

**Profit from Innovation** 



# Axelar announces positive interim results in Phase I/II study

STOCKHOLM, SWEDEN, APRIL 6, 2011. Axelar AB, a Karolinska Development portfolio company, today announces positive results from the completed first part of the combined Phase I/II clinical trial, evaluating AXL1717 as a new treatment for solid tumors. The study has successfully reached its primary endpoint, identifying the recommended Phase II dose as well as provided evidence that AXL1717 is safe and tolerable. Furthermore, data also supports Axelar's strategy to target AXL1717 in patients with squamous non-small cell lung cancer. Results will be presented later this year.

In the ongoing study, AXL1717 has been tested in total of more than 45 patients. The now completed first part of the study with a total of 35 patients, consisted of a single-day dosing as well as a multi dosing part. The study has been amended to a Phase II design. AXL1717 is now tested for 28 days BID (twice daily dosing) in two cycles with 14 days interval in order to confirm the Phase II regimens and explore the possible anti-tumor effects. A Phase II program is expected to start late 2011.

# Dr. Johan Harmenberg, CEO of Axelar:

"The successful completion of the first part of the Phase I/II study is an important milestone for Axelar. It also supports our beliefs that AXL1717 has the potential to become a new and effective treatment in cancer therapy. We are optimistic that the coming Phase II program will show clinical benefit to cancer patients."

## Dr. Torbjørn Bjerke, CEO at Karolinska Development:

"Karolinska Development is excited about the progress that Axelar has made with AXL1717. Data from this study looks promising for AXL1717 as a new treatment for cancer. Karolinska Development is the largest owner with 45 percent of the company and Axelar is therefore an important company within Karolinska Development's broad oncology portfolio, and we look forward to the coming Phase II program."

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#### TO THE EDITORS

#### **About Axelar**

Axelar AB is a Swedish biotech company founded in 2003. The company is developing insulin-like growth factor 1 (IGF-1) receptor inhibitors for treatment of cancer and other diseases. Axelar is part of the Karolinska Development portfolio of companies. www.axelar.se

## **About AXL1717**

Axelar's lead compound, AXL1717 provides a novel treatment regimen for a wide range of cancers. AXL1717 is the first targeted oral small-molecule IGF-1 receptor inhibitor with no effect on the closely related insulin receptor. AXL1717 is presently undergoing phase I/II clinical trials and the compound combines a superior preclinical efficacy against numerous tumors with an excellent tolerability profile. Most tumor cells are dependent on the IGF-1 receptor signal pathway and the IGF-1 receptor is therefore regarded as a promising target for cancer therapy. To date, there are no IGF-1 receptor inhibitor drugs on the market.

## **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 Institutet Innovations AB, along with other cooperation agreements with leading Nordic universities, delivers a continuous flow of innovations.

Karolinska Development's 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