

Press release

## **Ipsen's partner Inspiration Biopharmaceuticals announces the initiation of the second phase III pivotal clinical study of OBI-1 in congenital hemophilia A with inhibitors**

- **Ipsen subscribed to a newly issued US\$25 million convertible note**

**Paris (France), 28 November 2011** – Ipsen (Euronext: IPN, ADR: IPSEY) today announced that its partner Inspiration Biopharmaceuticals, Inc. (Inspiration) has initiated the treatment of the first patient in the second of two pivotal studies from the OBI-1's Accur8 clinical trial program. In this newly initiated clinical study, OBI-1, an intravenous recombinant porcine factor VIII (FVIII) product, will be evaluated for the treatment of individuals with congenital hemophilia A, who have developed inhibitory antibodies (inhibitors) against their human FVIII replacement therapy.

Under the partnership agreement signed with Inspiration in January 2010, the initiation of this clinical study triggers the subscription by Ipsen to a US\$25 million convertible note newly issued by Inspiration. Ipsen's fully diluted share ownership position in Inspiration now reaches about 40.7%.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** said: *"The initiation of the second OBI-1 phase III clinical trial in congenital hemophilia A with inhibitors is an important step forward in the development of our hemophilia franchise. Currently, patients suffering from hemophilia A who have developed inhibitors have limited therapeutic options. The advancement of OBI-1 clinical program paves the way towards potential major improvements in the therapeutic armamentarium within the coming years. We are pleased with the progress made by Inspiration who initiates in due time the second OBI-1 phase III clinical trial after having filed a Marketing Authorization Application in Europe for IB1001, a recombinant factor IX."*

### **About the 2<sup>nd</sup> phase III clinical study in congenital hemophilia A**

The OBI-1 phase III pivotal clinical study is a prospective, non-randomized, open-label study evaluating the efficacy of OBI-1 for the treatment of serious bleeding episodes, including episodes that are a threat to a patient's life or vital organs. The first patient is being treated at the Johannesburg Hospital in South Africa.

### **About the first phase III clinical study in acquired hemophilia A**

In November 2010, Inspiration initiated the first pivotal study of OBI-1 for the treatment of severe bleedings in individuals with acquired hemophilia A, caused by the development of inhibitors against human FVIII. Results from the first patients in this clinical study were presented in a Scientific Session held in conjunction with the 23rd Congress of the International Society on Thrombosis and Haemostasis (ISTH) in July 2011. Enrollment in the OBI-1 acquired hemophilia A clinical trial is ongoing.

### **About OBI-1**

OBI-1, a recombinant form of porcine FVIII which may possess low cross reactivity to antihuman FVIII antibodies, is a replacement therapy, activating the intrinsic hemostatic pathway. This should allow clinicians to correlate activity and efficacy with FVIII levels, a surrogate for efficacy in hemophilia, and therefore guide dosing to better monitor and predict treatment outcomes. OBI-1 presents a unique and alternative approach to address the needs of individuals who have developed inhibitors to FVIII and is highly desired by the medical community.

### **About Hemophilia**

Hemophilia is a bleeding disorder caused by low levels or the absence of a protein called a coagulation factor, essential for blood clotting. The two most common forms of hemophilia are types A and B. Hemophilia A is caused by a factor VIII deficiency and the congenital form occurs in ~1 out of every 5,000 male births. Hemophilia B is caused by factor IX deficiency and occurs in ~1 out of every 30,000 male births. Approximately 60% of patients with hemophilia have a severe clinical condition, which results in frequent spontaneous bleeding episodes, in addition to serious bleeding after injuries. The annual market for hemophilia treatments is estimated at \$8 billion worldwide.

Approximately one-third of individuals with hemophilia A develop an immune reaction (inhibitors) to FVIII (hFVIII), resulting in extremely limited therapeutic options.

### **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2010. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by four franchises: neurology / Dysport<sup>®</sup>, endocrinology / Somatuline<sup>®</sup>, uro-oncology / Decapeptyl<sup>®</sup> and hemophilia. Moreover, the Group has an active policy of partnerships. R&D is focused on innovative and differentiated technological patient-driven platforms, peptides and toxins. In 2010, R&D expenditure totaled more than €220 million, above 20% of Group sales. The Group has total worldwide staff of close to 4,500 employees. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipsen.com](http://www.ipsen.com).

### **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. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

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. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from Generics that might translate into loose of market shares.

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:**

**Ipsen**

**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**

**Pierre Kemula**

**Investor Relations Officer**

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)

**Stéphane Durant des Aulnois**

**Investor Relations Manager**

Tel.: +33 (0)1 58 33 60 09

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

E-mail: [stephane.durant.des.aulnois@ipsen.com](mailto:stephane.durant.des.aulnois@ipsen.com)