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Press release

Action Pharma obtains encouraging preliminary results in a phase II clinical trial with AP214

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Action Pharma A/S obtained encouraging preliminary blinded results in the second phase II clinical trial (named CS005) with its lead development candidate, AP214.

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

The phase II clinical trial is a randomized, double-blinded, placebo-controlled, sequential, dose-finding trial with three dose levels in 42 patients. Primary objectives are safety and tolerability. 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 preliminary results are blinded without the results from statistical analyses.

The results demonstrate that AP214 is well tolerated and safe at all three dose levels. At the highest dose level, AP214 prevents the increase in serum creatinine by 50-60%, and in the IL-6 response by 30-40%, compared to placebo (trends based on blinded data). This is consistent with a robust effect to prevent postsurgical acute kidney injury (AKI) and systemic inflammatory response.

“The encouraging preliminary results of treatment with AP214 in the CS005 phase II clinical trial 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 and corporate development strategy prior to the forthcoming final, unblinded data expected in September.”

“Many patients in the USA and Europe each year undergo major thoracic 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. Currently, there is no treatment available”, says Søren Nielsen, COO of Action Pharma. He continues, “consequently, this indication addresses a major unmet medical need, and we estimate the commercial potential to be approximately 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.

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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, AP1030 (completed phase IB) and AP214 (in phase II), and 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 is currently being tested in 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 and AP1189 is ready for 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