

## Press release

# Action Pharma completes dosing in phase IIb clinical trial with AP214 to prevent acute kidney injury associated with cardiac surgery

Aarhus, Denmark, May 9, 2011

Action Pharma A/S has completed dosing in a phase IIb clinical trial with its leading development candidate, AP214. Efficacy and safety data are expected during the third quarter of 2011.

AP214 is being developed for protection of kidney injury in patients undergoing cardiac surgery under cardiopulmonary bypass as the lead indication – an indication with a major unmet medical need and with no treatment available on the market.

“The completion of dosing in this phase IIb clinical study is a major milestone for Action Pharma and represents an important step forward in our partnering process related to this project”, says Ingelise Saunders, CEO of Action Pharma. She continues, “the area of acute kidney injury is very interesting and we expect the global commercial potential to exceed EUR 500 million with considerable expansion potential in additional indications. With AP214, we have the opportunity to be first to market.”

The clinical phase IIb trial is a randomized, double-blind, placebo-controlled trial with two dose levels of AP214. A total of 78 patients were recruited in the phase IIb study at sites in Denmark and in the USA. The objectives of the study include measuring the efficacy of AP214 in preventing kidney injury and systemic inflammatory response, and on safety and tolerability levels. The trial is focused on patients undergoing cardiac surgery on cardiopulmonary bypass and with increased risk of developing kidney injury. The protocol has been designed following detailed discussions with the FDA on the AP214 clinical development program.

“Many patients in the USA and the EU each year undergo major cardiac surgery, and approximately 10-20% of these patients experience various degrees of kidney injury which again is associated with increased mortality, co-morbidity and prolonged hospitalization”, says the principal investigator of the study, Professor Daniel Steinbrüchel, Department of Cardiac and Thoracic Surgery, Danish State Hospital, Copenhagen. Professor Daniel Steinbrüchel added, “with no treatment currently available, this indication addresses a major unmet medical need, which is recognized by key opinion leaders and regulatory authorities.”

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### About Action Pharma A/S

Action Pharma is a privately owned Danish biotech company. Action Pharma develops novel drug candidates targeting melanocortin receptors and bring these to the stage of clinical proof of concept for subsequent partnering. The drug candidates are the first in several new drug classes and exploit a novel mode of action profiles with an efficacy that is superior compared to compounds currently on the market. Action Pharma has a pipeline of several patent-protected, in-house developed drug candidates. Two drug candidates are currently in clinical development, AP214 is in phase IIb, and AP1030 has completed phase IB. Further, Action Pharma has two

drug candidates in late preclinical development. The Action Pharma team has significant scientific expertise and has published more than 400 scientific papers.

AP214 is being developed to prevent post-surgical kidney injury after major thoracic surgery. AP214 has completed phase IIa clinical trials investigating the effect of AP214 on organ protection in patients undergoing cardiac surgery, who are at increased risk of kidney injury. Every year, more than 150,000 patients in the USA and in the EU undergo major thoracic surgery. Approximately 10-20% of these patients experience various degrees of kidney injury, which again is associated with a marked increase in mortality, co-morbidity and prolonged hospitalization. Currently, there is no treatment to prevent or treat kidney injury associated with major thoracic surgery. Thus, there is a major unmet medical need. AP214 mediates its potent effect via the type 1 and type 3 melanocortin receptors. Results from a phase IIa US clinical trial, from a phase Ib trial in human volunteers subjected to LPS-induced inflammation, and initial results from a Danish phase IIa trial showed encouraging efficacy, safety and tolerability data for AP214.

Action Pharma's proprietary small molecule program further includes compounds for treatment of metabolic diseases and/or inflammatory diseases.

Action Pharma has a strong investor base of leading European investors, including Sunstone Capital, Global Life Science Ventures, SLS Invest, InnovationsKapital, Inventure Capital, and Oestjysk Innovation. For more information, please visit [www.actionpharma.com](http://www.actionpharma.com)