

Start of Phase IIa proof-of-concept clinical trial of AMPK activator O304 in Type 2 Diabetics

Betagenon AB/Baltic Bio AB announces the start of Phase IIa proof-of-concept clinical trial of the first-in-class AMPK activator compound O304 in type2 diabetics.

In the Phase I clinical trial O304 was administered to young healthy and to over-weight middle aged subjects and in combination with Metformin to subjects with Type 2 Diabetes (T2D). O304 did not cause any significant adverse effects, was very well tolerated and showed the expected pharmacokinetics. O304 also showed relevant metabolic and vascular effects.

Thomas Edlund, CEO of Betagenon AB; **“The Phase I trial established a safe dose range of O304 for further clinical studies. A single-centre, randomised, parallel-group, double-blinded, placebo controlled Phase IIa study (TELLUS) of O304 in subjects with T2D, monitoring metabolic and cardiovascular endpoints has now been initiated”.**

About type 2 diabetes (T2D) and associated complications.

The epidemic increase in obesity caused by energy imbalance has generated a concomitant epidemic in fatty liver and T2D, which in turn is associated with cardiovascular complications, including ischemic heart disease, heart failure and peripheral arterial disease. Less than 10% of the soon to be 400 million type 2 diabetics are expected to live a complication-free life. Thus, there is a large need for novel drugs that can simultaneously prevent/cure T2D and the multiple associated complications.

About AMP Activated Protein Kinase (AMPK)

AMPK is master regulator of energy balance both at the single cell and whole organism level. When activated by energy shortage AMPK restores energy balance by suppressing anabolic processes and by increasing glucose and lipid metabolism, as well as blood flow to deliver nutrients to target tissues. AMPK activity declines with aging, obesity and inactivity. Pharmacological activation of AMPK is therefore a promising approach to prevent/cure obesity, fatty liver, T2D and cardiovascular disease caused by or associated with energy imbalance.

About O304

As expected from an AMPK activator, in animal models O304 protects against diet-induced obesity, fatty liver, insulin resistance, β -cell dysfunction, glucose intolerance, hyperlipidemia and diabetes. Under these conditions O304 also exhibits favourable cardiovascular effects. O304 improves both diastolic and systolic function of the left ventricle, and increases stroke volume and cardiac output as well as peripheral blood flow and endurance (“Exercise mimetic”). O304 also works efficiently in combination with Metformin to reduce insulin resistance and to improve glucose homeostasis.

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.

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