



## **Ipsen's partner Roche announces that Taspoglutide meets its primary endpoint in a key phase III clinical trial**

### **Taspoglutide demonstrates superiority in HbA1c change versus placebo as add-on to metformin and pioglitazone**

**Paris (France), 29 April 2010** - Ipsen (Euronext: FR0010259150; IPN), a global biopharmaceutical group, today announced that its partner Roche has disclosed results of the phase III T-emerge 3 study in patients with diabetes with taspoglutide, the first once weekly glucagon-like peptide-1 (GLP-1) analogue based on a human sequence. Taspoglutide originating from Ipsen's research is developed by Roche.

The results of T-emerge 3 showed that taspoglutide demonstrated superiority in HbA1c change versus placebo following 24 weeks of treatment. The study analysis included 326 patients, randomized into three arms (taspoglutide 10 mg once weekly, taspoglutide 20 mg once weekly and placebo).

In this study taspoglutide was generally well tolerated and the most frequently reported adverse events among taspoglutide treated patients were nausea and vomiting.

In addition to the already released T-emerge 1, T-emerge 2, T-emerge 4, T-emerge 5 and T-emerge 7 studies, data from T-emerge 3 will be submitted for presentation at upcoming international scientific meetings. A further two T-emerge Phase III trials exploring taspoglutide in patients with diabetes are ongoing.

#### **About T-emerge 3**

T-emerge 3 is a combination therapy (add on to metformin and pioglitazone), double blind, placebo controlled, 24 week core study, to demonstrate superiority versus placebo, involving 326 patients equally randomised into three arms (taspoglutide at doses of 10 mg and 20 mg once weekly, and placebo). All patients continue into the 28-week long-term extension on taspoglutide.

#### **About the T-emerge Program**

Roche's T-emerge Phase III clinical trials are 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 program. 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 has elected to retain co-marketing rights.

## **About Ipsen**

Ipsen is a global biopharmaceutical group with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, which significantly contribute to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. Almost 900 people are dedicated to the discovery and development

of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. 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](http://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.

### **For further information:**

Media

**Didier Véron**

Director, Public Affairs and Corporate  
Communications

Tel.: +33 (0)1 58 33 51 16

Fax: +33 (0)1 58 33 50 58

E-mail: [didier.veron@ipsen.com](mailto:didier.veron@ipsen.com)

Financial Community



**David Schilansky**

Investor Relations and Financial Officer

Tel.: +33 (0)1 58 33 51 30

Fax: +33 (0)1 58 33 50 63

E-mail: [david.schilansky@ipsen.com](mailto:david.schilansky@ipsen.com)

**Pierre Kemula**

Investor Relations Manager

Tel.: +33 (0)1 58 33 60 08

Fax: +33 (0)1 58 33 50 63

E-mail:

[pierre.kemula@ipsen.com](mailto:pierre.kemula@ipsen.com)