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Press release

Last patient completes last visit in Action Pharma's phase IIb clinical trial with AP214 to prevent kidney injury associated with major cardiac surgery

Aarhus, Denmark, August 8, 2011

The final patient has performed the last visit of the study period in Action Pharma's US and Denmark based phase IIb study. Treatment with AP214 is designed to investigate whether acute kidney injury can be prevented in patients undergoing major cardiac surgery – a serious unmet medical need with no treatment currently available on the market. Top line results from the study are expected to be reported as planned, in September 2011.

The last patient in the US and Denmark based AP214 phase IIb clinical study has now completed the 3-month visit leading to the closure of the study period in the trial. This important achievement in the AP214 phase IIb program will be followed by data compilation from the 8 clinical sites in the US and Denmark, and from the central laboratory. The top line results are expected to be reported as planned, in September 2011. Following good results from the study, Action Pharma A/S will enter into partner discussions.

"This is a critical period for Action Pharma, for the investigating physicians, and for all the patients, who have chosen to participate in the clinical study. The clinical study is also of major importance for the entire field of cardiovascular and organ protection", says Ingelise Saunders, CEO of Action Pharma. She continues, "we estimate that the potential market for global renal protection in cardiac surgery exceeds EUR 500 million with considerable expansion potential in follow-on indications. With AP214, we have the opportunity to be first to market".

The clinical phase IIb trial has been conducted at 3 sites in Denmark and 5 sites in the US studying a total of 77 patients. The trial is a randomized, double-blind, placebo-controlled trial with two dose levels of AP214 administered during surgery and early in the postoperative period. The trial focused on evaluating the efficacy, safety and tolerability of AP214 in preventing acute kidney injury and systemic inflammatory response commonly seen in patients undergoing cardiac surgery on cardiopulmonary bypass and with increased risk of developing kidney injury.

Professor Daniel Steinbrüchel, Department of Cardiac and Thoracic Surgery, Danish State Hospital, Copenhagen, lead investigator for the trial, adds: "There is a serious unmet medical need and a significant interest both from clinical leadership and regulatory bodies, including the FDA, for the development of new potent pharmaceuticals in this area. More than 500,000 patients in the USA and the EU each year undergo major cardiac surgery, and a clinically significant fraction develops kidney injury resulting in increased mortality, co-morbidity and prolonged hospitalization. A therapeutic that addresses these needs, and is also applicable to the extensive related circumstances in which acute kidney injury can be a major cause of morbidity and mortality, would be a highly significant improvement of current treatment options".

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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 is currently in phase IIb clinical trials evaluating the efficacy, safety and tolerability of AP214 in preventing kidney injury and systemic inflammatory response 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 phase II clinical trials in the US and EU, 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, Incuba Venture, and Oestjysk Innovation. For more information, please visit www.actionpharma.com