Aprea Therapeutics Announces First Patient Enrolled in Phase Ib/II Clinical Study of APR-246 for the Treatment of Platinum-Resistant High-Grade Serous Ovarian Cancer

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August 2, 2017 —BOSTON, MA. and STOCKHOLM, SWEDEN, August 2, 2017 – Aprea Therapeutics, a privately held, clinical stage biopharmaceutical company developing novel anticancer therapies targeting the tumor suppressor protein p53, announced today that the first patient was enrolled in a Phase Ib/II clinical study of APR-246 in platinum-resistant high-grade serous ovarian cancer (HGSOC).

"We are excited to begin this important clinical study in a subset of high-grade serous ovarian cancer patients with few treatments options," said Christian S. Schade, President and Chief Executive Officer of Aprea Therapeutics. "This study complements our ongoing randomized Phase II study in platinum sensitive HGSOC patients and further enhances our growing clinical strategy of testing APR-246 with various combinations and in multiple tumor types, all with a high prevalence of mutated p53 protein. We look forward to seeing the results of this study in first half of 2018."

Professor Charlie Gourley, Chair of Medical Oncology at the Edinburgh Cancer Research Center of the University of Edinburgh, commented, "High-grade serous ovarian cancer is the most deadly form of ovarian cancer and nearly always carries one or more mutations in the p53 gene. The majority of patients with this cancer develop tumors that are resistant to platinum-based chemotherapy and there are very limited treatment options for platinum-resistant disease. By targeting mutated p53 and restoring its normal function, APR-246 may provide a much-needed therapeutic benefit for this difficult-to-treat, platinum-resistant patient population."

About p53 and APR-246

The p53 tumor suppressor gene is the most frequently mutated gene in human cancer, occurring in approximately 50% of all human tumors. These mutations are often associated with resistance to anticancer drugs and poor overall survival, representing a major unmet medical need in the treatment of cancer.
APR-246 has been shown to reactivate mutant p53 protein – by reconverting mutant p53 into wild-type p53 conformation and function – and thereby induce programmed cell death in human cancer cells. APR-246 has demonstrated compelling pre-clinical antitumor activity in a wide variety of solid and hematological (blood) tumors, including ovarian cancer, small cell lung cancer, oesophageal cancer and acute myeloid leukemia (AML), among others. Additionally, strong synergy has been seen with both traditional anticancer agents, such as chemotherapy, as well as newer mechanism-based anticancer drugs and immuno-oncology checkpoint inhibitors. In addition to pre-clinical testing, a Phase I/Ib clinical program with APR-246 has been completed, demonstrating a favorable safety profile and both biological and confirmed clinical responses in hematological malignancies and solid tumors with mutations in the p53 gene. The Company is enrolling a randomized Phase II study in platinum-sensitive ovarian cancer, a Phase Ib/II study in myelodysplastic syndrome and is expecting to initiate additional clinical studies of APR-246 in 2017.

About Aprea Therapeutics

Aprea Therapeutics is a Boston, Massachusetts- and Stockholm, Sweden-based biopharmaceutical company focused on the discovery and development of novel anticancer compounds reactivating the tumor suppressor protein, p53. The Company's lead program, APR-246, a first-in-class small molecule drug candidate, is in Phase II clinical development in ovarian cancer patients, and additional clinical studies with APR-246 in other cancer indications are planned. In March 2016, Aprea completed a EUR 46 million Series B financing with an international syndicate co-led by Versant Ventures and 5AM Ventures, with additional participation by Sectoral Asset Management, HealthCap, acting as local lead investor, and existing investor, Karolinska Development. For more information, please visit www.apreatherapeutics.com.

About High-Grade Serous Ovarian Cancer

High-grade serous ovarian cancer (HGSOC) is an aggressive and high-mortality form of ovarian cancer that accounts for as much as 70% of all ovarian cancer diagnoses, with nearly 90% of cases presenting at an advanced stage of disease. Treatment of HGSOC typically involves surgical debulking followed by chemotherapy, most commonly with platinum-containing agents. Platinum-sensitive HGSOC responds to treatment with platinum-containing chemotherapy regimens but relapse is common and the majority of patients develop platinum-resistant disease within 3-5 years. Platinum-resistant HGSOC is associated with diminished response to chemotherapeutic intervention and lower overall survival. Mutations in the p53 tumor suppressor protein occur in more than 96% of HGSOC patients and these mutations may contribute to the development of platinum-resistance and increased disease severity.

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