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Carrick Therapeutics Presents Encouraging Initial Efficacy for Samuraciclib (CT-7001) in Combination with Fulvestrant in Advanced HR+, HER2- Breast Cancer Patients at ESMO Congress 2021

Phase 2a Tolerability and Efficacy Data Supports Further Clinical Development of Samuraciclib in Combination with Fulvestrant in HR+, HER2- Breast Cancer Previously Treated with a CDK4/6 Inhibitor

DUBLIN, Ireland and BOSTON, Sept. 16, 2021 (GLOBE NEWSWIRE) -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today presented encouraging initial clinical data on samuraciclib (CT-7001), an oral and first-in-class inhibitor of CDK7, at the 2021 European Society of Medical Oncology (ESMO) Congress.

Data presented from a Phase 2a study of samuraciclib in combination with fulvestrant in women with hormone receptor positive (HR+), HER2- advanced breast cancer (BC) previously treated with a CDK4/6 inhibitor (abstract: 1346 (265P)) demonstrated clinical activity and tolerability that supports further clinical development of the combination.

“Today, for the first time, we presented data from a clinical trial of our oral CDK7 inhibitor, samuraciclib. Results of the Phase 2a study in combination with fulvestrant demonstrated clinical activity and tolerability in patients with HR+, HER2- advanced breast cancer, reinforcing our conviction that samuraciclib has potential to be a first and best-in-class treatment,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “As a reminder, the FDA recently granted Fast Track designation to samuraciclib in combination with fulvestrant for CDK4/6 inhibitor resistant patients. This patient population is particularly difficult to treat, with a recent trial showing only 8 weeks mPFS benefit when women are treated with fulvestrant alone. Based on this initial data, we believe samuraciclib has the potential to provide a clinically meaningful benefit for all patients, most notably in those women that are TP53 wildtype. In addition to fulvestrant, we are exploring additional samuraciclib combinations, including with giredestrant, a next-generation oral SERD, through our recently announced clinical collaboration with Roche in metastatic breast cancer. We thank the women that participated in this Phase 2a trial and look forward to continuing the fight against this and other types of cancer.”

As part of the Phase 2a study of samuraciclib in combination with fulvestrant in patients with advanced HR+, HER2- BC, 31 patients were enrolled with difficult-to-treat disease. 81% of

these patients had visceral disease, including 45% with liver metastasis. All patients enrolled previously progressed following treatment with a CDK4/6 inhibitor. Of the 31 patients enrolled in the study, 24 patients were evaluable for response at the time of data cut-off:

- 17 (71%) had tumour shrinkage, with a best RECIST response of partial response (PR) in two (8%) patients and stable disease (SD) in 13 (54%) patients.
- Median progression-free survival (mPFS) of the intent-to-treat (ITT) population was 16.1 weeks (n=31).
    - Notably, patients with no mutation in the TP53 gene had a mPFS of 32.0 weeks (n=18).
    - Prolonged disease control was also apparent in patients with no liver metastases at baseline (n=17), with mPFS having not yet been reached. At the point of this data cut-off, mPFS would be at least 28 weeks.
- Adverse events were predominantly low-grade gastrointestinal (GI) events that were reversible and manageable using standard prophylactic treatment. No significant neutropenia or myelosuppression associated with other CDK inhibitors were observed.
- This data supports the further development of samuraciclib in HR+ advanced BC.

“The data from this study show excellent preliminary evidence of activity of samuraciclib in combination with fulvestrant,” said Dr. Sacha Howell, The Christie NHS Foundation Trust, Manchester, UK and a primary investigator in the Phase 2a study. “This population of patients, previously treated with CDK4/6 inhibitors, are known to have previously demonstrated short PFS benefit from fulvestrant alone. The efficacy data, particularly in participants with wildtype TP53, exceeded my expectations and offers the potential for durable endocrine disease control, further delaying the need for chemotherapy. Those participants remained on therapy for prolonged durations demonstrates tolerability and the main GI toxicity was manageable with supportive medication.”

“Following the positive initial Phase 2a data, we are preparing to advance the randomized Phase 2b study of HR+, HER2-, post-CDK4/6 inhibitor breast cancer patients,” said Dr. Stuart McIntosh, Chief Medical Officer of Carrick Therapeutics. “A key distinction from the Phase 2a will be the inclusion of patients with RECIST non-measurable disease in addition to those with visceral disease in the Phase 2b, in-line with the real-world population. Given the success noticed in the sub-group of patients with no mutation in the TP53 gene population, we will prospectively evaluate and stratify by mutation status as well. This success aligns with the known biological function of TP53 since its activation has been shown to sensitize cancer cells to CDK7 inhibition. Approximately 75% of breast cancer patients are TP53 wild-type, and we believe this may be an important potential biomarker for future studies.”

In addition to the Phase 2a data presented today, data from the first-in-human study of samuraciclib in patients with advanced solid malignancies (abstract: 943 (230MO)) will be shared during an oral presentation at ESMO from 17:10 BST (12:10pm ET) on September 18, 2021. As part of the study, 44 patients were treated with escalating doses of samuraciclib monotherapy, which demonstrated evidence of antitumor activity with a manageable safety profile.

About Samuraciclib (CT7001)
Samuraciclib is the most advanced oral 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 resistance to anti-hormone therapy. Samuraciclib has demonstrated a favorable safety profile and encouraging efficacy in early clinical studies. In addition to the above study, it is currently being evaluated in triple negative breast cancer (TNBC) and prostate cancer with further potential in 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 and in combination with chemotherapy for the treatment of locally advanced or metastatic TNBC.

About Carrick Therapeutics

Carrick Therapeutics is an oncology-focused biopharmaceutical company leveraging its deep expertise to identify and develop highly differentiated novel therapies that address significant unmet needs. In addition to samuraciclib, Carrick is also developing a novel CDK12/13 inhibitor / Cyclin-K glue-degrader which has advanced into IND enabling toxicology studies.

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

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