



# Start of bridging pharmacokinetic and safety clinical trial of a novel solid pharmaceutical composition of AMPK activator O304

*Betagenon /Balticgruppen Bio AB announces the start of a bridging PK and safety clinical trial of a novel solid pharmaceutical composition of AMPK activator compound O304.*

In previous Phase I and Phase IIa clinical trials in healthy subjects and in type 2 diabetics, the small molecule AMPK activator compound O304 was administered as a suspension and with limited oral bioavailability. A novel formulation of O304 has now been developed that unexpectedly improved oral bioavailability markedly in animals. A patent application (matter of composition) with priority date to 2039 without extensions has been submitted.

Approvals from the Medicine Product Agency, Sweden, and the Ethics committee to conduct the clinical study have recently been granted. Thomas Edlund, CEO of Betagenon AB;

**“An open, randomised, parallel-group study evaluating the exposure of and safety of O304 Na-salt after single and multiple dosing and in combination with dapagliflozin (Forxiga) at steady state in healthy volunteers has now been initiated”.**

## **About AMP Activated Protein Kinase (AMPK)**

AMPK; a 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 as well as chronic kidney and cardiovascular disease caused by or associated with energy imbalance.

## **About O304**

As an AMPK activator, in animal models O304 protects against diet-induced obesity, fatty liver, insulin resistance,  $\beta$ -cell dysfunction, glucose intolerance, hyperlipidemia and diabetes. O304 also and improves both diastolic and systolic function 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 and in synergy with SGLT2 inhibitors to improve glucose homeostasis. O304 is clean in long term toxicology studies in animals.

In Phase I and Phase IIa clinical trials O304 showed good safety/tolerability with the expected pharmacokinetics. Moreover, the beneficial metabolic, micro- and macro-circulatory effects observed in animals successfully translated into findings in man. The available data support efficacy of O304 in obesity, diabetes, heart failure and chronic kidney disease.

**Betagenon/ Balticgruppen Bio AB** is a privately owned Swedish Biotechnology company. Betagenon has received funding from EU's research and innovation framework program Horizon 2020 (EU project 754268 - AMPK-DIAB). Contact: [thomas.edlund@betagenon.com](mailto:thomas.edlund@betagenon.com)