

Company announcement - No. 39/2017

Phase 1 trials for two novel treatments of obesity and/or diabetes initiated by Zealand partner Boehringer Ingelheim

- Both compounds were invented through Zealand and Boehringer Ingelheim research collaboration
- The novel compounds are a dual-acting glucagon/GLP-1 agonist and a long-acting amylin analog
- Zealand to receive a EUR 4 million (DKK 30 million) milestone payment related to initiation of Phase 1 with the long-acting amylin analog
- Results are expected in late 2018 on both compounds

Copenhagen, August 22, 2017 – Zealand Pharma A/S ("Zealand") reports that Boehringer Ingelheim has announced the initiation of two Phase 1 trials, the first with a glucagon/GLP-1 agonist that has the potential for once-weekly administration for the treatment of obesity and/or type 2 diabetes and the second with a novel differentiated long-acting amylin analog for the treatment of obesity and/or diabetes.

GLP-1/glucagon dual-acting agonist

The dual-acting glucagon/GLP-1 agonist activates both the GLP-1 and glucagon receptors, two key gut hormone receptors and may offer better blood sugar and weight loss control than currently available single agonist treatments. The compound builds partly on the effects of the natural gut hormone oxyntomodulin, which has been shown to decrease food intake and increase energy expenditure in humans.

The clinical development of this dual glucagon/GLP-1 agonist will start with a randomized, double-blind, first-in-human study to evaluate the safety and tolerability of single ascending doses in healthy subjects. The study will be conducted in Germany (EudraCT Number: 2017-000295-29; ClinicalTrials.gov Identifier: NCT03175211). Results are expected in late 2018.

Long-acting amylin analog

Amylin is a pancreatic peptide hormone that plays an important role in decreasing food intake and in the regulation of postprandial plasma glucose levels. The compound is a long-acting analog of amylin and it has demonstrated significant weight loss in preclinical models of obesity.

The Phase 1 trial is a randomized, double-blind, first-in-human study to evaluate the safety and tolerability of single ascending doses in healthy subjects. The study will be conducted in Germany (EudraCT Number: 2016-003224-24; ClinicalTrials.gov Identifier: NCT03195088) and funded by Boehringer Ingelheim, with results expected in late 2018.

The global prevalence of obesity has more than doubled since 1980. In 2014, more than 1.9 billion adults were classified as overweight and over 600 million of these were obese.ⁱ

Adam Steensberg, Executive Vice President, Chief Medical and Development Officer of Zealand, comments: "We are proud that Boehringer Ingelheim has chosen to move these two novel analogs forward to Phase 1. It demonstrates the quality of Zealand's approach in developing novel peptides for the potential benefit of millions of people needing adequate solutions for treating obesity and better treatment options for their diabetes. We have a strong partnership with Boehringer Ingelheim and look forward to future studies that will establish if the impressive preclinical weight loss results can be confirmed in clinical trials."



Zealand has two collaborations with Boehringer Ingelheim, and under the terms of the two agreements Boehringer Ingelheim funds all research, development and commercialization activities. Zealand is eligible to receive royalties and milestone payments as follows:

Long-acting amylin analog (2014 agreement)

- Initiation of Phase 1 trial triggers a milestone payment of EUR 4 million to Zealand
- EUR 283 million outstanding in milestone payments
- Mid single-digit to low double-digit percentage royalties on global sales

GLP-1/glucagon dual-acting agonist (2011 agreement)

- EUR 365 million outstanding in milestone payments
- High single-digit to low double-digit percentage royalties on global sales

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About Zealand Pharma A/S

Zealand (Nasdaq Copenhagen and New York: ZEAL) is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand is based in Copenhagen (Glostrup), Denmark.

Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, clinical development activities and anticipated results, product approvals and financial performance. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of clinical trials and other development activities, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Zealand's products, introduction of competing products, Zealand's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Zealand are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with a product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the United States, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Zealand, promotion of unapproved uses is strictly prohibited.

ⁱ http://www.who.int/mediacentre/factsheets/fs311/en/