

Axelar initiates a Phase II clinical study with AXL1717 for the treatment of non-small cell lung cancer

STOCKHOLM, SWEDEN - December 28, 2011. Axelar AB, a Karolinska Development AB portfolio company, today announces that the first patient has been dosed in a randomized Phase II study on non-small cell lung cancer (NSCLC) patients of its drug candidate AXL1717.

AXL1717 is the first targeted oral small-molecule Insulin-like Growth Factor 1 (IGF-1) receptor inhibitor clinically tested which does not affect the closely-related insulin receptor. In the recently completed Phase I/II study, AXL1717 demonstrated a good safety profile and signs that suggest clinical benefit were observed in some patients with NSCLC. (See Axelar press release issued September 26, 2011*)

The initiated study is a randomized open-label Phase II study that will compare AXL1717 with conventional cytotoxic chemotherapy (docetaxel) in patients with previously treated, locally advanced or metastatic NSCLC. A total of 140 patients with squamous cell carcinoma or adenocarcinoma of the lung will be included in the study. The aim of the study is to investigate the clinical efficacy of continuous dosing of AXL1717. The primary end-point is the number of patients with progression-free survival after 12 weeks.

NSCLC is the most common form of lung cancer with 420,000 new patients diagnosed in the industrial countries every year. The 5-year survival rate for these patients is only 10–15%, resulting in an annual mortality of approximately 330,000 patients. Treatment with standard cytotoxic chemotherapy is unsatisfactory provides only short term control of the disease.

Dr. Johan Harmenberg, CEO, Axelar:

“The recruitment of the first patients to the Phase II study is an important milestone for Axelar AB. The start of this study expresses our commitment to develop new and innovative treatments for lung cancer and the study is fully financed”.

Dr. Torbjörn Bjerke, CEO, Karolinska Development:

“We are very pleased that Axelar has initiated this important study. Based on data from the previous studies, we believe that AXL1717 has the potential to become an important novel treatment for patients with NSCLC. This is a patient group with a high medical need and a positive outcome from the Phase II-trial would be of importance for both patients and society.”

* <http://www.karolinskadevelopment.com/?cID=287&pid=1549849&y=2011&m=09>

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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 potential treatment regimen for a wide range of cancers. AXL1717 is the first targeted oral small-molecule Insulin-like Growth Factor 1 (IGF-1) receptor inhibitor with no observable effect on the closely-related insulin receptor. 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. AXL1717 has just completed its first-in-man phase I/II clinical trial in 49 patients and the compound has already demonstrated a superior preclinical efficacy against numerous tumors and an excellent tolerability profile.

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.