Press release

Roche moves investigational diabetes drug, Taspoglutide, into Phase III clinical trials

Positive Phase II results of Roche and Ipsen's first once-weekly human GLP-1 presented at the American Diabetes Association congress

Paris (France) and Basel (Switzerland), 10 June 2008 - Ipsen (Euronext: FR0010259150; IPN) announced today that Roche and Ipsen's investigational diabetes drug taspoglutide has been shown to be generally well-tolerated and efficacious for the treatment of patients with type 2 diabetes, resulting in significant improvements in glucose control and weight loss after only eight weeks of treatment.[1,2,] Taspoglutide, the first human once weekly glucagon-like peptide-1 (GLP-1) analogue originating from Ipsen's Research, is a compound similar to the natural hormone GLP-1 which has a key role in blood sugar regulation. Based on these promising Phase II results, presented at the American Diabetes Association (ADA) in San Francisco, U.S., Roche has made the decision to move taspoglutide into Phase III clinical trials with the programme anticipated to start in the second half of 2008.

"These data reinforce the role of GLP-1 in type 2 diabetes and Roche and Ipsen believe taspoglutide has the potential to be a best-in-class treatment," said William M. Burns, CEO Pharmaceuticals Division of Roche and Jean-Luc Bélingard, Chairman and CEO of the Ipsen Group. "GLP-1 analogues, which stimulate insulin secretion and suppress glucagon secretion, are true innovations in the diabetes field. Roche and Ipsen are pleased to move this potentially best-in-class product into phase III trials and look forward to working together to bring it to market" they said.

The Phase II studies showed that the safety profile of taspoglutide, which originates from Ipsen's research, supports the move into Phase III,[1,2] with the most common adverse event reported being mild-to-moderate nausea. These events were dose-dependent and in most cases, resolved spontaneously while continuing on therapy.

"These data show that taspoglutide is a promising and highly efficacious once-weekly treatment for obese patients with type 2 diabetes mellitus no longer controlled on oral antidiabetic medications," said lead author, Professor Michael Nauck, Head of the Diabeteszentrum Bad Lauterberg, Germany. "Like improved glucose control, drug-induced weight loss is particularly beneficial for this type of patients. We will wait to see the Phase III results with interest".

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 the studies

Eight Weeks of Treatment with the Long-Acting, Human GLP-1 Analogue Taspoglutide Improves Glycemic Control and Lowers Body Weight in Subjects with Type 2 Diabetes Mellitus (T2DM) Treated with Metformin: A Double-Blind Placebo-Controlled Phase 2 Study[1]

- Study evaluated the efficacy, safety and tolerability of taspoglutide in patients with Type 2 diabetes mellitus inadequately controlled with metformin
- 306 patients were randomized to 8 weeks of treatment with placebo (PLO) or taspoglutide, either 5, 10, or 20 mg weekly (QW), or 10 and 20 mg once every two weeks (Q2W) and followed-up for 4 additional weeks after the last administered dose
- Significant reductions in HbA1c were seen after 8 weeks of treatment compared to PLO. The percentage of patients who achieved target HbA1c ≤ 7% at end-of-study was 59%, 79 %, 81% in the 5 mg, 10 mg, 20 mg weekly arms and 44% and 63% in the 10 and 20 mg every two weeks respectively versus 17% with PLO
- Body weight decreased progressively and dose-dependently, with significant reductions from baseline in the 10 and 20 mg QW and 20 mg Q2W arms
- The most common adverse event (AE) was dose-dependent, transient, mild-to-moderate nausea. No episodes of pancreatitis were reported in this study

Safety and Tolerability of High Doses of the Long-Acting, Human GLP-1 Analogue Taspoglutide in Diabetic Subjects Treated with Metformin: A Double-Blind, Placebo-Controlled Phase 2 Study[2]

- Study evaluated safety and tolerability of escalating doses of taspoglutide in patients with Type 2 diabetes mellitus inadequately controlled with metformin
- 133 patients were randomized of which 129 patients received either placebo (PLO) or 20 mg taspoglutide weekly for 4 weeks, followed by either maintenance at 20 mg (20/20), or a dose increase to 30 mg (20/30) or 40 mg (20/40) weekly with matched PLO for additional 4 weeks. Patients were then followed up for 4 weeks after the last administered dose
- Significant improvements in glycemic control were observed in all active arms. At the end of treatment, the percentage of patients reaching HbA1c ≤ 7% was 72%, 53% and 70% with 20/20, 20/30 and 20/40 respectively versus 19% with PLO
- As expected, the most common AE was nausea: transient, mild-to-moderate, appearing early during therapy and resolving spontaneously while continuing on therapy in most cases. No episodes of pancreatitis were reported in this study

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 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. Taspoglutide is currently moving into Phase 3 clinical trials.

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.

Additional information

-Type 2 Diabetes: http://www.health-kiosk.ch/start_diabetes

References

1. **Eight Weeks of Treatment with the Long-Acting, Human GLP-1 Analogue R1583 Improves Glycemic Control and Lowers Body Weight in Subjects with Type 2 Diabetes Mellitus (T2DM) Treated with Metformin: A Double-Blind Placebo-Controlled Phase 2 Study.** Abstract number A-1604 Presented on June 7th 2008 at the 68th **Scientific Session of the American Diabetes Association, San Francisco**, U.S.
2. **Safety and Tolerability of High Doses of the Long-Acting, Human GLP-1 Analogue R1583 in Diabetic Subjects Treated with Metformin: A Double-Blind, Placebo-Controlled Phase 2 Study.** Abstract number A-2434. Presented on June 9th 2008 at the 68th **Scientific Session of the American Diabetes Association, San Francisco**, U.S.

About Ipsen

Ipsen is an innovation-driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders), 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 700 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 2007, Research and Development expenditure was about €185 million, in excess of 20% of consolidated sales, which amounted to €920.5 million while total revenues amounted to €993.8 million. Ipsen's shares are traded on Segment A of Eurolist by Euronext™ (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 statements

The forward-looking statements and targets contained herein are based on Ipsen's management's 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 Research and Development process involves several stages at each of which there is a substantial risk that the Group will fail to achieve its objectives and be forced to abandon its efforts in respect of 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, or that the regulatory authorities will be satisfied with the data and information provided by the Company. Ipsen 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. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French Autorité des Marchés Financiers.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at www.roche.com.

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