

Press release

## **Ipsen's partner Inspiration Biopharmaceuticals announces non-inferiority of IB1001, its recombinant factor IX for Hemophilia B**

**Paris (France), 3 February 2011** – Ipsen (Euronext: IPN, ADR: IPSEY) today announced that its partner Inspiration Biopharmaceuticals, Inc. (Inspiration) presented pharmacokinetic (PK) data on its lead product, IB1001, a recombinant factor IX (FIX) for the treatment and prevention of bleeding in individuals with hemophilia B. According to Inspiration, results of the Phase 1 portion of an ongoing IB1001 clinical study demonstrated non-inferiority of IB1001 in achieving overall levels of replacement factor compared to BeneFIX<sup>®</sup>, the only approved recombinant FIX product for the treatment of hemophilia B. Currently, IB1001 is in Phase 3 and safety and efficacy results are expected later this year.

The clinical results were presented at the 4th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD) in Geneva, Switzerland, in a poster presentation titled, "Pharmacokinetics of IB1001, a New Recombinant Factor IX"<sup>1</sup>.

**Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** said: *"Pharmacokinetic results presented by our partner Inspiration Biopharmaceuticals emphasize the encouraging medical potential of IB1001, a promising factor IX for the treatment of hemophilia B, a disease for which access to adequate care is a significant unmet medical need globally."*

### **About the study**

The randomized, double-blind, cross-over PK protocol was designed to show non-inferiority of IB1001 compared to the only marketed recombinant FIX product. The study enrolled 32 individuals with severe hemophilia B. Individuals in the study were infused with either IB1001 or the comparator, and their FIX levels were assessed at different time intervals. After a predetermined time period, individuals received the second product and FIX levels were assessed at the same time points.

### **About Hemophilia**

Hemophilia 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 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 \$7.5 billion worldwide.

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<sup>1</sup> Authors of the poster presentation were Uri Martinowitz, M.D., of the Israeli National Hemophilia Center; Amy D. Shapiro, M.D., of the Indiana Hemophilia and Thrombosis Center; Doris V. Quon, M.D., Ph.D., of the Hemophilia Treatment Center at Orthopaedic Hospital (Los Angeles, CA); Miguel A. Escobar, M.D., of the University of Texas Houston Health Sciences Center; Christine Kempton, M.D., of Emory University School of Medicine (Atlanta, GA); Peter W. Collins, M.D., of the Arthur Bloom Haemophilia Centre University Hospital of Wales School of Medicine, Cardiff University (Cardiff, UK); Pratima Chowdary, M.D., of the Royal Free Hospital (London, UK); Michael Makris, M.D., of the Royal Hallamshire Hospital (Sheffield, UK); Pier M. Mannucci, M.D., of the University of Milan Haemophilia & Thrombosis Center; Massimo Morfini, M.D., of Azienda Ospedaliero - Universitaria Careggi (Florence, Italy); Leonard A. Valentino, M.D., of Rush University Medical Center (Chicago, IL); and Ed Gomperts, M.D., and Martin Lee, Ph.D., both of Inspiration Biopharmaceuticals.



### **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 currently is in pivotal Phase 3 clinical testing. To date, IB1001 has been well-tolerated, and pharmacokinetic results have demonstrated non-inferiority to the one approved recombinant FIX product for the treatment of hemophilia B. Pending results from clinical studies, regulatory approval and commercialization, IB1001 is expected to be the second recombinant FIX product to market, and thereby to increase product supply and access to care worldwide.

### **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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