



Press release

## **Ipsen and Inspiration Biopharmaceuticals enter into partnership to create a world leading hemophilia franchise**

- **Portfolio covers all major hemophilia markets and worldwide sales could exceed \$1.0 billion by 2020**
- **Following the exclusive in-licensing of Ipsen's OBI-1 alongside its own IB1001, Inspiration's portfolio now includes two recombinant protein products ready to enter Phase III in 2010 and two earlier development compounds for the treatment of bleeding disorders**
- **Ipsen to acquire initial 20% stake in Inspiration for \$85 million with the potential to increase ownership up to 47% through up to \$174 million in additional milestone-based funding**

**Paris (France), and Laguna Niguel (California, USA), 21 January 2010** – Ipsen (Euronext: FR0010259150; IPN) and Inspiration Biopharmaceuticals, Inc. (Inspiration) today announced that they have entered into a partnership to create a world leading hemophilia franchise. The partnership is designed to leverage combined expertise and resources to advance a broad portfolio of recombinant proteins, which address all major hemophilia disorders in a unique way by focusing on two significant unmet needs: wider access to treatment with coagulation factors and treatment for inhibitor complications. The two lead product candidates are scheduled to begin Phase III clinical testing in 2010 including Ipsen's recombinant porcine factor VIII, OBI-1 (for the treatment of patients with acquired hemophilia and hemophilia A who have developed an inhibitory immune reaction to human forms of factor VIII), and Inspiration's recombinant factor IX product, IB1001 (for the acute and preventative treatment of bleeding in patients with hemophilia B). Combined with Inspiration's novel proprietary technology and an early-stage pipeline of additional hemophilia factors, this broad and unique portfolio would provide greater access to care and fulfill unmet needs for patients suffering from bleeding disorders.

Under the terms of the agreement, Ipsen will exclusively sub-license OBI-1 to Inspiration in exchange for \$50 million in convertible notes and a 27.5% royalty on future OBI-1 sales. Inspiration will also enter a separate agreement with Ipsen for supply of the OBI-1 product.

Ipsen will provide up to \$259 million of funding to Inspiration. The proceeds will be used for the development and commercialization of its hemophilia pipeline, including OBI-1.

1. Ipsen will make an upfront investment of \$85 million in Inspiration in exchange for shares of a new class of preferred stock constituting 20% of Inspiration's fully-diluted equity. In connection with the agreement, Ipsen will be entitled to appoint one member (out of a total of 7) to the Board of Directors of Inspiration.
2. In addition, milestone payments up to \$174 million would be paid to Inspiration based on the successful development of IB1001 and OBI-1. For each milestone payment, Ipsen would receive a note convertible into Inspiration equity with a 7- or up to 9-year maturity

and a 2.5% coupon. These notes would be redeemable in cash at maturity at Ipsen's discretion.

Assuming all milestones payments are made, and the notes are converted into Inspiration equity, Ipsen would hold approximately 47% of Inspiration's equity on a fully diluted basis.

Upon certain triggering events, Ipsen would also have the ability to acquire full control of Inspiration. The transaction is expected to close in the first quarter of 2010.

*"We are very pleased to partner with Ipsen, which has clearly demonstrated a thorough understanding of the hemophilia market and has helped create a strong, far-reaching partnership structure with Inspiration."* said **John Taylor, Co-Founder and Chairman of Inspiration**. *"Inspiration's goal is to bring a better quality of life to patients suffering from hemophilia and we believe Ipsen is the right partner to help make that happen. OBI-1 makes sense to us as a strategic fit in our portfolio of products. Not only does it add a valuable late-stage product to our pipeline, but it will benefit from our existing development infrastructure and future specialty sales force. With the addition of OBI-1, we will be a worldwide leader in hemophilia providing a broad range of treatment options for individuals suffering from bleeding disorders."*

