

**Profit from Innovation** 



# Aprea announces continuation of clinical Phase I/II-study of APR-246 in patients with leukemia

STOCKHOLM – December 12, 2011. Aprea AB today announces that the first patient has been dosed in a clinical Phase I/II-study of APR-246. The primary aim of the study is to evaluate safety and pharmacokinetics, but also to make an early assessment of effectiveness. Aprea is a Karolinska Development AB (publ) portfolio company. Other main owners are Industrifonden, Östersjöstiftelsen and Praktikerinvest.

"This Phase I/II-study is a continuation of an earlier completed dose finding study, which showed that APR-246 was safe at predicted therapeutic plasma levels. The previous study also demonstrated dose and time independent pharmacokinetics of the compound over the dose range studied. The primary aim of the current clinical trial is to further evaluate safety, pharmacokinetics and to establish the optimum dose and duration of exposure", says Ulf Björklund, CEO at Aprea AB.

The study is being carried out at five sites in Sweden under the supervision of Dr. Sören Lehmann at the Department of Hematology of the Karolinska University Hospital, Stockholm. It will include 10 patients with Acute Myeloid Leukemia (AML) and Chronic Lymphocytic Leukemia (CLL), refractory to standard treatment. The study is expected to be completed during the first half of 2012.

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.

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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. Other main owners are Industrifonden, Östersjöstiftelsen, and Praktikerinvest. www.aprea.com

#### **About APR-246**

APR-246 has been developed based on results from researcher at the Karolinska Institutet. The researchers have discovered that the substance is more efficacious in cancer cells than normal cells, which indicates that it could produce significantly fewer side effects than conventional cancer treatments. By reactivating the tumor suppressor protein p53 the compound induces the cellular suicide program that eliminates the cancer cells. This has been shown in both in vitro laboratory studies and animal in vivo studies with good results. A unique characteristic of the substance is that it can activate p53 even when the gene is mutated. Cancers with mutated p53 are often more resistant to conventional treatment.

#### **About Karolinska Development**

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 34 projects, of which 12 are in clinical development. For more information, please visit www.karolinskadevelopment.com.