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aprea

Aprea reports completion of the Phase I/II safety study with APR-246 in cancer patients

Stockholm, Sweden – February 23, 2011. Aprea has conducted a Phase I/II dose-escalating safety study with APR-246 in patients with refractory hematological malignancies or prostate cancer. The results show that the compound is safe at predicted therapeutic plasma levels.

“The results from this first-in-man study provides the base for further development of APR-246 in cancer patients”, says Ulf Björklund, CEO at Aprea AB.

Aprea´s drug candidate APR-246 belongs to a novel class of anticancer compounds shown to induce programmed cell death (apoptosis) through p53, a protein frequently changed in a wide range of tumors. The compound has been tested in a phase I/II clinical trial at seven clinics in Sweden. The open labeled, dose-escalating study included 22 patients with advanced blood or prostate cancer. The study was designed to reveal the highest feasible dose of APR-246 (primary endpoint) after 2 hours iv-infusions for up to four consecutive days in escalating doses. Dose limiting toxicity was shown at plasma levels well above predicted therapeutic plasma levels. The study also demonstrated dose and time independent pharmacokinetics of APR-246 over the dose range studied.

“Karolinska Development has five oncology drug development companies in its portfolio, making it an important area for the company. Aprea, of which Karolinska Development owns 43%, has now completed its Phase I/II trial, which is an important step for Aprea and hence for Karolinska Development "says Torbjørn Bjerke, CEO of Karolinska Development.

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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 Industrifonden, Östersjöstiftelsen and Praktikerinvest.

About APR-246

APR-246 has been developed based upon results from researcher at the Karolinska Institute. The researchers have discovered that the substance is more efficacious in cancer cells than normal cells, which indicates it could produce significantly fewer side effects than conventional cancer treatments. By inducing the protein p53 the compound makes sure that the cellular suicide program is activated to eliminate the cancer cells. This has been shown in laboratories and animal studies with good results. A unique characteristic of the substance is that it can activate p53 even when the gene is inactivated due to a mutation. Cancers with mutated p53 are often resistant to conventional treatment.

About Karolinska Development

Karolinska Development aims to create value for investors, patients, and researchers by developing innovations from world class research 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 these 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. This will result in upfront payments, milestone payments and royalties.

An exclusive deal flow agreement with Karolinska Innovations, along with cooperation agreements with other leading Nordic universities, ensures the first right of refusal to a continuous flow of innovations.

Karolinska Developments flexible exit strategy enables projects to be exited at whichever stage of development offers the greatest return on investment, usually after Phase II clinical trials have indicated the desired pharmaceutical effect on patients – this being an important value enhancing step.

Today, the portfolio consists of over 40 projects at various stages, from concept development to Phase II clinical trials, twelve projects are in clinical trials with six in Phase II. The portfolio is particularly strong in the areas of cancer, dermatology, inflammation, cardiovascular disease, women's health and diseases that affect the central nervous system. www.karolinskadevelopment.com