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Carrick Therapeutics Announces Positive Results from Phase 2 Randomized Trial of Samuraciclib in Combination with Fulvestrant in Patients with Hormone Receptor Positive, HER2 Negative Advanced Breast Cancer

Overall response rate (ORR) of 55% and median progression-free survival of 14.5 months in patients without TP53 gene mutation

Phase 2 results presented at 2025 San Antonio Breast Cancer Symposium

BOSTON, Dec. 10, 2025 (GLOBE NEWSWIRE) -- Carrick Therapeutics Inc., an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today announced positive results from the Phase 2 SUMIT-BC clinical trial evaluating samuraciclib in combination with fulvestrant in patients with second-line advanced hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) breast cancer who were previously treated with a CDK4/6 inhibitor therapy. The clinical trial results were presented today in a late-breaking poster presentation at the 2025 San Antonio Breast Cancer Symposium (SABCS). Samuraciclib is an oral first-in-class CDK7 inhibitor (CDK7i).

“These Phase 2 trial results show that samuraciclib in combination with fulvestrant provided a very notable and clinically meaningful benefit in a broad patient population with HR positive, HER2 negative metastatic breast cancer whose disease progressed following treatment with a CDK4/6 inhibitor. Carrick now has positive efficacy and safety data from three independent clinical trials of samuraciclib in advanced breast cancer,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “The best-in-class PFS and ORR of samuraciclib positions it to be a meaningful therapy that could transform how women with advanced breast cancer are treated following treatment with CDK4/6 inhibitors. We have achieved clinical proof of concept and look forward to advancing samuraciclib into a Phase 3 clinical trial in 2026 to build on these promising results.”

Overall Response Rate (ORR)	Clinical Benefit Rate at 24 weeks (CBR24)	Median Progression-Free Survival (mPFS)

Samuraciclib + Fulvestrant (360mg)			
All Patients	33%	60%	7.8 months
TP53 mutation not detected (pre-specified stratification)	**55%**	**69%**	**14.5 months**
Fulvestrant Alone – Control Arm			
All Patients	14%	40%	5.6 months
TP53 mutation not detected	**29%**	**46%**	**6.8 months**

Results among study participants without a TP53 gene mutation per baseline circulating tumor DNA (ctDNA), a pre-specified stratification, indicated improved CBR, ORR and mPFS compared to those with the mutation. In the trial, the median PFS of samuraciclib combined with fulvestrant in this TP53wt population was 14.5 months versus 6.8 months with fulvestrant alone, an incremental improvement of 7.7 months.

“Identifying the optimal treatment strategy for patients with HR positive, HER2 negative breast cancer following progression on CDK4/6 inhibitor therapy remains a significant clinical challenge,” said Dr. Sonia Pernas, Breast Medical Oncologist at the Catalan Institute of Oncology, L’Hospitalet, Barcelona (Spain), and lead author of the SABCS poster. “The SUMIT-BC results indicate that the combination of samuraciclib and fulvestrant may offer a promising new therapeutic option, with the potential for particularly favorable outcomes in patients with TP53 wild-type tumors.”

“We are encouraged by the results of the SUMIT-BC trial of samuraciclib, which demonstrated strong efficacy and durable responses regardless of ESR1 or PI3K mutation status with a tolerable side effect profile,” said Dr. Stuart McIntosh, Chief Medical Officer of Carrick Therapeutics. “SUMIT-BC is now the third study to demonstrate enhanced efficacy in the TP53wt patient population, which makes up 70% of patients in second line setting. The use of baseline ctDNA means this selection biomarker should be straightforward to integrate into clinical practice.”

The late-breaking poster presentation at the 2025 San Antonio Breast Cancer Symposium is available on the Posters & Publications page of Carrick Therapeutics’ website.

About the Phase 2b SUMIT-BC Trial

SUMIT-BC is a randomized, multicenter Phase 2b clinical trial (NCT05963984) evaluating the efficacy and safety of oral samuraciclib (360mg or 240mg) in combination with fulvestrant, an intramuscularly injected selective estrogen receptor degrader (SERD), versus fulvestrant alone in 60 patients with HR+, HER2- locally advanced or metastatic breast cancer who were previously treated with a CDK4/6 inhibitor and aromatase therapy. The primary endpoint is clinical benefit rate, defined as the overall compete response (CR), partial response (PR) or stable disease (SD) ≥ 24-weeks according to RECIST version 1.1 from randomization until disease progression or death due to any cause. Secondary endpoints included objective response rate, duration of response, progression-free survival and safety.

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. CDK7 activity mechanistically suppresses the TP53 gene so when CDK7 is inhibited, the activity of p53 is restored thereby further adding to the suppression of tumors by CDK7 inhibition (Reference below). TP53 status is available using commercially available ctDNA tests. 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 was discovered by scientists at Imperial College London, in work funded by Cancer Research UK and 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. Additionally, Carrick is developing CT7439, a novel CDK12/13 inhibitor / Cyclin-K glue-degrader, which is currently in a Phase 1 clinical trial.

Reference: Wang, Y., Zhang, Z., Mi, X. *et al.* Elevation of effective p53 expression sensitizes wild-type p53 breast cancer cells to CDK7 inhibitor THZ1. *Cell Commun Signal* **20**, 96 (2022). https://doi.org/10.1186/s12964-022-00837-z

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

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