Santhera and Ipsen Enter into Licensing Agreement for Fipamezole for the Treatment of Dyskinesia in Parkinson’s Disease

Liestal (Switzerland) and Paris (France) - September 3, 2010 – Santhera Pharmaceuticals (SIX: SANN) and Ipsen (Euronext: IPN; ADR: IPSEY) today announced a license agreement for the development and commercialization of fipamezole (antagonist of the adrenergic alpha-2 receptor) for territories outside of North America and Japan. This first-in-class compound is currently under investigation for the treatment of levodopa-induced dyskinesia in Parkinson’s Disease. Initiation of a first Phase III study by Biovail is scheduled for 2011. Today’s agreement stipulates a data sharing, under which Ipsen has the right to use these data for its own purposes.

Klaus Schollmeier, Chief Executive Officer of Santhera, said: “We are pleased to be partnering with Ipsen to advance the potential of fipamezole as a possible first treatment for Dyskinesia in Parkinson’s Disease. Dyskinesia is a condition that is functionally disabling to patients and limits effective treatment of the underlying Parkinson’s Disease. Ipsen complements perfectly our North American partnership with Biovail. Today’s agreement is another strong endorsement for fipamezole and proves that our out-licensing strategy for this innovative drug candidate is working well for the benefit of all parties.”

Stéphane Thiroloix, Ipsen’s Executive Vice-President, Corporate Development said: “L-dopa induced dyskinesia is a serious unmet medical need, and we look forward to providing patients with a positive transformation in the management of their condition. This agreement with Santhera will further enrich Ipsen’s pipeline with a new promising first-in-class compound thus complementing our fast-growing neurology franchise, in clear medical and operational synergy with our existing portfolio. We have been impressed with the scientific and development capabilities of both Santhera and Biovail. Ipsen will benefit from the Biovail development and collaborate fully to achieve regulatory filings excluding North America planned for 2015.”

About the agreement

Under the agreement, Ipsen acquires the rights to fipamezole outside the United States, Canada and Japan for an upfront payment of EUR 13 million and additional payments contingent to future development, regulatory and sales milestones of up to EUR 128 million. In addition, Santhera is entitled to royalty payments on Ipsen’s future net sales.

In a similar transaction in August 2009, Santhera granted Biovail (Canada’s largest specialty pharmaceutical company) the development and commercial rights to fipamezole in the United States and Canada. The first Phase III study is scheduled for 2011 in the treatment of
levodopa induced dyskinesia. Santhera has the right to use and sublicense data generated by Biovail for development and commercialization purposes outside of the United States and Canada. Today’s agreement stipulates that Ipsen has acquired the right to use these data for its own development and commercialization purposes outside the United States, Canada and Japan, whereas the Japanese rights for fipamezole remain with Santhera.

About Fipamezole

Fipamezole is an antagonist of the adrenergic alpha-2 receptor with a novel mode of action in the treatment of dyskinesia in Parkinson’s disease. The rationale behind the development is to increase noradrenergic release in certain areas of the brain resulting in the rebalance of the distorted brain network and potentially alleviating symptoms of advanced Parkinson’s disease such as dyskinesia, motor fluctuations and other disturbing symptoms without exacerbating the underlying Parkinsonian features of the disease. Encouraging phase 2b data exist in support of this rationale. Loss of motor control and dyskinesia is feature of the majority of Parkinson patients after 5 years of levodopa therapy, and remains a clear unmet medical need.

About Ipsen

Ipsen is a global biopharmaceutical group, with sales exceeding 1 billion euros in 2009. The Group has total worldwide staff of more than 4,400 employees, of which nearly 900 contribute to the discovery and development of innovative drugs for patient care. Ipsen’s development strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and on primary care drugs. This strategy is supported by an active policy of partnerships. Ipsen’s research & development (R&D) centers and its peptide & protein engineering platform give the Group a strong competitive edge. In 2009, R&D expenditure totaled close to €200 million, representing nearly 20% of Group sales. 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 our website at www.ipsen.com.

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of severe neuromuscular diseases, an area of high unmet medical need which includes many orphan indications with no current therapy. Santhera’s first product, Catena® to treat Friedreich’s Ataxia, is marketed in Canada. Following positive clinical results in Leber’s Hereditary Optic Neuropathy, the drug is prepared for regulatory filings for marketing approval. Catena® is also being investigated in a Phase III study in Duchenne Muscular Dystrophy. Commercial rights in Europe for Friedreich’s Ataxia and Duchenne Muscular Dystrophy are licensed to Takeda Pharmaceutical. Santhera’s second compound fipamezole has demonstrated efficacy in reducing levodopa-induced Dyskinesia in Parkinson’s Disease. Phase III development and commercialization rights in the United States and Canada are partnered with Biovail, and outside North America and Japan with Ipsen. For further information,
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 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 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. 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 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.

Santhera Disclaimer/Forward-looking statements

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