**Jean-Luc Bélingard, Chairman and Chief Executive Officer of Ipsen**, said, *"Inspiration has both a strong development experience and a broad pipeline that will provide the opportunity for new growth on our way to building a new, multi-product global franchise for Ipsen in hematology. We are impressed by the track record of Inspiration's management team in this field. We are confident that the structure we have designed will continue to foster the exceptional environment that has made Inspiration successful until a time when the company has OBI-1 and IB1001 commercialized, and would synergistically benefit from Ipsen's specialist care global footprint."* Jean-Luc Bélingard added, *"Subject to the products in development being approved by the relevant regulatory authorities and upon successful commercialization, we believe Inspiration's portfolio, including OBI-1, could exceed sales of \$1 billion in the next 10 years. After entering the US market last year, we remain committed to growing Ipsen's specialist disease areas on a global basis. This new partnership reflects Ipsen's long-term strategy to build a successful global specialty care franchise that will benefit both patients, doctors and shareholders"*.

*"We are committed to do everything that we can to ensure that patients suffering from hemophilia have more choices and greater access to therapies that also provide a better quality-of-life, and we are very excited that two companies, Ipsen and Inspiration that share this value are going to be working together to make this vision a reality"*, stated **Mark Skinner, President, World Federation of Hemophilia**. *"We are looking forward to the potential introduction of Inspiration's products as they will address the two greatest unmet medical needs of the community, access to treatment and improving the lives of people with hemophilia and inhibitor complications"*.

**Claude Négrier, Head of the Hematology Department at Edouard Herriot University Hospital in Lyon, France** said: *"Providing wider access to treatment with coagulation factors, and improving treatment for inhibitor complication are two significant unmet needs for the hemophilia community. The combination of OBI-1 (the recombinant factor VIII with low cross-reactivity based on porcine amino acid sequence), IB1001 (recombinant factor IX under clinical trial) and recombinant factors VIIa and VIII developed by Inspiration create a portfolio of therapies which address these needs, and represent a significant addition to the treatment armamentarium available to Hemophilia Treatment Centers worldwide. I am pleased to see these two teams joining forces to improve hemophilia care"*

### **Ipsen's Media conference call and webcast (in French)**

Ipsen will host a conference call on January 21 at 09.30 a.m. (Paris time – GMT+1). A live webcast will be available at [www.ipsen.com](http://www.ipsen.com). Callers should dial in approximately 5 to 10 minutes prior to the start of the call. No reservation is necessary to participate in the call. The telephone numbers to join the conference call are, from France and Europe: +33 (0)1 70 99 42 78. No access code is necessary.

A replay will be available soon after the live call and will be available for one week. The telephone numbers to access the replay are, from France and Europe: +33 (0) 1 74 20 28 00. The access code is 4267297#

### **Ipsen's Analyst and Investor conference call and webcast (in English)**

Ipsen will host a conference call on January 21 at 1.00 p.m. (Paris time – GMT+1). A live webcast will be available at [www.ipsen.com](http://www.ipsen.com). The webcast will be archived on the Ipsen website for 3 months following the live call. Callers should dial in approximately 5 to 10 minutes prior to the start of the call. No reservation is necessary to participate in the call. The telephone numbers to join the conference call are, from France and Europe: + 33 (0) 1 70 99 42 88 and from the United States: +1 212 444 08 95. No access code is necessary.

A replay will be available soon after the live call and will be available for one week. The telephone numbers to access the replay are, from France and Europe: +33 (0) 1 74 20 28 00 and from the United States: +1 347 366 95 65. The access code is 4805874#.

### **About Hemophilia**

Hemophilia, congenital or acquired, is a bleeding disorder caused by low levels or absence of a protein called a coagulation factor, essential for blood clotting. The two most common forms of hemophilia are types A & B. Hemophilia A is caused by a factor VIII deficiency and 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 25,000 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 market for hemophilia treatment is in excess of seven billion dollars annually.

