



Press release

## **Ipsen establishes optimal biological dose for BN83495 steroid sulphatase (STS) inhibitor in ER-positive metastatic breast cancer**

### **Preliminary results of on-going Ipsen-sponsored phase I in ER-positive metastatic breast cancer trial presented at the 32<sup>nd</sup> San Antonio Breast Cancer Symposium (SABCS)**

**Paris (France), 14 December 2009** - Ipsen (Euronext: FR0010259150; IPN) today announced the preliminary results of a phase I trial in metastatic breast cancer with BN83495, Ipsen's lead and first-in-class orally available irreversible steroid sulfatase (STS) inhibitor. In the course of the study, the optimal biological dose was determined as 40 mg once daily oral administration for future phase II trials in this indication.

Preliminary results were the subject of a poster (#4097) entitled "A Phase I Dose Escalation Study of Steroid Sulfatase Inhibitor BN83495 (STX64) in Postmenopausal Women with ER-Positive Breast Cancer" presented at the 32<sup>nd</sup> San Antonio Breast Cancer Symposium held from December 9 to December 13, 2009, in San Antonio (Texas, USA).

The compound is currently in further clinical development for advanced endometrial cancer (phase II) as well as in Phase I clinical evaluation for castrate resistant prostate cancer in North America.

**Professor R. Charles Coombes**, Imperial College, Clinical Professor, Division of Surgery, Oncology, Reproductive Biology and Anaesthetics London, UK, lead author of the poster said: *"To date, four of the patients who received BN83495 had tumours that remained stable for at least 6 months. One of these had cutaneous metastases that improved after one month of treatment. This is very encouraging, as these women are patients who are reaching the end of their hormonal treatment options. Importantly, BN83495 was well tolerated at the selected dose."* He added: *"I am confident that BN83495 will become a new hormonal option in the treatment of post-menopausal women with ER-positive metastatic breast cancer"*.

**Stéphane Thiroloix**, Executive Vice-President, Corporate Development commented: *"Metastatic breast cancer clearly deserves R&D effort to identify new hormonal agents that can delay disease progression and prolong overall survival. Following this important clinical milestone, we look forward to progressing the global development of BN83495 in this indication and in other selected hormone-dependent cancer indications."*



### **About the study**

Thirty-five post-menopausal women with estrogen receptor (ER) positive metastatic breast cancer, having already received one or two different types of hormonal therapy for their disease, were treated with increasing doses of BN83495 given orally once daily.

#### Key findings are:

- The primary endpoint of determining the optimal biological dose (OBD) was met. It was established as being once daily oral 40 mg. This dose will be used for future phase II trials in this indication.
- An almost complete (95%) inhibition of the target enzyme (STS) was achieved in peripheral blood mononuclear cells at the 40 mg dose level. Thus, it resulted in a decrease of circulating steroid hormones.
- BN83495 was well-tolerated with no Grade 3 or higher toxicity observed during the first 28 days of treatment.
- Four patients in the three higher dose groups had stable disease > 6 months (according to RECIST criteria)

The trial presented at SABCS is ongoing and is being conducted in five centres in France, Belgium and the UK. 15 additional patients are being enrolled to evaluate metabolic anti-tumour activity.

### **About BN83495**

Ipsen's lead oncology development candidate, BN83495, 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 tumours.

### **About Metastatic Breast Cancer**

Breast cancer is the second most common form of cancer and the second leading cause of cancer death among American women. In 2009 in the USA, according to the American Cancer Society, an estimated 192,000 women will be diagnosed with breast cancer and approximately 40,000 will die from the disease. Approximately 75 percent of women with newly diagnosed metastatic breast cancer are ER+.

### **About SABCS**

The SABCS is one of the largest annual symposium in the world devoted to breast cancer research and physician education. The symposium provides an important venue for cancer experts to review the latest information on the experimental biology, etiology, prevention, diagnosis and therapy of breast cancer and premalignant disease.

### **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 medicine, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and haematology), and primary care products which contribute significantly to its research financing. The location of its four Research & Development centres (Paris, Boston, Barcelona, 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.

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