

Press release

## **Ipsen's partner Inspiration Biopharmaceuticals announces the treatment of the first patient in phase III pivotal study of OBI-1 for acquired hemophilia A**

- **Ipsen has subscribed to a newly issued \$50 million convertible note**

**Paris (France), 19 November 2010** – Ipsen (Euronext: IPN, ADR: IPSEY) announced today that its partner Inspiration Biopharmaceuticals, Inc. (Inspiration) has initiated treatment of patients in the first of two phase III pivotal clinical studies of OBI-1, an intravenous recombinant porcine factor VIII (FVIII) product, for the treatment of acquired hemophilia A, a rare, though potentially life-threatening bleeding disorder. Under the terms of their partnership agreement signed in January 2010, Inspiration in-licensed OBI-1 from Ipsen, and is responsible for the clinical development, regulatory process and commercialization of the product. In the context of this first phase III clinical study initiation, Ipsen has subscribed to a US\$50 million newly issued convertible note by Inspiration, bringing its fully diluted share ownership position in Inspiration to about 34.0%.

**Jean-Luc Bélingard, Chairman and Chief Executive Officer of Ipsen** said: *“The initiation of this OBI-1 phase III clinical trial marks a milestone in the treatment of acquired hemophilia. Currently, patients suffering from acquired hemophilia do not have access to a reliable satisfactory therapeutic response. The advancement of OBI-1 development paves the way towards radical improvement in the therapeutic armamentarium available to the medical practice within the coming years. Ipsen is proud to have started the development of this compound and is convinced that the partnership with Inspiration may result not only in the optimization of the clinical development of OBI-1’s but also in a promising pipeline in the field of hemophilia.”*

### **About the study (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. In addition, the study will obtain data about the pharmacokinetic behavior of OBI-1. For more information on the OBI-1 pivotal study for the treatment of individuals with acquired hemophilia, please visit <http://clinicaltrials.gov/ct2/show/NCT01178294>.

### **About Hemophilia and Acquired Hemophilia**

Hemophilia is a group of bleeding disorders caused by low levels or absence of proteins called a coagulation factors, 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 individuals 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 c. \$7.5 billion worldwide.

Acquired hemophilia is a rare, though potentially life-threatening, bleeding disorder caused by the development of autoantibodies (inhibitors) against coagulation factors. Unlike congenital hemophilia, acquired hemophilia is typically a disorder of older adults, and occurs in both males and females. Also, the pattern of bleeding seen in acquired hemophilia is different from that observed in the more common congenital form. In acquired hemophilia, individuals typically bleed into the skin, muscles and soft tissues, as opposed to bleeding into joints, which is more typical in congenital hemophilia.

### **About OBI-1**

Approximately one-third of individuals with hemophilia A develop an immune reaction (inhibitors) to human FVIII (hFVIII) and can no longer respond to treatment with the coagulation factor. Current therapies, specifically human factor VIIa (NovoSeven<sup>®</sup>) and FEIBA, work by bypassing the natural hemostatic pathway and forcing coagulation with much higher levels of FVIIa than normal. In contrast, OBI-1, a recombinant form of porcine FVIII that typically possesses low cross reactivity to anti-hFVIII antibodies, is a replacement therapy, activating the natural hemostatic pathway. This should allow clinicians to correlate activity and efficacy with a biomarker, and therefore guide dosing to better predict treatment outcomes. OBI-1 presents a unique and alternative approach to address the needs of individuals who have developed inhibitors to hFVIII and is highly desired by the medical community.

OBI-1 has been evaluated in a Phase 2 study in patients with congenital hemophilia A who have developed inhibitors to hFVIII, and who presented with a non-life/non-limb threatening bleed. The Phase 2 study demonstrated OBI-1 was well-tolerated and can be given over a short infusion time. In addition to the recently initiated pivotal trial of OBI-1 in individuals with acquired hemophilia A, Inspiration expects to initiate a separate pivotal trial in individuals with congenital hemophilia A who have developed inhibitors against hFVIII.

### **About Ipsen**

Ipsen is a global biopharmaceutical group, with sales exceeding 1 billion euros in 2009. The Group has total worldwide staff of more than 4,400 employees, of which nearly 900 contribute to the discovery and development of innovative drugs for patient care. Ipsen's development strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and on primary care drugs. This strategy is supported by an active policy of partnerships. Ipsen's research & development (R&D) centers and its peptide & protein engineering platform give the Group a strong competitive edge. In 2009, R&D expenditure totaled close to €200 million, representing nearly 20% of Group sales. 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 our website at [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. 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 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 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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