For Immediate Release

Aprea Therapeutics Announces Efficacy and Safety Data in High-Grade Serous Ovarian Cancer Patients Treated with APR-246 in Presentation at 2016 European Society for Medical Oncology (ESMO) Annual Meeting

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, today presented clinical data from the Phase Ib part of the ongoing PiSARRO Phase Ib/II clinical study in collaboration with the European Network for Translational Research in Ovarian Cancer (EUTROC). The Phase Ib portion of the PiSARRO clinical study investigated the safety and efficacy of APR-246 in combination with carboplatin and pegylated liposomal doxorubicin (PLD) in patients with relapsed, p53-mutated high-grade serous ovarian cancer.

The Phase Ib 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 for a maximum of 6 cycles.

Results presented at ESMO showed:

- APR-246 can be combined with the standard chemotherapy at relevant doses, allowing the highest of the tested doses to be selected as the dose for continuing the trial in a randomized Phase II clinical study.
- 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.
- Of 2 patients with non-measurable disease, 1 had complete response and 1 had progressive disease.
- Median progression-free survival for 22 evaluable patients, as measured by RECIST or GCIG, was 316 days (95% CI, 280-414 days) and was not influenced by the length of previous platinum treatment-free interval or dose cohort.
- APR-246 showed linear pharmacokinetics with no accumulation and low intra-patient variability. There was no indication of interaction between APR-246 and chemotherapy, supporting the combination of APR-246 with carboplatin and PLD at relevant doses.

- The most frequent treatment-emergent adverse events have been low grade GI (nausea/vomiting), CNS (dizziness and fatigue) and hematological (neutropenia and thrombocytopenia) events. The hematological side effects can be attributed to the chemotherapy even if a contribution from the addition of APR-246 cannot be ruled out at this time.

Professor Charlie Gourley, Chair of Medical Oncology at the Edinburgh Cancer Research Center of the University of Edinburgh and clinical investigator for the study, commented, “TP53 is the gene which is most frequently altered in human cancer and is almost ubiquitously mutated in the most deadly form of ovarian cancer known as high-grade serous ovarian cancer. APR-246 targets mutated p53 protein, restoring its normal function. This study shows that APR-246 can be successfully combined with standard chemotherapy to treat high-grade serous ovarian cancer with minimal additional toxicity. The percentage of patients whose cancer responded to this treatment regime was highly encouraging and we look forward to validating these findings in a larger clinical trial.”

Dr. Mikael von Euler, Aprea Therapeutics’ Senior Vice President and Chief Medical Officer said, “We are pleased both with the results and to be able to move this drug candidate forward into a randomized Phase II clinical study. It is especially important that the patients who have more difficult-to-treat disease appear to get as much therapeutic benefit as those with less aggressive disease. The current safety profile combined with the evidence of clinical activity suggests that APR-246 might become a very important drug for patients with ovarian cancer. Furthermore, the mechanism of action suggests that APR-246 might have relevance in other tumor types and we look forward to pursing those indications.”

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 has commenced a Phase II study on ovarian cancer and is also expecting to begin additional clinical studies of APR-246 in other cancer indications.

About Aprea Therapeutics AB

Aprea Therapeutics AB is a Stockholm, Sweden and Boston, Massachusetts-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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