December 19, 2022

Carrick Therapeutics and The Menarini Group Announce Clinical Trial Collaboration to Evaluate Samuraciclib and Elacestrant Combination

Carrick to execute Phase 2 clinical trial in patients with CDK4/6i resistant HR+, HER2- metastatic breast cancer

DUBLIN and FLORENCE, Italy, Dec. 19, 2022 /PRNewswire/ -- Carrick Therapeutics, an oncology-focused biopharmaceutical company discovering and developing highly differentiated therapies, and the Menarini Group ("Menarini"), a privately-held, leading international pharmaceutical company, today announced a clinical trial collaboration and supply agreement.

This agreement covers the execution of a Phase 2 clinical trial to evaluate the novel combination of Carrick's samuraciclib (CT7001), an oral and first-in-class inhibitor of CDK7, and Menarini's oral selective estrogen receptor degrader (SERD), elacestrant, in patients with CDK4/6i resistant HR+, HER2- metastatic breast cancer. Menarini and Carrick will jointly sponsor the clinical trial.

"We are excited to initiate this collaboration with Menarini to explore the potential of samuraciclib in combination with elacestrant for the treatment of advanced breast cancer," said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. "Our pre-clinical work and prior clinical studies have validated the biology for SERD combinations with CDK7, pointing to potential synergies when combining samuraciclib with Menarini's oral SERD, elacestrant. This collaboration represents a shared commitment to maximizing the potential of novel combination therapies to improve outcomes for people living with breast cancer."

"This new clinical collaboration with Carrick Therapeutics is yet another step we are making to develop elacestrant in an extensive way to address unmet needs of patients resistant to CDK4/6 therapies in HR+, HER2- metastatic breast cancer," said Elcin Barker Ergun, Chief

Executive Officer of Menarini. "Menarini will continue to pursue research collaborations that have the potential to improve patients' lives in breast cancer."

Carrick anticipates initiating the Phase 2 clinical trial in 2023. This new study will expand Carrick's portfolio of ongoing clinical trials with samuraciclib. The company presented encouraging results from a clinical study combining samuraciclib with fulvestrant at the 2021 San Antonio Breast Cancer Symposium.

About The Menarini Group

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

About Elacestrant (RAD1901) and the EMERALD Phase 3 Study

Elacestrant is an investigational selective estrogen receptor degrader (SERD). In 2018, elacestrant received Fast Track designation from the FDA. Preclinical studies completed prior to EMERALD indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+, HER2- advanced/metastatic breast cancer patients. The study enrolled 478 patients who had received prior treatment with one or two lines of endocrine therapy, including a CDK 4/6 inhibitor. Patients in the study were randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoints of the study were progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints included evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR) and safety.

About Samuraciclib (CT7001)

Samuraciclib is the most advanced 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. Carrick is also collaborating with Roche to evaluate a novel combination of samuraciclib and Roche's oral SERD giredestrant in CDK4/6i resistant HR+, HER2- metastatic breast cancer. Carrick also intends to evaluate samuraciclib for the treatment of prostate cancer, where CDK7 has been shown to act as a regulator of transcription, the cell cycle and androgen receptor signalling.

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

Logo - https://mma.prnewswire.com/media/1958938/MENARINI_GROUP_Logo.jpg

View original content:https://www.prnewswire.com/news-releases/carrick-therapeutics-and-the-menarini-group-announce-clinical-trial-collaboration-to-evaluate-samuraciclib-and-elacestrant-combination-301706188.html

SOURCE Menarini Industrie Farmaceutiche Riunite