December 9, 2021

Carrick Therapeutics Presents Encouraging Clinical Data for Samuraciclib (CT7001) at the 2021 San Antonio Breast Cancer Symposium

DUBLIN, Ireland and BOSTON, Mass., Dec. 09, 2021 (GLOBE NEWSWIRE) -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today at the 2021 San Antonio Breast Cancer Symposium (SABCS), presented encouraging clinical data on samuraciclib (CT7001), an oral and first-in-class inhibitor of CDK7, that support its continued development in breast cancer.

Carrick presented updated data from a Phase 1b/2 clinical trial for 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: GS3-10) that reinforces encouraging clinical activity and tolerability and supports further development of the combination.

“The data we announced at SABCS both demonstrated clinical activity and tolerability, which has reinforced our conviction that samuraciclib has potential to be a first and best-in-class treatment,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “Our pre-clinical studies have established that CDK7 inhibition activates the p53 pathway in TP53 wild-type, HR+ breast cancer cells. More importantly, p53 pathway activation by samuraciclib in combination with CDK7 inhibition has been effective in controlling cancer growth in our HR+ clinical study. Samuraciclib, provides meaningful benefit most notably in those women that are TP53 wildtype, which accounts for nearly 70% of patients in this setting. Samuraciclib in combination with fulvestrant in the post CDK4/6 setting has demonstrated a median mPFS of 32 weeks. This is a meaningful prolongation of PFS considering the limited benefit these patients have with endocrine monotherapy therapy, which is limited to only ~8 weeks mPFS with fulvestrant alone in previously reported studies. Having now validated the biology for SERD combination, we continue to explore additional options, including our collaboration with Roche’s giredestrant, a next-generation oral SERD. We believe there is potential for synergy in combining samuraciclib with oral SERDs to significantly enhance the benefits already demonstrated with fulvestrant . We are excited with the progress we’ve made, and we look forward to additional data readouts from our ongoing programs.”

The study recruited patients with advanced HR+, HER2- BC, 31 patients were enrolled with difficult-to-treat disease. All patients enrolled had progressed following treatment with a CDK4/6 inhibitor and 23% had received chemotherapy for advanced disease. All patients had advanced disease with 81% having visceral involvement, including 45% with liver metastasis and only 6% with bone only disease.

Of the 31 patients enrolled in this ongoing study, 25 patients were evaluable for response at the time of data cut-off:

- Overall the clinical benefit rate (CBR) of patients who received treatment for at least 24 weeks was 36% (9 patients).
- However clinical benefit was particularly evident in patients with no deleterious mutation in the TP53 gene and patients without liver metastases.
    - Median progression-free survival (mPFS) TP53 wild-type (n=19) was 32 weeks vs 7.9 weeks for TP53 mutant (n=6).
    - mPFS with no liver metastases (n=17) was not reached (≥48 weeks) vs 11.9 weeks for patients with liver metastases (n=14).
- 18 (72%) had tumour shrinkage including 3 partial responses (1 confirmed, 2 unconfirmed)
- The combination treatment was generally well tolerated. Adverse events were predominantly low-grade gastrointestinal (GI) events such as nausea, vomiting and diarrhea with the majority of patients staying on treatment until disease progression.
- This additional data supports the further development of samuraciclib in HR+ advanced breast cancer.

Carrick also presented data for the use of samuraciclib in patients with advanced triple negative breast cancer (TNBC) (abstract: P1-18-10) which demonstrated evidence of antitumor activity that support its further development as a platform for combination approaches in TNBC. In this study, 23 patients with advanced TNBC were recruited and dosed with samuraciclib 360mg OD.

- Samuraciclib demonstrated evidence of long-term benefit in patients who had received one to three lines of prior chemotherapy:
    - One patient had a partial response as defined by RECIST, and stable disease was achieved in 11 patients.
    - Five patients have been on treatment for at least 24 weeks of whom 3 have exceeded 1 year.
- Treatment was generally well tolerated with all patients staying on treatment until disease progression. Adverse events were predominantly GI events of low-grade.
- Samuraciclib has shown evidence of target engagement on several biomarkers that supports its mechanism of action. In addition, plasma thymidine kinase activity, a measure of cell cycle progression, was inhibited with samuraciclib administration.

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 studies, it is currently being evaluated in 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 visitwww.carricktherapeutics.com

Contact

Carrick Therapeutics
Jenny Horsfield, Senior Vice President Business Development
jenny.horsfield@carricktherapeutics.com

Investors and Media
William Slattery, Jr., Real Chemistry
wslattery@realchemistry.com

Source: Carrick Therapeutics Ltd.