%), decreased hemoglobin (26%), vomiting (19%), increased ALT (17%), decreased sodium (16%), increased creatinine (16%), decreased appetite(15%), diarrhea(13%), headache (12%), constipation (12%), abdominal pain (11%), hot flush (11%), and dyspepsia (10%).

Drug interactions
Concomitant use with CYP3A4 Inducers and/or inhibitors: Avoid concomitant use of strong or moderate CYP3A4 inhibitors with ORSERDU. Avoid concomitant use of strong or moderate CYP3A4 inducers with ORSERDU.

Use in specific populations
Lactation: Advise lactating women to not breastfeed during treatment with ORSERDU and for 1 week after the last dose.

Hepatic Impairment: Avoid use of ORSERDU in patients with severe hepatic impairment (Child-Pugh C). Reduce the dose of ORSERDU in patients with moderate hepatic impairment (Child-Pugh B).

The safety and effectiveness of ORSERDU in pediatric patients have not been established.
To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Elacestrant is also being investigated in several clinical trials in metastatic breast cancer

disease, alone or in combination with other therapies: ELEVATE (NCT05563220); ELECTRA (NCT05386108); and ELCIN (NCT05596409). Elacestrant is also planned to be evaluated in early breast cancer disease.

About The Menarini Group
The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4.4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for oncology, cardiology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

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 designations 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 and Menarini Group to evaluate novel combinations of samuraciclib with Roche's oral SERD giredestrant and Menarini Group's oral SERD elacestrant in 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 the first half of 2024.

For more information about Carrick Therapeutics, please visit www.carricktherapeutics.com

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