

Press release

Ipsen and Spirogen's SJG-136 shows encouraging results in the treatment of refractory solid tumours at ASCO

Paris (France), and London (United Kingdom), 2 June 2008 - Ipsen (Euronext: IPN) and Spirogen Ltd. announced today that final results from a Phase I clinical trial of the DNA sequence recognizing minor groove binder SJG-136 sponsored by the US National Cancer Institute (NCI) under a Cooperative Research and Development Agreement (CRADA) with Ipsen were presented today at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago by Dr. Igor Puzanov from Vanderbilt-Ingram Cancer Center (Nashville, USA).

SJG-136 (SG2000/BN2629/NSC 694501) is a small molecule which spans six base pairs of DNA and is currently undergoing clinical development in refractory solid tumours and haematological malignancies under the CRADA with the NCI.

The phase I results presented by Dr. Puzanov show that SJG-136 administered on a daily x 3 basis at 30 µg/m²/day (recommended phase II dosing) resulted in confirmed partial response as defined by RECIST criteria in 1 out of 6 patients evaluated and a second unconfirmed partial response. Of these two patients, one had ovarian cancer and the second a poorly differentiated ovarian carcinoma. In addition disease stabilisations lasting 3-4 months were observed in patients with Small Cell Lung Cancer (SCLC), leiomyosarcoma and bladder cancer. Importantly the direct pharmacodynamic effect of SJG-136 was evidenced by DNA crosslinkage in peripheral blood mononuclear cells (PBMCs) on Day 3 following treatment and correlated in a linear fashion with pharmacokinetic data. While delayed transient hepatotoxicity and soft tissue oedema have been observed, a premedication with dexamethasone and spironolactone diuresis can successfully manage these side effects. The phase I clinical program was supported by NIH U01 CA099177 and M01 RR00095 grants.

Stéphane Thiroloix, Executive Vice President, Corporate Development of Ipsen said: *"Though we are still in the early stages of clinical development for SJG-136, the results reported by Dr. Puzanov are encouraging and warrant further evaluation in the most refractory forms of solid and haematological tumours. This data confirms that the initial responses observed in ovarian cancer were achieved with a manageable toxicity profile using the Vanderbilt dosing schedule. We are grateful for the support of the NCI in sponsoring this phase I study and for the commitment of the Vanderbilt and Spirogen teams."*

Chris Martin, Chief Executive Officer of Spirogen stated: *"SJG-136 was rationally designed to maintain activity in refractory and hard-to-treat tumors. It is gratifying to see this translate into these early clinical results. We look forward to the Phase II trials where the plan is to use gene expression profiling to build an understanding of the role of gene on efficacy. Spirogen much appreciates the contribution of the Vanderbilt, NCI and Ipsen teams in achieving these encouraging Phase I results and a recommended Phase II regimen."*

About the Ipsen and Spirogen relationship

In May 2003, Ipsen signed a partnership agreement with Spirogen, Ltd. This partnership comprises among other a development and licensing agreement covering the development and marketing by the Group of a patented anti-cancer drug, SJG-136. Pursuant to the SJG-136 development and licensing agreement, Ipsen holds an exclusive worldwide license on Spirogen's patents and expertise related to the manufacture, use and sale of SJG-136 and its analogue or replacement compounds. At 31 December 2007, Ipsen held 19.94% of Spirogen's share capital.

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 Eurolist by Euronext™ (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.ipсен.com.

Ipsen Forward-looking statements

The forward-looking statements and targets contained herein are based on Ipsen's management's 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. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Moreover, 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 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. Ipsen 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 also faces the risk of product liability claims relating to their safety, notably for its neuromuscular disorders products (marketed under the brand name Dysport® notably) that may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed. The Group is subject to adverse event reporting pharmacovigilance obligations that require to report to regulatory authorities if the Group's products are associated with serious adverse events, including patient death or serious injury. These adverse events, among others, could result in additional regulatory constraints, such as additional requests from the regulatory authorities during reviews of applications filed for marketing approvals in various countries which could delay the launch time of the given products in new markets, the performance of costly post-approval clinical studies or revisions to the approved labeling limiting the indications or patient population for the Group's products or could even lead to the withdrawal of a product from the market. Such events could harm the sales of the product and therefore have a material negative impact on the Group's financial situation. Furthermore, any adverse publicity associated with such an event could cause consumers to seek alternatives to the Group's products, which may cause sales to decline, even if the Ipsen product at stake is ultimately determined not to have been the cause of the reported serious adverse event. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French *Autorité des Marchés Financiers*.

About Spirogen

Spirogen is a privately owned UK company, founded in 2001 by Professor David Thurston and Dr Phillip Howard (now at the School of Pharmacy, University of London), Professor John Hartley (University College London) and Dr Chris Martin. The company is pioneering the discovery and development of a unique class of low molecular weight sequence-specific DNA-interactive drugs designed to treat gene-mediated diseases.



Spirogen's proprietary chemistry-based platform technology forms the basis of a research effort that began over a decade ago to develop novel therapeutics with potential application in a number of markets.

Spirogen's initial investors were: Cambridge Research Bioventures (lead investor), Xenva Ltd, CRIL and Bloomsbury Bioseed Fund.

Spirogen's website is www.spirogen.com

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