

**Ipsen and Inspiration Biopharmaceuticals announce that OBI-1 has received Fast Track designation from FDA for acquired hemophilia A**

**BLA Submission in the US planned for the first half of 2013**

**Paris (France) and Cambridge, Mass. (USA) 20 November 2012** – Ipsen (Euronext: IPN, ADR: IPSEY) and Inspiration Biopharmaceuticals Inc. (Inspiration) today announced that Inspiration has received Fast Track designation from the US Food and Drug Administration (FDA) for OBI-1 in acquired hemophilia A. OBI-1, an intravenous recombinant porcine factor VIII (FVIII), is being evaluated for the treatment of individuals with acquired hemophilia A, who have developed inhibitory antibodies (inhibitors) against their innate FVIII.

Fast track is a designation that the FDA reserves for a drug intended to treat a serious disease and has a potential to fill an unmet medical need. Fast track designation is designed to facilitate the development and expedite the review of new drugs. Marketing applications for fast track development programs are likely to be considered appropriate for priority review, which implies an abbreviated review time of eight months. Inspiration intends to submit a biologics license application (BLA) to FDA in the first half of 2013.

OBI-1 received Orphan Drug Designation from the FDA in March 2004 and from the European Medicines Agency (EMA) in October 2010.

**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 bleeding in individuals with acquired hemophilia A. The pivotal phase III study is a prospective, non-randomized, open-label study evaluating the efficacy of OBI-1 for the treatment of serious bleeding episodes in individuals with acquired hemophilia caused by development of autoimmune inhibitory antibodies to human FVIII. Serious bleeding episodes include those that are a threat to a patient's life or vital organs or limbs, or which require a blood transfusion. For more information on the OBI-1 Phase III pivotal study for the treatment of individuals with acquired hemophilia, please visit <http://clinicaltrials.gov/ct2/show/NCT01178294>.

Results from the first 12 subjects in this clinical study were presented during the World Federation of Hemophilia (WFH) Meeting in July 2012. Enrollment in the OBI-1 acquired hemophilia A clinical trial is ongoing.

**About OBI-1**

In the fourth quarter of 2010, OBI-1 entered late-stage clinical testing in individuals with acquired hemophilia, a rare, potentially life-threatening bleeding disorder, which, unlike congenital hemophilia, typically affects older adults and occurs equally in both males and females. Further, Inspiration has initiated a second pivotal clinical trial in individuals with congenital hemophilia A who have developed inhibitors against human FVIII. OBI-1 provides clinicians with a unique, alternative approach to address the needs of individuals who have developed inhibitors to FVIII, and has been greeted with enthusiasm 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. Acquired hemophilia A, a rare condition, is caused by autoantibodies formed against the person's own FVIII, often brought on by an underlying medical condition mostly in the elderly population. Hemophilia B is caused by a deficiency of coagulation factor IX and occurs in ~1 out of every 30,000 male births. Approximately 60% of persons with hemophilia have a severe 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.

## About the partnership agreement between Inspiration and Ipsen and the product portfolio

In January 2010, Inspiration entered into a strategic agreement with Ipsen, leveraging the combined expertise and resources of the two companies, to develop a broad portfolio of hemophilia products and two products in phase III. IB1001, an investigational intravenous recombinant factor IX (rFIX) therapy for the treatment and prevention of bleeding episodes in people with hemophilia B, and OBI-1, an investigational intravenous recombinant porcine factor VIII (rpFVIII) therapy for the treatment of patients with i) acquired hemophilia A and ii) congenital hemophilia A who have developed inhibitors against human FVIII.

In August 2011, Ipsen and Inspiration announced the extension of their agreement to create a hemophilia business unit structure that will act as the exclusive sales organization for all hemophilia products commercialized under the Inspiration brand in Europe.

On 21 August 2012, Ipsen and Inspiration renegotiated their 2010 partnership. This agreement aimed to establish an effective structure whereby Ipsen gained commercial rights in key territories. Inspiration remains responsible for the world-wide development of OBI-1 and IB1001. Ipsen paid Inspiration an upfront payment \$30 million for these rights, providing Inspiration with time to secure independent third party financing and Ipsen with time to assess potential ways forward.

On 31 August 2012, Ipsen paid Inspiration \$7.5 million and received a warrant for 15% of Inspiration's equity, which Ipsen later terminated in October 2012.

Ipsen had agreed to pay Inspiration an additional \$12.5 million if Inspiration had raised third party financing by the contractual deadline of 30 September 2012. Inspiration did not manage to raise external funding by this contractual deadline.

On 30 October 2012, Inspiration filed for protection under Chapter 11 of the United States Bankruptcy Code. Inspiration is seeking a strategic buyer through a formal sale process. Ipsen will include the commercialization rights obtained from Inspiration in August 2012 in the sale, as well as Ipsen's OBI-1 manufacturing facility in Milford, Massachusetts.

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2011. 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. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2011, R&D expenditure totaled more than €250 million, above 21% 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.ipсен.com](http://www.ipсен.com).

### **Ipsen's 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 a loss of market share.

Furthermore, the Research and Development process involves several stages each of which involves 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 favorable 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 cannot be certain that its partners will fulfill their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance.

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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