

# Press release

# Ipsen's partner Roche announces that Taspoglutide meets its primary endpoints in head-to-head study with sitagliptin (Januvia®) and versus placebo

# Taspoglutide provides potent and durable glycemic control with superiority versus Januvia®

Paris (France), 2 December 2009 - Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical group, today announced that its partner Roche has disclosed the results of the second and third of eight T-emerge phase III studies in patients with diabetes for taspoglutide, the first human once weekly glucagon-like peptide-1 (GLP-1) analogue originating from Ipsen's research and developed by Roche. T-emerge 1 (subcutaneous weekly taspoglutide versus placebo in treatment-naïve patients) and T-emerge 4 (subcutaneous weekly taspoglutide versus sitagliptin versus placebo) both met their respective primary endpoints of change in HbA1c. In both studies taspoglutide was generally well tolerated. The most frequently reported adverse events among taspoglutide treated patients were nausea and vomiting.

This compound is similar to the natural hormone GLP-1 which has a key role in blood sugar regulation. GLP-1 analogues, which stimulate insulin secretion and suppress glucagon secretion, are true innovations in the diabetes field.

## About T-emerge 1

T-emerge 1 is a double-blind, randomized, placebo-controlled, 24 week study, to demonstrate superiority of taspoglutide versus placebo in 373 treatment-naïve type 2 diabetic patients. The results of T-emerge 1 showed that taspoglutide demonstrated superior HbA1c reduction versus placebo. The study analysis included 373 patients, enrolled into three arms (taspoglutide 10 mg once weekly, taspoglutide 10 mg once weekly titrated up to 20mg once weekly after 4 weeks, and placebo).

# **About T-emerge 4**

T-emerge 4 is a head to head comparison study versus sitagliptin (Januvia<sup>®</sup>) as an add-on to metformin. It is a double blind, active and placebo controlled, 24 week study to demonstrate the non-inferiority of taspoglutide to sitagliptin with a statistical test for superiority to placebo, involving 636 patients who have failed to reach their treatment targets with metformin. T-emerge 4 showed that taspoglutide demonstrated superior HbA1c reduction versus sitagliptin. The study analysis included 636 patients, enrolled into four arms (taspoglutide at doses of 10 mg and 20 mg, sitagliptin 100 mg and placebo) in a ratio of 2:2:2:1.

# **About the T-EMERGE Program**

Roche's T-EMERGE Phase III clinical trial programme is designed as multicenter, multi-country, randomized, controlled (active or placebo), double-blind and open studies. Over 6,000 patients will be enrolled in the eight studies that comprise the T-EMERGE programme. Studies include two parallel taspoglutide arms including 10 mg once weekly and 10 mg once weekly titrated up to 20 mg once weekly after 4 weeks. Four of the eight studies have active comparators, including exenatide, sitagliptin, insulin glargine and pioglitazone.



# **About Taspoglutide (R1583)**

Taspoglutide was selected from a family of human once-weekly long-acting glucagon-like peptide-1 (GLP-1) analogues with structural modifications which confer intrinsic controlled release properties. Ipsen is the originator of the concept of matrix free sustained release formulation applied to therapeutic peptides and proteins. Taspoglutide is being developed, by Roche, as a novel and innovative treatment for patients with type 2 diabetes mellitus, the fourth leading cause of death in most developed countries. The structure of the molecule is similar to that of the natural human hormone GLP-1, and has the potential for intervals of up to two weeks in between administration without the use of a matrix.

#### **About Diabetes**

Diabetes is a disease characterized by excess blood glucose due to a deficiency in insulin availability and/or resistance to its action. Type 2 diabetes accounts for 90% to 95% of all diabetes cases worldwide and occurs almost entirely in adults. Complications from diabetes, such as coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness, are resulting in increasing disability, reduced life expectancy and enormous health cost for virtually every society. According to current estimates by the World Health Organization, the number of people with diabetes is set to more than double in the next 20 years to over 300 million by the year 2025.

## About the agreement

Roche exercised its licensing option for taspoglutide from Ipsen in 2006 and acquired exclusive worldwide rights to develop and market taspoglutide, except in Japan where these rights are shared with Teijin and in France where Ipsen may elect to retain co-marketing rights.

#### **About Ipsen**

Ipsen is an innovation-driven global specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty medicine, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and haematology), and primary care products which contribute significantly to its research financing. The location of its four Research & Development centres (Paris, Boston, Barcelona, London) and its peptide and protein engineering platform give the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. More than 800 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. This strategy is also supported by an active policy of partnerships. In 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion. Ipsen's shares are traded on Segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Service de Règlement Différé" ("SRD") and the Group is part of the SBF 120 index. For more information on Ipsen, visit our website at www.ipsen.com.

#### **Ipsen Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the



safe and effective nature of the product concerned. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

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