Aprea Therapeutics Announces First Patients Enrolled in Phase II Clinical Study of APR-246 for the Treatment of High-Grade Serous Ovarian Cancer

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October 10, 2016 –BOSTON, MA. and STOCKHOLM, SWEDEN, October 10, 2016 – Aprea Therapeutics AB, a privately held, clinical stage biopharmaceutical company developing novel anticancer therapies targeting the tumor suppressor protein p53, announced today that it enrolled the first patients in the Phase II part of the ongoing clinical study of APR-246 for the treatment of high-grade serous ovarian cancer.

"The initiation of the Phase II clinical study marks an important milestone for Aprea," said Christian S. Schade, President and Chief Executive Officer of Aprea Therapeutics AB. "We are committed to developing and advancing therapies targeting p53 and, together with upcoming clinical studies of APR-246 in other tumor types, this Phase II study in ovarian cancer affirms the progress Aprea is making toward the development of next-generation anticancer treatments."

In the Phase II clinical study, Aprea will enroll up to 400 relapsed high-grade serous ovarian cancer patients in Europe and the United States. Patients will be randomized between carboplatin and pegylated liposomal doxorubicin with or without APR-246; the primary endpoint for the study is progression-free survival. This study follows successful completion of Phase Ib clinical studies showing that APR-246 is generally well-tolerated while showing robust signals of efficacy in patients with serious disease.

Dr. Mikael von Euler, Aprea's Senior Vice President and Chief Medical Officer added, "APR-246 is an exciting new agent because it targets tumors with mutant forms of p53, the gene most frequently altered in human cancers. The Phase Ib portion of this study demonstrated not only that APR-246 can be safely combined with standard chemotherapy for relapsed ovarian cancer but also that a favorable impact on progression-free survival could be achieved with the combination regimen in this difficult-to-treat population. We are pleased to continue development of this drug candidate and look forward to validating these Phase Ib findings in the randomized Phase II part of the study."

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, esophageal cancer and AML (acute myeloid leukemia), among others. Additionally, strong synergy has been seen with both traditional anticancer agents, such as chemotherapy, as well as newer mechanism-based anticancer drugs. In addition to pre-clinical testing, a Phase I clinical study has been completed, demonstrating a favorable safety profile and both biological and clinical responses in hematological tumors with mutations in the p53 gene. The Company is also expecting to begin additional clinical studies of APR-246 in other cancer indications.

Safety and efficacy data from the Phase Ib part of the ongoing PiSARRO Phase Ib/II clinical study of APR-246 in relapsed high-grade serous ovarian cancer was presented at the 2016 annual meeting of the European Society for Medical Oncology. The Phase Ib part of the clinical study included 28 patients, in a 3+3 dose escalation design of APR-246 (35, 50 and 67.5 mg/kg intravenously over 6 hours on days 1-4) in combination with carboplatin AUC 5 and PLD 30 mg/m^2 given on day 4 of a 28-day schedule. Treatment was continued to a maximum of 6 cycles, demonstrating a favorable safety profile and encouraging clinical responses. Of 22 patients with radiologically measurable lesions, 3 had confirmed complete response, 10 had confirmed partial response, 8 had stable disease and 1 was not evaluable. Additionally, of 2 patients with non-measurable disease, 1 had complete response and 1 had progressive disease. Median progression free survival for 22 evaluable patients was 316 days (95% CI 280-414 days), similar for partially platinum-sensitive and platinum-sensitive patients, and was independent of the dose-cohort.

About Aprea Therapeutics AB

Aprea Therapeutics AB 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 Ib/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.

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