May 15, 2025

Carrick Therapeutics Announces New Clinical Data Supporting Biomarker-driven Patient Selection for Samuraciclib (CDK7i) in Combination with SERDs in Hormone Receptor Positive Advanced Breast Cancer

Two independent Phase 2 trials demonstrate extended progression-free survival in patients without TP53 mutations or without liver metastases

Results presented at 2025 ESMO Breast Cancer Annual Congress

BOSTON, May 15, 2025 (GLOBE NEWSWIRE) -- Carrick Therapeutics Inc., an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today announced results from a new analysis of two Phase 2 clinical trials of samuraciclib, a novel investigational oral and first-in-class inhibitor of CDK7, in patients with hormone receptor positive (HR+) advanced breast cancer who had received prior CDK4/6 inhibitor therapy. The MORPHEUS trial evaluated samuraciclib in combination with giredestrant and the Module 2A trial evaluated samuraciclib in combination with fulvestrant.

The analysis indicated that study participants with no evidence of a deleterious mutation in the TP53 gene in circulating tumor DNA at baseline or separately, without liver metastases at baseline, experienced extended durations of progression-free survival. This further supports the Company's biomarker-driven patient selection strategy. Results of the data analysis were presented in a poster session at the 2025 ESMO Breast Cancer Annual Congress held in Munich, Germany.

"Based on the results from these two independent studies, we have identified patient populations showing improved progression-free survival, highlighting the potential of samuraciclib in combination with SERDs as an effective new treatment option for these patients. Carrick is further validating these two selection strategies in two additional Phase 2 studies reading out later this year with the intent to advance to Phase 3 in 2026, enriching for one of these two patient groups," said Tim Pearson, Chief Executive Officer of Carrick Therapeutics.

Results of the data analysis indicated improved progression-free survival both for patients with no TP53 mutation, compared to those with mutation, and also for patients without liver metastases, compared to those with liver metastases.

Median Progression-Free Survival, Months

	MORPHEUS Trial (n=15) (Samuraciclib + Giredestrant)	Module 2A Trial (n=31) (Samuraciclib + Fulvestrant)
No TP53 Mutation	14.2	7.4
TP53 Mutation	1.8	1.8
Without Liver Metastases	14.2	13.8
Liver Metastases	1.8	2.8

“Patients with HR positive, HER2 negative advanced breast cancer are typically treated with a CDK4/6 inhibitor in combination with an endocrine therapy, but unfortunately almost all patients eventually develop resistance to therapy,” said Dr. Stuart McIntosh, Chief Medical Officer of Carrick Therapeutics. “Those patients are in need of effective new targeted therapies that are durable and tolerable in combination with endocrine therapy, including oral SERDs. These results from two independent trials of samuraciclib in combination with a SERD are very encouraging.”

Carrick is further evaluating its patient-selection strategy in two ongoing Phase 2 clinical trials. In collaboration with the Menarini Group, Carrick is executing the SUMIT-ELA trial evaluating the efficacy and safety of samuraciclib in combination with the oral SERD elacestrant in patients with HR+, human epidermal growth factor receptor 2 negative (HER2-) locally advanced or metastatic breast cancer who were previously treated with a CDK4/6 inhibitor and aromatase therapy. The randomized SUMIT-BC trial is evaluating the efficacy and safety of samuraciclib in combination with fulvestrant vs. fulvestrant alone in patients with HR+, HER2- locally advanced or metastatic breast cancer who were previously treated with a CDK4/6 inhibitor and aromatase therapy. With the results of the multi-center international SUMIT studies, Carrick will have studied CDK7i plus SERD combination therapy in over 150 patients.

About Samuraciclib (CT7001)
Samuraciclib is the most advanced cyclin dependent kinase 7 (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, an oral CDK7 inhibitor, has demonstrated a favorable safety profile and encouraging efficacy in early clinical studies in HR+ breast cancer. Because of its ability to inhibit CDK7, samuraciclib has the potential to treat prostate, pancreatic, small cell lung cancer, triple negative breast (TNBC), 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.

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 oral first-in-class inhibitor of CDK7 currently in multiple Phase 2 clinical trials for metastatic HR+ breast cancer. The Company is collaborating with Roche and Menarini Group to evaluate novel combinations of samuraciclib with oral SERD

endocrine therapies. Additionally, Carrick is developing CT7439, a novel CDK12/13 inhibitor / Cyclin-K glue-degrader, which is currently in a Phase 1 clinical trial.

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

Carrick Contacts

Carrick Therapeutics
Jenny Horsfield, Chief Business Officer
jenny.horsfield@carricktherapeutics.com

Investors and Media
Luke Heagle, Real Chemistry
lheagle@realchemistry.com

Source: CARRICK THERAPEUTICS LIMITED