

Press release

## **Inspiration Biopharmaceuticals and Ipsen Expand their Partnership in Preparation for the Commercial Launch of Inspiration's Hemophilia Pipeline in Europe**

***Agreement establishes European commercial partnership, leveraging Ipsen's  
pan-European presence and infrastructure***

***MAA filing in Europe for IB1001, potentially the second recombinant FIX product  
on the market, expected before the end of this year***

**Paris (France), and Laguna Niguel (California, USA), August 30, 2011** – Ipsen (Euronext: IPN, ADR: IPSEY) and Inspiration Biopharmaceuticals Inc. (Inspiration) today announced they have entered into a strategic partnership agreement, to create a European hemophilia commercial organization, to launch Inspiration's hemophilia product portfolio in Europe. This partnership is designed to leverage the combined strengths of Ipsen's well established European commercial infrastructure and medical network, with Inspiration's expertise in the field of hemophilia. Inspiration and Ipsen will work together to hire and train a highly specialized commercial team to serve as the exclusive sales organization in Europe for all hemophilia drugs commercialized under the Inspiration brand. This commercial organization will take the form of a hemophilia business unit nested within Ipsen's existing commercial organization.

Inspiration currently has two product candidates in pivotal clinical testing: **IB1001**, an intravenous (IV) recombinant factor IX (FIX) product being developed for the treatment and prevention of bleeding in individuals with hemophilia B, and **OBI-1**, an IV porcine recombinant factor VIII (FVIII) product being developed for the treatment of bleeding in individuals with acquired hemophilia A and individuals with congenital hemophilia A who have developed inhibitors against human FVIII. Inspiration anticipates filing a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for IB1001 by the end of this year.

**John Taylor, Co-Founder and Chairman of Inspiration**, commented, "*As Inspiration transitions toward becoming a commercial-stage company, accessing Ipsen's commercial infrastructure and expertise in Europe will facilitate our entry into this important region of the world. The commercial partnership agreement with Ipsen is an important step forward in achieving our business objectives, while leveraging Ipsen's resources, presence and experience in Europe. I am proud of Inspiration's accomplishments, and the progress we have made to date, in the development of our hemophilia product portfolio. As a company, we continue to be focused on the objectives of improving access to care and expanding product choice for individuals with hemophilia.*"

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen**, stated, "*We are pleased to further expand our partnership with Inspiration. Ipsen once again demonstrates its commitment to becoming a leader in specialty healthcare solutions for targeted debilitating diseases, for the benefit of patients, prescribers and all stakeholders.*"

### **About the agreement**

Under the terms of the commercial agreement announced today, the hemophilia business unit will act as the exclusive commercial agent for all Inspiration products sold in the European Union, Russia and other European countries (in a total of 53 countries). Sales in the business unit will be booked by Inspiration. Ipsen will book all related sales and marketing expenses, rebill them to Inspiration and record them in Other Revenues. Additional financial terms of the agreement were not disclosed.

In January 2010, Inspiration and Ipsen entered into a broad strategic partnership to develop and commercialize a portfolio of hemophilia products, which included Inspiration in-licensing OBI-1 from Ipsen, as well as Ipsen providing Inspiration with \$259 million in milestone-based funding, to support the development of Inspiration's two lead development programs.

### **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 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.

### **Development Programs for IB1001 and OBI-1**

IB1001, Inspiration's lead product candidate, is in Phase III clinical testing, in an ongoing study in Europe, the US, Israel and India. Pending the outcome from these clinical studies and subsequent regulatory approvals, IB1001 is positioned to be the second recombinant FIX product to come to the market for hemophilia B, providing additional product supply, and eliminating reliance by the hemophilia community on a single-source supplier of recombinant product.

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 plans to initiate a second pivotal clinical trial by the end of this year 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.

For more information about enrolling in one of Inspiration's clinical trials, please visit [www.hemophiliaregistry.com](http://www.hemophiliaregistry.com) or call 1-800-361-3227 (from the US only). For more information on the ongoing clinical studies, please visit <http://www.clinicaltrials.gov>.

### **About Inspiration Biopharmaceuticals**

Inspiration Biopharmaceuticals is the only company exclusively dedicated to developing treatments for hemophilia, with a primary mission to broaden access to care, including prophylactic therapy, and to improve the treatment of individuals with inhibitor complications. Inspiration has a broad portfolio of recombinant hemophilia products, which includes two late-stage products in clinical development and two preclinical programs.

Inspiration's lead product candidates are IB1001, an intravenous recombinant factor IX (FIX) for the treatment and prevention of bleeding in individuals with hemophilia B, and OBI-1, an intravenous recombinant porcine factor VIII (FVIII) for the treatment of individuals with congenital hemophilia A who have developed inhibitors against human FVIII and for individuals with acquired hemophilia. Both products are in clinical development. Earlier-stage preclinical programs at Inspiration are focused on human recombinant factor VIIa (FVIIa), for individuals with either hemophilia A or hemophilia B who have developed inhibitors, and for individuals with factor VII deficiency; and human recombinant FVIII, to treat individuals with hemophilia A.

Inspiration has extensive expertise and experience in hemophilia product development, biologics manufacturing, regulatory approval and global commercialization. The Company's senior leadership was directly responsible for the development and commercialization of the majority of hemophilia products currently on the market. In addition, in January 2010, Inspiration entered into a strategic

partnership with the Ipsen Group, leveraging the combined expertise and resources of the two companies. For further information on Inspiration, please visit <http://www.inspirationbio.com>.

### **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.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 loss 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)

**Inspiration Biopharmaceuticals Inc.**

**Media**

Justin Jackson

Maroussia Czarny

Burns McClellan

Tel: +1-212-213-0006

Email: [jjackson@burnsmc.com](mailto:jjackson@burnsmc.com)

[mczarny@burnsmc.com](mailto:mczarny@burnsmc.com)

**Company**

Mary Bauman

VP, Global Commercial Development

Email: [mbauman@inspirationbio.com](mailto:mbauman@inspirationbio.com)