

## **Eziclen<sup>®</sup> / Izinova<sup>®</sup> a new product for bowel cleansing successfully completed European decentralised registration procedure**

**The launch of Braintree's drug is expected by end 2013**

**Braintree (Massachusetts, United States) and Ipsen (Paris, France), 7 February 2013** - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical group and Braintree Laboratories, Inc., a US-based company specializing in the development, manufacturing and marketing of specialty pharmaceuticals announced today that Eziclen<sup>®</sup> / Izinova<sup>®</sup> (BLI-800)<sup>1</sup> successfully completed its European decentralized registration procedure involving sixteen countries. The product will be indicated in adults for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualization including bowel endoscopy and radiology or surgical procedure).

Each Member States [France (reference member state), Belgium, Czech Republic, Estonia, Germany, Greece, Italy, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Romania, Spain and UK] should now adopt a national decision within 30 days. In practice the grant of the national marketing authorization may vary from one to several months.

**Jean Fabre, Senior Vice-President Intercontinental Operations and Franchise "Primary Care", Ipsen** stated: *"The completion of the decentralized procedure for Eziclen<sup>®</sup>/Izinova<sup>®</sup> (BLI-800) is an important step forward to national marketing authorizations in Europe. The availability of Eziclen<sup>®</sup>/Izinova<sup>®</sup> (BLI-800) will provide physicians and patients with a valuable agent for pre-colonoscopy colonic cleansing, particularly in the screening of colorectal cancer. This decision gives also perspectives for our plant in Dreux where Eziclen<sup>®</sup>/Izinova<sup>®</sup> will be manufactured".*

**Harry Keegan, President of Braintree Laboratories, Inc.** stated: *"Braintree looks forward to the introduction of this important product to European physicians and patients. Braintree is excited and enthusiastic to continue our relationship with Ipsen".*

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<sup>1</sup> The drug will be registered under the trade name Eziclen<sup>®</sup> in the large majority of the concerned EU countries and under the name Izinova<sup>®</sup> in the other few countries including France & UK

### **About the condition**

Colorectal cancer is the second leading cause of cancer-related deaths in Western countries. Colorectal-cancer mortality and incidence are reduced with survey programs, and colonoscopy is recommended in that objective. The quality of bowel cleansing is key for the efficiency of colonoscopy (detection rate), as well as other visualization techniques (videocapsule) and current endoscopic therapies as polypectomy, endoscopic mucosal resection.

### **About Eziclen<sup>®</sup> / Izinova<sup>®</sup>**

Eziclen<sup>®</sup> / Izinova<sup>®</sup> a new bowel cleansing preparation, is a sulphate-based formulation (sodium, magnesium and potassium sulphates).

- The clinical efficacy and safety of Izinova<sup>®</sup> / Eziclen<sup>®</sup> was demonstrated in two randomized, actively-controlled (versus a 2-liter polyethylene glycol (PEG) plus electrolytes solution), multi-centre, investigator-blinded phase III pivotal clinical trials which confirmed the non-inferiority of BLI-800 versus the comparator with regards to the bowel cleansing effectiveness.
- The dose for cleansing the colon will require two administrations of approximately 0.5 litre / 16 ounces of the product diluted in water, each followed by approximately 1 litre, 32 ounces, of clear liquids, each.

Izinova<sup>®</sup> / Eziclen<sup>®</sup> (BLI800) was developed in the USA by Braintree and has been approved by the FDA since 2010. Launched in the US in September 2010, BLI800 (SuPrep<sup>®</sup>) has gained acceptance in the hyper competitive U.S. colonoscopy preparation market.

### **About the agreement between Ipsen and Braintree**

In 2009, Ipsen acquired the exclusive manufacturing, marketing and distribution rights of Braintree's proprietary formulation BLI-800. The agreement covers countries within the European Union, Commonwealth of Independent States, selected Asian countries (including China) and some North African countries.

### **About Braintree**

Braintree is a United States based specialty pharmaceutical company formed in 1982. Braintree has been an innovative development company which has developed drugs in gastroenterology, nephrology, primary care and pediatrics. The company has commercial operations in the United State including development, manufacturing and sales. Braintree works through licensees and distributors outside the United States.

## **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2012. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and uro-oncology. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2011, R&D expenditure totalled more than €250 million, above 21% of Group sales. The Group has total worldwide staff of close to 4,500 employees. 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 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. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

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. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from Generics that might translate into a loss of market share.

Furthermore, the Research and Development process involves several stages each of which involves 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 cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance.

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:**

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