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Press release

Action Pharma reports positive results in a proof of concept phase IB study in obese human volunteers treated with small molecule oral once-daily AP1030 targeted for type II diabetes associated with obesity

Holte, Denmark, March 8, 2010

Action Pharma A/S has completed a proof of concept clinical phase IB study with AP1030 currently being developed for treatment of type II diabetes associated with obesity. In a phase IB study the effect of AP1030 on glucose metabolism in obese human volunteers was investigated. AP1030 administered orally once-daily for two weeks in obese human volunteers significantly improved glucose metabolism.

AP1030 is the first in a new drug class developed for oral once-daily treatment based on a new mode of action (a positive allosteric modulator through new pharmacological targets, the melanocortin receptors) and is part of Action Pharma's small molecule program. The mode of action of AP1030 involves a hypothalamic melanocortin type 4 receptor mediated effect, thereby modulating appetite and central regulation of glucose metabolism. In addition, AP1030 exerts anti-inflammatory effects mediated through melanocortin type 1 receptors aimed at reverting low grade inflammation in fatty tissues and thereby reducing peripheral insulin resistance.

"The positive results obtained for AP1030 in the phase IB study is a major milestone for Action Pharma", says Ingelise Saunders, CEO of Action Pharma, and continues: "In contrast to other weight reducing anti-diabetics, including GLP-1 analogues, AP1030 has the major advantage of being administered once-daily orally potentially making it very attractive for the anti-diabetes market."

The clinical phase IB trial investigating the effect of AP1030 in obese human volunteers was conducted in Paris, France, at SGS Aster's phase I unit. The study was a randomized, double-blind placebo-controlled dose escalation study. A total of 50 obese volunteers with a body mass index larger than 30, were enrolled in 5 cohorts.

Søren Nielsen, COO of Action Pharma, says: "The results show that oral once-daily administered AP1030 for two weeks exerts a positive effect on glucose metabolism in obese individuals. This is a group of volunteers where many display dysregulation of glucose metabolism in a pre-diabetic stage. The positive clinical results with AP1030 as an orally available first-in-class anti-diabetic drug candidate are very encouraging. It is also important to add that AP1030 is well tolerated and, due to the novel mode of action, does not increase blood pressure which has been a challenge with earlier drug candidates targeting MCR4 receptors."

The lead program in Action Pharma's portfolio, AP214, is currently finalizing recruiting in a phase II clinical trial and key results are expected Q3 2010. The initial target indication for AP214 is the prevention of post-surgical kidney injury after major cardiac surgery. These patients are at increased risk of kidney injury which again is associated with a marked increase in mortality, co-morbidity and, prolonged hospitalization. Action Pharma is in the process of partnering the AP214 program to pharmaceutical companies with a focus in critical care medicine.

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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. Initial results from an earlier phase II US clinical trial and from a phase IB trial in human volunteers subjected to LPS-induced inflammation, revealed positive effects of AP214.

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 and has completed a two-week phase IB clinical trial with positive effects on glucose metabolism. AP1030 has the potential to be superior to other anti-diabetics, including GLP-1 analogues, DPP-4 inhibitors and glitazones. Importantly, AP1030 can be administered orally (once daily) in contrast to GLP-1 analogues. Moreover, the marked weight reducing effects of AP1030 observed in non-clinical pharmacodynamic models contrast the absence of weight reduction by other orally available anti-diabetics, including DPP-4 inhibitors. Thus, this makes AP1030 highly attractive in the market for type II diabetes associated with obesity. The mode of action of AP1030, first in its drug 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.

In addition, Action Pharma develops AP1189, an oral 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.