

Successful completion of clinical Phase I trial of AMPK activator O304 for type 2 diabetes and cardiovascular disease

Betagenon AB/Baltic Bio AB announces the successful completion of the first-in-human Phase I clinical (SAD and MAD) trial of AMPK activator compound O304.

The Phase I study of O304 was a dose-escalating study conducted to assess the safety, tolerability and pharmacokinetics of both single and repeat doses of O304. In the single dose-escalating study, O304 was administered at 100-2400 mg in young healthy subjects. No significant adverse effects and the expected pharmacokinetics were observed. In the multiple ascending dose study O304 was administered to both over-weight middle aged subjects and, in combination with Metformin, to type 2 diabetics. O304 showed an excellent safety profile and was very well tolerated. Preliminary expected pharmacodynamic effects were observed.

Thomas Edlund, CEO of Betagenon AB; **“We have now established a safe dose range to initiate Phase II proof-of-concept studies of O304 in type 2 diabetics by monitoring metabolic and cardiovascular effects”.**

About type 2 diabetes (T2D) and associated complications.

The epidemic increase in obesity has generated a concomitant epidemic in T2D, which in turn is associated with cardiovascular (CV) complications, including ischemic heart disease, heart failure and peripheral arterial disease. Less than 10% of the soon to be >350 million type 2 diabetics are expected to live a complication-free life. Thus, there is a large need for novel drugs that can simultaneously address T2D and the associated CV complications.

About AMP Activated Protein Kinase (AMPK)

AMPK is master regulator of energy balance at both the single cell and whole organism level. AMPK activation increases cellular energy levels by increasing glucose and lipid metabolism, and by modulating blood flow to deliver nutrients to target tissues, hence mimicking caloric restriction and physical activity. Pharmacological activation of AMPK is therefore a promising approach to prevent/cure obesity, T2D and CV complications.

About O304

As expected from an AMPK activator in preclinical animal models, O304 protects against diet-induced obesity, fatty liver, insulin resistance, β -cell dysfunction, glucose intolerance, hyperlipidemia and diabetes. In addition, O304 increases peripheral blood flow and improves left ventricular stroke volume and contractibility. O304 also improves endurance and acts as “Exercise in a pill”. In animals, O304 is more efficient and “safer” than metformin, and efficient in combination with Metformin.

Betagenon AB is a privately owned Swedish Biotechnology company, and **Baltic Bio AB** is a subsidiary of the investment company Fort Knox Forvaring AB, Umea, Sweden.

Contact: thomas.edlund@betagenon.com