Ipsen’s partner, Inspiration Biopharmaceuticals, announces acceptance of European marketing authorization application for IB1001 for the treatment of hemophilia B

Paris (France), 3 October 2011 – Ipsen (Euronext: IPN, ADR: IPSEY) today announced that its partner, Inspiration Biopharmaceuticals, Inc. (Inspiration), has been informed that the European Medicines Agency (EMA) has validated and accepted the filing of the Marketing Authorization Application (MAA) for Inspiration’s IB1001, a recombinant factor IX (FIX) product for the treatment and prevention of bleeding in individuals with hemophilia B. In doing so, the EMA has verified that it will begin its regulatory review process of the MAA.

The application includes safety and efficacy data from Inspiration’s clinical program for IB1001, which was conducted in the U.S., Europe, Israel and India. In January 2010, Inspiration and Ipsen entered into a broad strategic partnership to develop and commercialize a unique portfolio of hemophilia products, which included Inspiration in-licensing OBI-1 from Ipsen, as well as Ipsen providing Inspiration with milestone-based funding to support the development of Inspiration’s two lead development programs, including FIX IB1001. Based on this partnership, by receiving the IB1001 MAA submission acceptance for review from the EMA, Inspiration will receive a $35 million milestone payment from Ipsen. In return, Inspiration will issue a convertible note to Ipsen, bringing Ipsen’s fully diluted equity ownership position in Inspiration to approximately 38%. In late August, Ipsen and Inspiration entered into a new agreement to create a hemophilia business unit structure being established within Ipsen’s existing European commercial organization, which will be the exclusive commercial agent for all products marketed under the Inspiration brand in Europe, including IB1001.

Marc de Garidel, Chairman and Chief Executive Officer of Ipsen, stated, “The filing of IB1001 by the European Medicines Agency is an important step forward in the development of our hemophilia franchise. We believe the hemophilia community will positively receive an alternative to the single recombinant Factor IX currently on the market. As we have announced in late August, Ipsen and Inspiration’s newly created Hemophilia Business Unit will actively prepare the marketing, medical and regulatory plans prior to the launch of IB1001 in Europe, pending regulatory authorization expected in late 2012”.

About IB1001

IB1001, Inspiration’s lead product candidate, is an intravenous recombinant FIX product being developed for the treatment and prevention of bleeding in individuals with hemophilia B. IB1001 has completed the pivotal Phase 3 clinical testing for the European regulatory submission, while clinical testing for the US regulatory submission is ongoing. To date, IB1001 has been well tolerated by patients and pharmacokinetic results have demonstrated non-inferiority to the one approved recombinant FIX product currently available for the treatment of hemophilia B.

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 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.

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.

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®, endocrinology / Somatuline®, uro-oncology / Decapeptyl® 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.

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.

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