

Press Release

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Novo Nordisk starts phase 1 trial with oral insulin analogue

Merrion Pharmaceuticals earns USD 2 million milestone payment

Novo Nordisk today announced that it has initiated its first phase 1 clinical trial with an oral insulin analogue (NN1952). This milestone releases a USD 2 million payment to Merrion Pharmaceuticals plc, whose GIPET® technology is used in the formulation of NN1952.

The aim of the trial, which is conducted in Germany, is to investigate the safety, tolerance, pharmacokinetics (exposure of drug) and pharmacodynamics (effect) of NN1952 in healthy volunteers and people with type 1 and type 2 diabetes. Results from the trial, which is planned to enrol about 80 people, are expected to be reported in the first half of 2011.

There are many challenges with the development and production of a reliable insulin formulation for oral use. They include avoiding enzymatic degradation in the gastrointestinal tract, overcoming poor spontaneous insulin permeability over the intestinal wall, limiting variability of absorption (caused, for example, by interaction with food), and producing insulin in sufficient scale cost-effectively.

"We still have many challenges to overcome, and it is far too early to say whether or when oral insulin will become an alternative to insulin injections," says Peter Kurtzhals, senior vice president and head of diabetes research at Novo Nordisk. "However, I am encouraged by the progress our research and development teams have made during the past two years, and which has led us to this important milestone."

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NN1952 has been designed to address some of the key challenges relating to oral insulin delivery. Furthermore, it utilises the GIPET® formulation technology from Merrion Pharmaceuticals to facilitate insulin absorption from the gut.

John Lynch, chief executive of Merrion, says, "The USD 2 million milestone payment, which we have achieved by meeting all necessary deadlines, is an extremely positive development for Merrion. This is a major programme for Merrion and we are determined to ensure that our highly motivated team of specialists maximises the likelihood of success for Novo Nordisk's oral insulin candidates."

In November 2008, Merrion entered into a development and licence agreement to develop and commercialise oral formulations of Novo Nordisk's proprietary insulin analogues, using Merrion's proprietary GIPET® technology (Gastrointestinal Permeation Enhancement Technology). This is the first development milestone achieved by Merrion under this agreement.

Novo Nordisk is a healthcare company and a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs more than 29,000 employees in 81 countries, and markets its products in 179 countries. Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange under the symbol 'NVO'. For more information, visit novonordisk.com.

Merrion Pharmaceuticals (www.merrionpharma.com) is engaged in the development of oral forms (tablets/capsules) of drugs that have poor absorption and are generally given by injection. Merrion was established in 2003 to commercialize various technologies acquired from Elan Corporation, plc. Merrion Pharmaceutical's patented drug delivery technologies increase bioavailability, by improving absorption in the gastrointestinal tract, of drugs that are otherwise poorly absorbed. Merrion utilizes its technology to develop new oral drugs in two ways; it develops its own proprietary drugs using GIPET and partners with other pharmaceutical companies in developing oral GIPET formulations of their products. Merrion is listed at the Dublin Stock Exchange under the symbol MERR.

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