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Axelar

Preliminary results of a Phase II study indicates that Axelar's AXL1717 is efficacious in 2nd line treatment of patients with lung cancer

STOCKHOLM, April 2, 2013. Axelar AB, part of the Karolinska Development AB portfolio, announced today that preliminary interim results of its Phase II study AXL-003, indicates that AXL1717 is effective in treating patients with non-small cell lung cancer (NSCLC). Thus, the company assesses that it has sufficient data to guide further development of the drug, and will finalize the study with fewer patients than initially planned.

Dr. Carl Harald Janson, CEO, Axelar AB
"We are delighted to see the impact of AXL1717 in this difficult to treat patient population. The encouraging trial data provides a platform for the further development of AXL1717. I look forward to finalizing this trial and preparing for the next step in development."

The study is a randomized open-label Phase II clinical study that compares AXL1717 with docetaxel, a well-established anti-cancer treatment, in patients with previously treated, locally advanced or metastatic NSCLC. The clinical study is conducted at 25 centers in five countries and has rate of progression free survival (PFS) after 12 weeks as the primary endpoint. Preliminary analysis suggests that AXL1717 has similar rate of PFS after 12 weeks as docetaxel. The most frequent serious adverse events in the study were cases with neutropenia, which occurred in both treatment regimes.

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. Approximately 90-95% of NSCLC patients do not respond to the most common second line treatments*. AXL1717 has the potential to become a new treatment that could extend the lifespan and decrease the suffering for these non-responders. The data add to the positive results obtained with AXL1717 in its Phase I/II study, which was reported in October 2011.

Based on the interim data from AXL-003, Axelar has decided to finalize the trial with approximately 100 patients instead of the planned 140. As of today, 97 patients have been enrolled in the trial and these patients will continue to be treated and monitored according to the study protocol. More detailed data from the study, including secondary read-outs and safety, will be presented at a coming scientific meeting.

Dr. Torbjörn Bjerke, CEO, Karolinska Development AB
"This is an important milestone for Axelar and encouraging for lung cancer patients as there is a lack of effective and tolerable treatments for patients who relapse after second line therapy. Based on these interim results, we believe that AXL1717 has the potential to become an important part of future treatment options available to clinicians as well as a valuable asset for Karolinska Development."

*Pivotal trials as presented on FDA approved drug labels for docetaxel, pemetrexed and erlotinib

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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 the 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 pathway 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. Axelar is currently conducting a randomized phase II clinical trial with AXL1717 in non-small cell lung cancer patients. A first-in-man phase I/II clinical trial with AXL1717 including 49 patients has been completed demonstrating a good tolerability profile of the compound, in addition to its superior preclinical efficacy against numerous tumors.

About Karolinska Development AB
Karolinska Development aims to create value for patients, researchers, and investors 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 universities, delivers a continuous flow of innovations. Today, the portfolio consists of 34 projects, of which 15 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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