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Press release

Action Pharma obtains positive results in a phase II clinical trial with AP214 to prevent acute kidney injury associated with cardiac surgery

Aarhus, Denmark, September 13, 2010

Action Pharma A/S has obtained positive safety, tolerability and efficacy results in the second phase II clinical trial (CS005) with its leading development candidate, AP214.

AP214 is being developed for protection of acute kidney injury (AKI) in patients undergoing cardiac surgery under cardiopulmonary bypass as the lead indication.

The clinical phase II trial is a randomized, double-blind, placebo-controlled sequential dose-finding trial with three dose levels, and safety and tolerability as primary objectives. Secondary objectives include effects on kidney function/injury and on the systemic inflammatory response by determinations of changes in serum creatinine and plasma IL-6.

The results demonstrate that AP214 is well tolerated and safe at all three dose levels. At the highest dose level, AP214 markedly reduced the development of AKI by 70%, and reduced the IL-6 response by 40%, compared to placebo. This is consistent with a robust effect to prevent postsurgical acute kidney injury and systemic inflammatory response associated with major cardiac surgery.

“The very encouraging key results in the CS005 phase II clinical trial with AP214 is a major milestone for Action Pharma”, says Ingelise Saunders, CEO of Action Pharma. She continues, “this also represents an important step forward in our partnering process related to the project.”

“Many patients in the USA and Europe each year undergo major cardiovascular 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 Søren Nielsen, COO of Action Pharma. He added, “with no treatment currently available, this indication addresses a major unmet medical need, and we expect the global commercial potential to exceed EUR 500 million with expansion potential in additional indications.”

The clinical trial has been conducted in Denmark at the Department of Cardiac and Thoracic Surgery at Rigshospitalet (the Danish State Hospital) in Copenhagen, and at Odense University Hospital in Odense, respectively.

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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 first in new drug classes and exploit 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 II, 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 developed to prevent post-surgical kidney injury after major thoracic surgery. AP214 has completed a phase II clinical trial 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 marked increase in mortality, co-morbidity and prolonged hospitalization. Currently, there is no treatment to prevent or treat kidney injury associated with major 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 II US clinical trial, from a phase IB trial in human volunteers subjected to LPS-induced inflammation, and initial results from an ongoing phase II trial show 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.

AP1030 and second generation compounds have potent pre-clinically documented anti-diabetic and anti-obesity effects and AP1030 administered once daily orally for two weeks in obese human volunteers results in positive effects on glucose metabolism. Thus the program has the potential for development of drug candidates that are superior to other anti-diabetics, including GLP-1 analogues, DPP-4 inhibitors and glitazones.

Action Pharma develops AP1189 for oral treatment of systemic inflammatory diseases such as rheumatoid arthritis, inflammatory bowel diseases, atopic dermatitis, COPD and others. AP1189 awaits clinical development. Similarly, AP405 is developed for topical treatment of inflammatory skin diseases, such as atopic dermatitis, and is ready for clinical development.

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