

Press release

## Ipsen acquires exclusive marketing rights of BLI-800 from Braintree for colonic cleansing before colonoscopy

- A new drug in the primary care gastro-enterology franchise of Ipsen

**Braintree (Massachusetts, United States) and Paris (France), 9 October 2009** – Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical Group and Braintree Laboratories, Inc., a US-based company specializing in the development, manufacturing and marketing of specialty pharmaceuticals, announced today the signature of an agreement for the exclusive manufacturing, marketing and distribution rights of Braintree's proprietary formulation BLI-800 in colonic cleansing before colonoscopy, the best diagnostic procedure for colorectal cancer screening. Subject to obtaining its relevant marketing approvals, BLI-800 will allow colonic cleansing with reduced volumes of liquid ingested compared to some existing drugs, including Ipsen's currently marketed Fortrans®. The agreement covers countries within the European Union, Commonwealth of Independent States, selected Asian countries (including China) and some North African countries.

In the context of this agreement, Braintree will receive payments upon achievement of certain milestones such as product launches and commercial thresholds. Additionally, Braintree will receive royalties on Ipsen's sales.

**Stéphane Thiroloix**, Executive Vice-President, Corporate Development, Ipsen Group said "*Ipsen's business model is based on the complementarity of a strategic focus on targeted disease areas (oncology, endocrinology, neurology, haematology) and an optimization of our primary care products portfolio in selected territories. The agreement with Braintree over BLI-800 will further contribute to the implementation of our Primary Care strategy by complementing Ipsen's well established gastro-enterology portfolio. Once approved, BLI-800 will provide physicians and patients with a valuable agent for pre-colonoscopy colonic cleansing, particularly in the screening of colorectal cancer.*"

**Harry P. Keegan III**, CEO of Braintree Laboratories, Inc. added: "*This agreement represents a major step in Braintree's pursuit of the globalization of our portfolio. We are very confident in the far-reaching and accomplished development, marketing and distribution networks that Ipsen has established across the territories involved in this agreement.*"

### About the condition

Studies show that colonoscopy decreases the risk of cancer death by more than 80%, provided the screening is started by the age of 50 and repeated every 5 or 10 years.<sup>1</sup> Colonoscopy is also the preferred procedure for the screening of colorectal inflammatory diseases<sup>2</sup>. With 655,000 deaths worldwide per year, colorectal cancer is the third most common form of cancer and the

<sup>1</sup> Winawer SJ, Zauber AG, Ho MN, O'Brien MJ, Gottlieb LS, Sternberg SS, Waye JD, Schapiro M, Bond JH, Panish JF, Ackroyd F, Shike M, Kurtz RC, Hornsby-Lewis L, Gerdes H, Stewart ET, The National Polyp Study Workgroup. Prevention of colorectal cancer by colonoscopic polypectomy. *N Engl J Med* 1993;329:1977-81. PMID 8247072.

<sup>2</sup> American Society for Gastrointestinal Endoscopy (ASGE) guidelines : Gastrointest Endosc 2006, 63 (4) : 558-65



third leading cause of cancer-related death in the Western world.<sup>3</sup> Most colorectal cancers arise from adenomatous polyps. These lesions can be detected and removed during colonoscopy.

### About the agreement

Braintree's proprietary formulation, which is in pre-registration phase, has demonstrated a remarkable efficacy for colonic cleansing in 2 pivotal Phase III studies (more than 750 randomized adult patients).

Under the terms of agreement Ipsen gains access to the Braintree's proprietary formulation. Ipsen will have primary responsibility for the product's registration in the countries covered by the agreement. Braintree will receive compensation through a mix of milestones and royalties.

### About Braintree Laboratories, Inc.

Braintree Laboratories, Inc. is a privately held specialty pharmaceutical company that was founded in 1982. Braintree has four prescription product lines in the US market in two therapeutic categories — colon cleansing preparations and a GERD (Gastro Esophageal Reflux Disease) treatment. Braintree first pioneered the formulation and distribution of prescription GI (gastro-intestinal) bowel preparations with GOLYTELY® (PEG-3350 and electrolytes for oral solution) in 1984. Among other prescription and OTC products, Braintree has developed two additional novel bowel preparations: NuLYTELY® (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) and HalfLyteLy® and Bisacodyl Tablets Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablets). HalfLyteLy® and Bisacodyl Tablets Bowel Prep Kit is the current market leader among branded prescription bowel preparations in the United States.

### 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 4,200. 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).

<sup>3</sup> "Cancer". World Health Organization. February 2006. <http://www.who.int/mediacentre/factsheets/fs297/en/>. Retrieved 2007-05-24.



### 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 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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