

Ipsen Announces FDA Approval of a New Delivery Device for Somatuline[®] Depot[®] (lanreotide) Injection

Device Incorporates Safe'n'Sound[®] Syringe Technology and Offers Enhanced Safety Features

BASKING RIDGE, N.J., November 6, 2014 – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced that the U.S. Food and Drug Administration (FDA) has approved a new device to deliver Somatuline[®] Depot[®] (lanreotide). The device has an enhanced, prefilled, low-volume syringe that supports full-dose delivery with no reconstitution requirements.

The single use syringe is available in 60 mg, 90 mg and 120 mg dosages. Additional safety features have also been incorporated, including a retractable needle guard, which automatically engages to help avoid needle stick injury, a common hazard for healthcare workers. According to the Centers for Disease Control and Prevention, each year 385,000 needlestick and sharps-related injuries, or an average of approximately 1,000 incidents a day, are sustained by U.S. hospital-based healthcare personnel. The retractable needle in this device was designed with the Needlestick Safety and Prevention Act and accompanying Occupational Safety & Health Administration (OSHA) regulations in mind. Needlestick safety remains a continuing concern of healthcare worker advocacy groups including the American Nurses Association.

The device is manufactured without latex or natural dry rubber, which is important because healthcare workers can develop allergies to these substances over time. The sturdy construction includes a transparent syringe to help verify successful drug delivery, as well as a plunger protector to aid in preventing accidental product loss. When the new device enters the marketplace, each shipment of Somatuline[®] Depot will be accompanied by robust instructions for use which provide step-by-step instructions to healthcare professionals for proper administration of the product.

The updated design has been available in the EU since January 2012 and will be available in the U.S. beginning in January 2015.

“We are continually looking for ways to better serve those who rely upon our medications,” said **Cynthia Schwalm, President and CEO of Ipsen Biopharmaceuticals, Inc.** “For patients who must get regular injections of Somatuline Depot, and the healthcare professionals that administer their medication, this updated design, incorporating Safe'n'Sound[®] syringe technology, can help support full dose delivery and help prevent accidental needle sticks, an important benefit for those on the frontlines of delivering care.”

About Somatuline[®] Depot

Somatuline[®] Depot Injection is a somatostatin analog indicated for the long-term treatment of patients with acromegaly who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

The active substance in Somatuline[®] Depot is lanreotide acetate, a somatostatin analogue that inhibits the secretion of several endocrine, exocrine and paracrine amines and peptides.

Select Important Safety Information about Somatuline[®] Depot for Patients

Somatuline[®] Depot may cause serious side effects including:

- Gallstones
- Changes in your blood sugar (high blood sugar or low blood sugar)
- Slow heart rate
- High blood pressure

The most common side effects of Somatuline[®] Depot include diarrhea, gallstones, stomach area (abdominal) pain, nausea, and pain, itching, or a lump at the injection site.

These are not all the possible side effects of Somatuline[®] Depot. Tell your healthcare professional if you have any side effect that bothers you or that does not go away.

Before you receive Somatuline[®] Depot, talk to your healthcare professional about all of your medical conditions, including:

- Gallbladder, thyroid, heart, kidney, or liver problems
- Diabetes
- Allergy to latex or natural dry rubber
- Pregnancy or plans to become pregnant
 - It is not known if Somatuline[®] Depot could harm your unborn baby
- Breast-feeding or plans to breast-feed
 - It is not known if Somatuline[®] Depot passes into breast milk

Any medicines (prescription and nonprescription) you are taking, including:

- Insulin or other diabetes medicines
- A cyclosporine (such as Gengraf[™], Neoral[®], or Sandimmune[®])
- A medicine called bromocriptine (such as Parlodel[®])
- Medicines that lower your heart rate (such as beta blockers)

While on Somatuline[®] Depot:

- Tell your healthcare professional if you have sudden pain in your upper right stomach (abdominal) area or in your right shoulder or between your shoulder blades, or if you have yellowing of your skin and whites of your eyes, fever with chills, or nausea as these could be symptoms related to gallstones.
- If you have diabetes, test your blood sugar as your healthcare professional tells you to. Your healthcare professional may change your dose of diabetes medicine especially when you first start receiving Somatuline[®] Depot or if your dose of Somatuline[®] Depot changes.

- Before each treatment, read the Patient Information that comes with each Somatuline[®] Depot package as there may be new information. Talk with your healthcare professional about your medical condition or your treatment. Your healthcare professional is your primary source of information about treatment.

Please see the Patient Information for Somatuline[®] Depot at http://somatulinedepot.com/assets/files/fpo_patient_pi.pdf.

Select Important Safety Information about Somatuline[®] Depot for Healthcare Professionals

Contraindications

Somatuline[®] is contraindicated in patients with hypersensitivity to lanreotide or related peptides.

Warnings and Precautions

- Somatuline[®] may reduce gallbladder motility and lead to gallstone formation. Periodic monitoring may be needed.
- Patients may experience hypoglycemia or hyperglycemia. Glucose level monitoring is recommended and antidiabetic treatment adjusted accordingly.
- Somatuline[®] may decrease heart rate. In cardiac studies, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension. Dose adjustment of coadministered drugs that decrease heart rate may be necessary.
- Somatuline[®] may decrease bioavailability of cyclosporine. Cyclosporine dose may need to be adjusted.

Adverse Reactions

The most common adverse reactions (incidence >5%) were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reaction (9%), constipation (8%), flatulence (7%), headache (7%), arthralgia (7%), vomiting (7%), and loose stools (6%).

Use in Special Populations

Patients with moderate and severe renal impairment or moderate and severe hepatic impairment: Initial dose is 60 mg every 4 weeks.

Please see the full Prescribing Information for Somatuline[®] Depot at http://somatulinedepot.com/pdf/pi_2013november.pdf.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding EUR1.2 billion in 2013. 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 2013, R&D expenditure totaled close to EUR260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 4,600 employees worldwide. 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, visit www.ipsen.com.

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. 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. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. 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 generic products 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. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to

accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. 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 fulfill 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.

SOMATULINE DEPOT is a registered trademark of IPSEN PHARMA S.A.S.

SAFE'N'SOUND is a registered trademark of NEMERA LA VERPILLIERE SAS.

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