

Press release

Ipsen announces discontinuation of the development  
of Irosustat in monotherapy

**Opportunities for Irosustat in combination  
with other hormonal therapies will be further evaluated**

**Paris (France), 6 June 2011** – Ipsen (Euronext: IPN - ADR: IPSEY) today announced its decision to assess the alternative development of Irosustat (BN 83495) in combination with other hormonal therapies. This decision is based on the futility analysis from the proof-of-concept trial phase II clinical study carried out in Europe in monotherapy in endometrial cancer, and on the phase I/II clinical study results obtained in metastatic prostate and breast cancers.

The futility analysis of the European study in patients suffering from endometrial cancer demonstrates that the primary endpoint will not be reached (patients on treatment for more than 6 months without progression) and that the superiority will not be demonstrated with Irosustat versus megestrol acetate in terms of progression free survival (PFS). Thus, Ipsen has decided to discontinue the development of Irosustat in monotherapy. Of note, the treatment was well tolerated and has shown an inhibition of the steroid sulfatase associated with a significant reduction in the levels of some circulating steroid hormones and with in some patients, prolonged clinical partial responses, demonstrating the clinical interest of sulfatase inhibition.

On the basis of this clinical safety profile associated with the reduction of hormonal parameters and with this potentially encouraging clinical efficacy signal in monotherapy, Ipsen will explore options to develop Irosustat in combination with other hormonal therapies in hormone-dependent cancers. This perspective comes in line with the recommendation of clinical expert committees.

**About Irosustat**

Irosustat is a first-in-class orally available irreversible steroid sulfatase (STS) inhibitor. The steroid sulfatase pathway gives rise to oestrone and dehydroepiandrosterone (DHEA) that in turn produce oestradiol and androstenediol (Adiol) that can both stimulate the growth of hormone-dependent tumors. This compound has been tested for postmenopausal metastatic breast cancer as well as in PI/II clinical development for castrate resistant prostate cancer. There are three Ipsen sponsored ongoing clinical studies for which Ipsen is discontinuing patient recruitment.

**About this phase II European trial in endometrial cancer**

The European clinical trial compares single-agent Irosustat to megestrol acetate (MA) in post-menopausal women with histologically confirmed hormone receptor positive endometrial cancer, presenting with recurrent or advanced disease not eligible for treatment with surgery and radiotherapy.



The primary endpoint for the study was the proportion of patients who have neither progressed nor died after 6 months of treatment with Irosustat. Progression free survival (PFS), clinical benefits and overall survival were evaluated as secondary endpoints.

### **About Endometrial Cancer**

Endometrial cancer, which develops from the inner lining of the uterus, is the most common cancer found in the female reproductive system.

According to the American Cancer Society, about 40,100 new cases of endometrial cancer were diagnosed in the United States and approximately 7,470 women died from this disease in 2008. There is a strong medical need for new products to be available in this indication.

### **About Ipsen**

Ipsen is a global biopharmaceutical group, with sales exceeding €1.1 billion in 2010. The Group has total worldwide staff of more than 4,400 employees, of which more than 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 2010, R&D expenditure totaled more than €220 million, above 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 [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. 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.

**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

**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

**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