

Press release

Action Pharma in new phase II clinical trial

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Action Pharma has initiated a new clinical phase II trial for its leading development candidate AP214, investigating the effect of AP214 on organ protection in patients undergoing cardiac surgery, who are at increased risk of kidney injury. The clinical trial has been launched in Denmark at "Rigshospitalet".

"The phase II clinical trial is a major milestone for Action Pharma and we are very impressed with the efficient and professional team at Rigshospitalet headed by chief consultant, professor Daniel Steinbrüchel as principal investigator", says Søren Nielsen, MD, DMSci, CEO of Action Pharma "Many patients in the USA and Europe undergo major thoracic surgery every year, 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. Thus, in this indication there is a major unmet medical need".

The clinical trial investigating AP214 in cardiac surgery is conducted at Rigshospitalet, Department of Cardiac and Thoracic Surgery is a randomized, double-blind placebo-controlled dose-finding phase II trial in patients undergoing cardiac surgery. A total of 42 patients will be enrolled in the trial. Dosing of the first patient was initiated in June 2009 and dosing of the first cohort was completed in August 2009.

"AP214 is a new first in class drug candidate with novel mode of action and mediates its action through new pharmacological targets, the melanocortin receptors. AP214 is expected to reduce the inflammatory response as well as post-surgical reperfusion injuries, factors known to cause kidney injury", says Thomas Jonassen, MD, CSO of Action Pharma. "We have completed part of a phase II study conducted in the US at Shands Hospital in Gainesville, Florida and a phase Ib clinical trial at AKH in Vienna investigating the effect of AP214 in the setting of experimentally induced inflammation in human volunteers with positive results. Based on these studies and preclinical studies we conclude that AP214 is safe and well tolerated and is a very potent drug candidate to treat or prevent organ injury", adds Thomas Jonassen.

The Action Pharma team has significant scientific expertise in the areas of cardiovascular pharmacology, kidney function and kidney diseases with more than 250 published scientific papers within these areas. Action Pharma is dedicated to the discovery, research and development of novel drugs targeting melanocortin receptors. In addition to prevention of kidney injury, stimulation of melanocortin receptors has shown promise as a treatment for type 2 diabetes, obesity and inflammatory diseases. The current pipeline of 4 compounds in development provides outstanding business development potentials.

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About Action Pharma A/S

Action Pharma is a privately owned Danish biotech company. The main strategy of Action Pharma is to develop novel drug candidates targeting melanocortin receptors and bring these to clinical proof of concept for subsequent partnering. The drug candidates are first in class and exploit novel mode of action profiles with efficacy that is superior compared to the current market. Action Pharma has a pipeline of several patent protected drug candidates of which two currently are in clinical development and two in late preclinical development.

AP1030, the lead compound within the company's small molecule program, has potent pre-clinically documented anti-diabetic and anti-obesity effects. AP1030 is currently in clinical development in obese individuals in a two week clinical trial. AP1030 has the potential to be superior to other anti-diabetics including GLP-1 analogues, DPP-4 inhibitors and glitazones. AP1030 can be administered orally in contrast to GLP-1 analogues. The marked weight reducing effects observed in non-clinical pharmacodynamic models contrast the absence of weight reduction by other orally available antidiabetics (DPP-4 inhibitors and others). Thus, this makes AP1030 highly attractive in the market for Type II diabetes associated with obesity. The mode of action of AP1030, first in class, involves a central melanocortin type 4 receptor mediated effect, thereby modulating appetite and central regulation of glucose metabolism plus a systemic anti-inflammatory melanocortin type 1 receptor mediated anti-diabetic effect aimed at reverting low grade inflammation in fatty tissue and thereby reducing peripheral insulin resistance.

Action Pharma is developing AP214 to prevent post-surgical kidney injury after major thoracic surgery. AP214 is currently being tested in a phase II clinical trial in the USA and Denmark investigating the effect of AP214 on organ protection in patients undergoing cardiac surgery, who are at increased risk of kidney injury. More than 150,000 patients in the USA and EU undergo major thoracic surgery every year. Approximately 10-20% of these patients experience various degrees of kidney injury which again is associated with increased mortality, morbidity and prolonged hospitalization. AP214 mediates its potent effect via the type 1 and type 3 melanocortin receptors. Initial results from an earlier phase II clinical trial in the US and from a phase IB trial in human volunteers subjected to LPS-induced inflammation revealed positive effects of AP214.

In addition, Action Pharma develops AP1189 which is targeted for oral administration for treatment of systemic inflammatory diseases such as rheumatoid arthritis and inflammatory bowel diseases. Similarly, AP405 is developed for topical treatment of inflammatory skin diseases, such as atopic dermatitis.

Action Pharma has a strong investor base of leading European investors including Sunstone Capital, Global Life Science Ventures, InnovationsKapital, SLS Venture, Inventure Capital, and Oestjysk Innovation. For more information, please visit www.actionpharma.com