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Carrick Therapeutics Receives FDA Fast Track Designations for Two Samuraciclib Combinations for the Treatment of HR+, HER2 Advanced Breast Cancer and Locally Advanced or Metastatic Triple Negative Breast Cancer

DUBLIN, Ireland and BOSTON, Aug. 16, 2021 (GLOBE NEWSWIRE) -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designations to samuraciclib in combination with fulvestrant for CDK4/6i resistant HR+, HER2- advanced breast cancer and samuraciclib in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC).

“The FDA’s decision to grant Fast Track designations for both samuraciclib combinations underscores the urgent need for innovative therapies that can significantly improve HR+, HER2- advanced breast cancer and locally advanced or metastatic TNBC patient outcomes,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “This is a meaningful milestone for our development in samuraciclib as we work to advance innovative combination treatment approaches for patients who have few treatment options available today.”

The FDA’s Fast Track program is designed to facilitate and expedite the development of investigational treatments that demonstrate a potential to address unmet medical needs in serious or life-threatening conditions. Programs with Fast Track designation can benefit from early and frequent communication with the FDA in addition to a rolling submission of the marketing application.

Samuraciclib in combination with fulvestrant is currently being evaluated in a Phase 2a study for CDK4/6i resistant HR+, HER2- metastatic breast cancer and the Company expects to present the new data from the ongoing study at the European Society for Medical Oncology (ESMO) Congress 2021 in September. Meanwhile, samuraciclib in combination with chemotherapy for the treatment of treatment of TNBC is currently undergoing IND-enabling studies.

About Fast Track Designation
Fast Track is a process designed to facilitate the development, and expedite the review of, drugs to treat serious conditions that address an unmet medical need, by providing a therapy where none exists or providing a therapy which may be potentially better and shows some

advantage over available therapy. Fast Track designation includes opportunities for more frequent meetings with the FDA to discuss trial design, development plans, data needed to support drug approval, submission of a New Drug Application (NDA) on a rolling basis, and eligibility for accelerated approval and priority review, if relevant criteria are met.

Visit the FDA's website for more information on Fast Track Designation.

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. 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 samuraciclib in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC).

About Carrick Therapeutics
Carrick Therapeutics is an oncology-focused biopharmaceutical company leveraging its deep expertise to discover highly differentiated novel therapies that address significant unmet needs. Samuraciclib, the most advanced oral CDK7 inhibitor in clinical development, is currently being evaluated in Phase 2a studies targeting CDK4/6 inhibitor resistant second-line HR+, HER2- metastatic breast cancer. Samuraciclib is also being evaluated in triple negative breast cancer (TNBC) and prostate cancer with further potential in pancreatic, ovarian and colorectal cancers. 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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