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Aprea announces positive data from a clinical Phase I/II study with APR-246 in patients with advanced cancers

STOCKHOLM – September 18, 2012. Aprea today announced positive data from a completed Phase I/II clinical study with its investigational drug APR-246. The results from the study have been published in the Journal of Clinical Oncology. Based on the positive data, Aprea is planning to advance APR-246 into a Phase II proof-of-concept study in ovarian cancer. Aprea is a Karolinska Development portfolio company.

In the Phase I/II-trial, escalating doses of APR-246 were administered as monotherapy to 22 patients with advanced blood- or prostate cancer during up to four consecutive days. Dose limiting toxicity was shown at plasma levels well above predicted therapeutic plasma levels. The study also demonstrated dose-proportional and time-independent pharmacokinetics for APR-246 over the dose range studied.

The results from the study have been published in the Journal of Clinical Oncology. In addition to reporting that the drug was well tolerated, the authors conclude from the study that APR-246 induces biological effects and that there are cases of clinical effects on tumor burden. One patient with advanced blood cancer demonstrated a 50 percent reduction in the number of blast cells in the bone marrow.

Ulf Björklund, CEO, Aprea:

“These are very encouraging study results. We are now planning to take the p53-activating compound APR-246 forward into a Phase II-trial in epithelial ovarian cancer with mutated p53 in combination with conventional chemotherapy.”

In the new proof-of-concept study, APR-246 will be administered in combination with the reintroduction of a carboplatin-based regimen. A striking synergistic effect between APR-246 and the very active and frequently used cancer product carboplatin has been observed in pre-clinical experiments.

Torbjörn Bjerke, CEO, Karolinska Development:

“This is indeed promising data. Although it was primarily a safety trial, the data indicates that APR-246 has an anti-tumor effect. APR-246 was well tolerated and, importantly, the safety profile is different from traditional cytostatic drugs. With these new results we can see a clear path forward for APR-246, especially in carboplatin-resistant patients.”

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TO THE EDITORS

About Aprea

Aprea AB is a Swedish biotech company focusing on discovery and development of novel anticancer compounds targeting the tumor suppressor protein p53. Aberrations in p53 are common in many various cancer forms and are associated with increased resistance to standard chemotherapy and thus poor prognosis. Aprea is a Karolinska Development AB (publ) portfolio company. The other main owners are Östersjöstiftelsen, Praktikerinvest and KCIF Co-Investment Fund KB. For more information, please visit www.aprea.com .

About Karolinska Development AB

Karolinska Development aims to create value for investors, patients, and researchers by developing innovations from world class science into products that can be sold or out-licensed with high returns. The business model is to: SELECT the most commercially attractive medical innovations; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading Nordic universities, delivers a continuous flow of innovations. Today, the portfolio consists of 35 projects, of which 15 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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