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Axelar announces final data from Phase II study with AXL1717 in lung cancer

STOCKHOLM, SWEDEN – December 27, 2013. Axelar AB announced today the final results from its Phase II study AXL-003 in patients with non-small cell lung cancer (NSCLC). The final data showed no statistically significant difference in rate of progression-free survival (PFS) between the patients treated with AXL1717 compared with the group treated with docetaxel, which confirms the previously communicated preliminary data. A conference call will be held today at 1.00pm CET.

"Although we did not see an improved outcome for the patients with NSCLC that received AXL1717 compared to patients receiving docetaxel, we are still encouraged by the results from AXL-003. The clinical data taken together with new data on a second mechanism of action suggest that AXL1717 has the potential to be developed for patients that have relapsed after treatment with docetaxel in this difficult to treat indication", says Mikael von Euler, CEO of Axelar.

A total of 101 patients with locally advanced or metastatic non-small cell lung cancer (NSCLC, stage IIIB or IV) were randomized in the AXL-003 study (see 'About AXL-003'). The primary objective was to compare the rate of progression-free survival (PFS) at 12 weeks between the group of patients treated with AXL1717 and the docetaxel group. The 12-week PFS rate for the 99 patients who received study medication was 25.9% in the AXL1717 group and 39.0% in the docetaxel group, the difference was not statistically significant (p=0.19).

The main secondary endpoints were PFS and overall survival (OS), yielding the results shown in the table below. Neither of these endpoints showed a statistically confirmed difference between the two treatment groups for all patients or for any of the histological subgroups. The OS results for patients with adenocarcinoma suggested a more favorable outcome following treatment with AXL1717 compared with the outcome for patients with squamous cell carcinoma.

"AXL1717 has been tested in more than 140 patients to date and data suggest that it has a clinical effect in one of the most deadly cancers. Based on the clinical data package, Axelar is now planning future studies in parallel with ongoing partner discussions", says Torbjörn Bjerke, CEO of Karolinska Development.

The main side effects in both groups were hematological; mainly reduced neutrophil granulocyte counts in blood (neutropenia): 22.4% of the AXL1717 treated patients reported at least one event of CTCAE (Common Terminology Criteria for Adverse Events) grade 3/4 neutropenia compared with 53.7% of the docetaxel treated patients. Some of the early neutropenic episodes in the AXL1717 group developed into serious events and some of these were fatal. The neutropenia side effects were managed with a dose reduction of AXL1717 coupled with increased supervision of the patients.

"There is increasing evidence that AXL1717, in addition to the IGF-1R pathway inhibition, also suppress tumor cell division by arresting cells in mitosis through a non-IGF-1R dependent mechanism. This proposed additional mechanism of action would explain the differences in efficacy and side effect profile compared with other substances inhibiting the IGF-1R pathway", says Mikael von Euler.

Axelar is planning to present more data from AXL-003 at scientific meetings during 2014.

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Main secondary end-points

Endpoint	Months (median) AXL1717	Months (median) Docetaxel	Hazard Ratio	p-value (log rank test)
OS – all patients	7.52	9.41	1.03	0.91
OS - AC	13.18	5.70	0.88	0.75
OS - SCC	6.53	9.41	1.21	0.63
PFS – all patients	2.83	2.85	1.26	0.32
PFS - AC	2.99	2.85	0.85	0.62
PFS - SCC	2.83	2.85	1.82	0.08

OS-Overall Survival, PFS-Progression Free Survival, AC-Adenocarcinoma, SCC-Squamous Cell Carcinoma

Telephone conference and webcast today at 1.00pm CET:
Participant access numbers: SE: +46 (0)8 5065 3938, UK: +44(0)20 3427 1914, or US: +1 646 254 3364. Access code: 5075052. A link to the webcast is available on the Karolinska Development website.

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TO THE EDITORS

About Axelar AB
Axelar AB is a Swedish biotech company founded in 2003. The company is developing AXL1717, a novel anti-cancer compound, currently in clinical Phase II development for non-small cell lung cancer. Axelar is part of the Karolinska Development portfolio of companies. For more information, please visit www.axelar.se.

About AXL-003
A total of 101 patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC, stage IIIB or IV) were randomized into the study AXL-003. Patients with squamous cell carcinoma had one prior line of therapy while patients with adenocarcinoma had one or two prior lines of therapy. Patients had Eastern Cooperative Oncology Group (ECOG) performance status 0–2 after optimization of analgesics and a life expectancy ≥ 3 months at the time of study enrollment. The patients were randomized to either AXL1717 or to docetaxel as monotherapy, in a 3:2 ratio for each NSCLC subtype. AXL1717 was administrated as an oral suspension given twice daily as a dose of 400 mg (later changed to 300 mg) and docetaxel was administered at 75 mg/m2 on Day 1 of every 21-day cycle. The study duration was 12 weeks.

About Karolinska Development AB
Karolinska Development aims to create value for patients, researchers, investors and society 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 35 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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