### **About Inspiration's IB1001**

IB1001 is an intravenous recombinant factor IX product for the acute and preventative treatment of the bleeding disorder associated with hemophilia B. IB1001 is produced with Inspiration's proprietary recombinant protein manufacturing technology and has clinical trial ongoing in Europe, the US and Israel. The design of the clinical trial facilitates continuous evaluation through the study phases, and allows study subjects to continuously receive treatment with IB1001 throughout the pharmacokinetic, safety and efficacy phases of the study. The study is expected to transition into the Phase III efficacy evaluation phase in early 2010. To date the product has been well tolerated by all subjects with no serious adverse events associated the treatment

### **About Ipsen's OBI-1**

About a third of patients with congenital hemophilia A and patients with acquired hemophilia develop an immune reaction to human forms of FVIII (hFVIII) and can no longer respond to human Factor VIII. Since OBI-1 possesses low cross reactivity to anti-hFVIII antibodies, it is expected that OBI-1 can provide therapeutic benefits to patients who are not able to use hFVIII.

OBI-1, a recombinant B-domain deleted FVIII bioengineered for low cross reactivity to anti-human FVIII inhibitors based on the porcine amino acid sequence, has recently been tested in a Phase II trial. OBI-1 was administered to patients with congenital hemophilia A complicated by the presence of human FVIII inhibitors experiencing a non-life/non-limb threatening bleed. In patients with a measurable anti-hFVIII antibody titer, dosing was initiated with a loading dose (LD) followed by up to 8 doses of 50 to 150 U/kg of OBI-1 administered at 6 hour intervals until the bleed was controlled. The pharmacokinetic (PK) profile of OBI-1 was assessed for the first OBI-1 infusion of each patient. FVIII levels were measured 30 minutes after each infusion. Inhibitor titers were evaluated for a minimum of 6 months after the first OBI-1 infusion. A total of 25 bleeding episodes in 9 patients were treated with OBI-1, and all were successfully controlled. One subject had a mild infusion reaction and when re-treated for a subsequent bleed the subject did not report any adverse event. Eight out of nine (89%) subjects developed anti-pFVIII antibodies following exposure to OBI-1 and in subjects receiving repeated OBI-1 treatment higher anti-pFVIII titres did not affect efficacy or safety. The study demonstrated that OBI-1 is well-tolerated and can be given as a short infusion. OBI-1 is expected to enter Phase III in 2010.

### **Additional Development Projects**

In addition to OBI-1 and IB1001, Ipsen is using its proprietary technology platform to develop a portfolio of products that address a broad range of hemophilia and bleeding disorders. These products include recombinant Factor VIII for hemophilia A and recombinant Factor VIIa for hemophilia A & B. The most advanced of these products is Factor VIIa and it is expected to enter the clinic in 2011.

### **About Ipsen**

Ipsen is an innovation-driven global specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty medicines, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and hematology), and primary care products which contribute significantly to its research financing. The location of its four Research and Development centres (Paris, Boston, Barcelona and 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 800 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 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion. Ipsen's shares are traded on Segment A of Euronext Paris (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](http://www.ipsen.com).

### **Ipsen 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 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.

### **About Inspiration Biopharmaceuticals**

Inspiration Biopharmaceuticals was founded in 2004 with the mission to revolutionize treatments for hemophilia. The Company is focused on developing products that have the potential to broaden patient access to therapy, including prophylactic use. Greater access and more frequent prophylactic therapy have been shown to reduce complications of the disease and enhance patients' long-term health and quality of life. Underlying the Company's programs is a novel, proprietary manufacturing technology that allows a greater yield of high-quality protein. Inspirations' lead product candidate, IB1001 is an intravenous recombinant factor IX product for the acute and preventative treatment of bleeding in patients with hemophilia B. The development of Inspiration's lead product, IB1001 for the treatment of Hemophilia B and its earlier stage coagulation factor product candidates have been partially funded to date by Celtic Pharma, a global private equity and drug development firm.

Inspiration is utilizing its proprietary technology to develop a broad portfolio of hemophilia and bleeding disorder products that address a \$7.5 billion market worldwide, which has grown historically at a 12% CAGR. With over 130 years of combined management experience in commercializing hemophilia products at firms such as Baxter and Bayer, Inspiration has been able to rapidly and efficiently develop protein therapeutics for hemophilia.

### **For further information**

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