

Press Release

## **Ipsen announces the signature of a co-promotion agreement with Novartis for Exforge<sup>®</sup> in France**

**Paris (France), 28 January 2009** – Ipsen (Euronext: IPN) announced today that it has signed an agreement with Novartis for the co-promotion in France of the antihypertensive drug Exforge<sup>®</sup>. Already in partnership with Novartis since 2003 in the area of hypertension, with the co-marketing in France of Nisis<sup>®</sup> & Nisisco<sup>®</sup>, Ipsen's new agreement strengthens the commitment of its French teams to the management of cardiovascular risk factors.

Hypertension is currently the leading cause of deaths worldwide<sup>1</sup>. Despite simple screening and the existence of effective therapies, this disease remains under-diagnosed and insufficiently treated. Available since August 2007, Exforge<sup>®</sup> combines in a single tablet the power of two of the most widely-prescribed and widely studied antihypertensive drugs: valsartan, a sartan issued from Novartis research, and amlodipine, a calcium inhibitor. In addition, Exforge<sup>®</sup> meets the need for increased efficacy to allow for better control of the condition in a higher number of patients, in accordance with the guidelines issued by the French National Health Authority (HAS)<sup>2</sup>.

**Christophe Jean**, Executive Vice-President, Chief Operating Officer of the Ipsen Group, stated: *"After the success of Nisis<sup>®</sup> and Nisisco<sup>®</sup>, we are delighted to extend our collaboration with Novartis Pharma, and to be able to offer patients and physicians a product with high added value in the field of cardiovascular medicine, which represents a major public health priority."* He added: *"This partnership will mean that this product will be available to Ipsen's existing sales force in France, in line with our current strategy to optimize our primary care franchise."*

### **About hypertension**

Hypertension remains a major public health concern. Often asymptomatic, it can nevertheless have devastating effects on vital organs, causing arterial lesions that weaken the heart, kidneys and brain<sup>2</sup> and significantly increase the risk of cardiovascular diseases, the leading cause of deaths in France. Eight million people are treated for this condition in France<sup>3</sup>, but despite the efficacy of different classes of antihypertensive drugs, blood pressure values are still not controlled in seven out of ten treated patients<sup>4</sup>. It is also important to note that half of all hypertensive patients need to use at least two medications to achieve satisfactory control of their blood pressure<sup>5</sup>.

### **About Exforge<sup>®</sup>**

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<sup>1</sup> Ezzati et al. Selected major risk factors and global regional burden of disease. Lancet 2002; 360: 1347-60.

<sup>2</sup> HAS. Prise en charge des patients adultes atteints d'hypertension artérielle essentielle. Actualisation 2005. Recommandations. Juillet 2005

<sup>3</sup> Girerd et al. Évolution dans l'utilisation des traitements non médicamenteux et médicamenteux pour le traitement de l'hypertension artérielle en France. Enquête FLASH 2004. Arch Mal Cœur Vaiss 2005 ; 98 ; 813-6

<sup>4</sup> Chobanian AV, et al. and The National High Blood Pressure Education Program Coordinating Committee. The seventh report of the Joint National Committee on prevention detection, evaluation and treatment of high blood pressure. Hypertension 2003 ; 42: 1206-52

<sup>5</sup> Brown MJ, Cruickshank JK, Dominiczak AF, et al. Better blood pressure control: how to combine drugs. Journal of Human Hypertension 2003 ; 17: 81-6 (Brown, 2003 ; Girerd, 2005)

Hypertension is a complex condition that is difficult to treat, but where combination therapies are able to optimize treatment, in patients who do not achieve adequate blood pressure control.

At the set up of a drug combination, it is advised<sup>2</sup> to choose associations that have proved their efficacy (additive effect or potentiation), their good tolerance from a pharmacological point and have been validated by clinical studies. In practice, preferred following associations are recommended:

- Beta-blocker and thiazide diuretics;
- Thiazide diuretics and ACE-I (Angiotensin-Converting Enzyme Inhibitor) (or thiazide diuretic and ARB (Angiotensin II Receptor Blocker));
- Beta-blockers and calcium channel blocker-type dihydropyridine;
- Calcium channel blocker and ACE-I (or calcium channel blocker and ARB);
- Calcium channel blocker and thiazide diuretics

The fixed combination of valsartan/amlodipine enables the treatment of hypertension in patients who do not achieve adequate blood pressure control with either component alone. The different dosage forms of the valsartan/amlodipine combination offer the possibility of individual dosage adjustments: 5 mg/80 mg, 5 mg/160 mg and 10 mg/160 mg<sup>6</sup>.

Clinical trials conducted with Exforge<sup>®</sup> have shown an additive antihypertensive effect of the two active substances, thus offering physicians synergistic efficacy in terms of blood pressure values together with a lower incidence of edemas of the lower limbs<sup>7</sup> when compared against treatment with amlodipine alone.

### **About Nisis<sup>®</sup> and Nisisco<sup>®</sup>**

Nisis<sup>®</sup> is an oral formulation containing valsartan, while Nisisco<sup>®</sup> contains valsartan and hydrochlorothiazide. The products are used in the treatment of arterial hypertension. Valsartan, one of the active substance in Nisis<sup>®</sup> and Nisisco<sup>®</sup> is a synthetic angiotensin II antagonist compound.

### **About Ipsen**

Ipsen is an innovation-driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders), 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 700 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 2007, Research and Development expenditure was about €185 million, in excess of 20% of consolidated sales, which amounted to €920.5 million while total revenues amounted to €993.8 million. 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)

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<sup>6</sup> RCP Exforge

<sup>7</sup> Data on file (Exforge Summary Clinical Efficacy). Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 07936

### **Ipsen Forward-looking statements**

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 any other 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 given that a new product can appear to be promising at a preparatory stage of development or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons. The Group must deal with or may have to deal with competition from generic that may result in market share losses, which could affect its current level of growth in sales or profitability. Furthermore, the Research and Development process involves several stages at each of which there is a substantial risk that the Group will fail to achieve its objectives and be forced to abandon its efforts in respect of 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 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.

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Its goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,700 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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