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Press release

Action Pharma initiates phase IIb clinical trial in the USA and Denmark with AP214 to prevent kidney injury associated with major cardiac surgery

Aarhus, Denmark, November 8, 2010

Action Pharma A/S has administered the first dose to the first patient in a phase IIb clinical trial being undertaken in the USA and Denmark with its leading drug candidate AP214. This follows the positive results obtained on safety, tolerability and efficacy in the phase IIa clinical trial announced in September 2010.

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 dosing of the first patient 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. The objectives are efficacy of AP214 in preventing kidney injury and systemic inflammatory response, and on safety and tolerability. 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.

“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 Søren Nielsen, COO of Action Pharma. He added, “with no treatment currently available, this indication addresses a major unmet medical need which is recognized by key opinion leaders and regulatory authorities. The phase IIb clinical trial and the development program are based on positive discussions with FDA.”

For further information, please contact:

Ingelise Saunders, CEO
E-mail: ils@actionpharma.com
Phone: +45 2020 3687

Søren Nielsen, COO
E-mail: sn@actionpharma.com
Phone: +45 2324 4533

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 being 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 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.

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