

Ipsen's partner Inspiration Biopharmaceuticals announces hold of phase III clinical trials evaluating IB1001 for the treatment and prevention of hemophilia B

Paris (France), 10 July 2012 - Ipsen (Euronext: IPN; ADR: IPSEY) announced today that its partner Inspiration Biopharmaceuticals Inc. (Inspiration) was notified by the Food and Drug Administration (FDA) that both clinical trials evaluating the safety and efficacy of IB1001, an investigational intravenous recombinant factor IX (rFIX) therapy for the treatment and prevention of bleeding episodes in people with hemophilia B, were placed on clinical hold.

The clinical hold impacts two ongoing IB1001 clinical trials – a phase III study evaluating the safety and efficacy of IB1001 to treat and prevent bleeding episodes in adults with hemophilia B, and a phase III study evaluating the safety and efficacy of IB1001 to treat and prevent bleeding episodes in previously treated pediatric subjects with hemophilia B. The adult study has completed its primary analysis period. Following the FDA's request, Inspiration has notified clinical sites in the U.S. to hold treatment of patients with IB1001. Inspiration is also sharing the FDA directive with regulators in countries outside of the U.S. where the studies are being conducted.

During the course of routine laboratory evaluations conducted as part of the ongoing phase III clinical trials, Inspiration observed, and reported to the FDA, a trend towards a higher proportion of IB1001 treated individuals developing a positive response to testing of antibodies to Chinese Hamster Ovary (CHO) protein, the product's host cell protein (HCP).

Small amounts of host cell protein are expected and documented in recombinant therapeutic products of all types. Nevertheless, the higher than expected rate of anti-CHO antibody development in people treated with IB1001 has led Inspiration to initiate a thorough investigation.

A total of 86 people with hemophilia B have received IB1001 in clinical studies and, to date, no adverse events (anaphylaxis or other serious allergic type reaction and nephrotic syndrome) related to the development of antibodies to CHO protein have been reported. Furthermore, no relationship has been demonstrated between the development of antibodies to CHO protein and the development of any antibodies to factor IX. Inspiration continues to follow subjects enrolled in clinical trials of IB1001 to collect safety-related information and will share this information with regulators.

While this finding may be a potential safety concern, no evidence suggests a change in the current overall clinical benefit and risk profile of IB 1001.

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 Inspiration Biopharmaceuticals

As the only biopharmaceutical company dedicated solely to hemophilia, Inspiration is committed to improving the care of people with this condition by broadening treatment choices, expanding global access to care, and advancing innovative therapies. Founded by two families whose sons have hemophilia, Inspiration is inspired to make a difference in the lives of people impacted by hemophilia around the world.

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[®], endocrinology / Somatuline[®], uro-oncology / Decapeptyl[®] 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.ipsen.com.

About the partnership agreement between Inspiration and Ipsen

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. As announced in late August 2011, Ipsen and Inspiration extended 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. In the context of their partnership, Ipsen and Inspiration continue to assess various financing alternatives for Inspiration.

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 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 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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