

Telesta Therapeutics and Ipsen announce exclusive license agreement for MCNA¹ for the treatment of non-muscle invasive bladder cancer in major ex-United States territories

Paris (France) and Montreal (Canada), 28 October 2015 - Ipsen (Euronext: IPN - ADR: IPSEY) and Telesta Therapeutics Inc. (TSX:TST; PNK:BNHLF) today announced that they have entered into an exclusive licensing agreement for Ipsen to develop and commercialize MCNA¹ for the treatment of high risk non-muscle invasive bladder cancer (NMIBC) in all countries of the world, with the exception of the United States, where Telesta is establishing commercial operations, Canada, South Africa, Mexico, South Korea and Japan.

Telesta recently filed a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for MCNA for the treatment of high risk non-muscle invasive bladder cancer patients who are refractory or relapsing from BCG front-line treatment. The FDA has assigned priority review to Telesta's BLA with a review (PDUFA) date of February 27, 2016. Telesta retains full and sole ownership of MCNA rights in the US and Japan and will be responsible for the commercial launch of MCNA in the United States while Ipsen will initiate discussions with regulatory authorities to identify the regulatory path and potential requirements for the product in Europe and other key licensed territories.

Commenting on this partnership, **Dr. Michael Berendt, Chief Executive Officer and Chief Scientist of Telesta Therapeutics** noted: *"Ipsen is the ideal commercial partner to bring MCNA to patients in the key pharmaceutical markets outside of the United States. They are a recognized development and commercial leader in the field of uro-oncology and are committed to collaborating with our team to ensure that MCNA is brought forward as rapidly as possible to provide a therapeutic option for this underserved patient population. Their extensive knowledge of the regulatory and commercial landscape, their commercial presence in more than 100 countries across the globe, as well as their commitment to their core urology franchise, particularly bladder cancer, is why we are convinced that they will successfully bring MCNA to urologists and their patients, outside of the United States, and generate significant value for Telesta's shareholders."*

Marc de Garidel, Chairman and Chief Executive Officer of Ipsen stated: *"Ipsen is pleased to enter into a partnership with Telesta Therapeutics for Europe and key Rest of the World territories. We believe MCNA, which received priority review from FDA, is a promising second line bladder cancer treatment that would perfectly fit our urology-oncology portfolio in Europe."* **Marc de Garidel** added: *"This licensing agreement fits our business development strategy, focusing on selected niche therapeutic areas"*.

¹ *Mycobacterium phlei* cell wall-nucleic acid complex

Under the financial terms of the agreement, Telesta is eligible to receive up to US\$137 million in upfront and milestone payments comprising a US\$10 million upfront payment and additional payments contingent upon achievement of regulatory and sales milestones. In addition, Telesta is eligible to receive meaningful tiered double-digit royalties on net sales of MCNA in the licensed territories.

About MCNA

MCNA is a biologic therapy developed to provide high risk non-muscle invasive bladder cancer patients who are refractory to or relapsing from first line therapy with bacillus Calmette-Guérin (BCG), with a therapeutic alternative to surgery. MCNA is derived from the cell wall fractionation of a non-pathogenic bacteria. Its activity is believed to be through a dual mechanism of immune stimulation and direct anti-cancer effects. MCNA was developed to be delivered as a sterile suspension for intravesical administration by urologists and urology nurses, following the same dosing paradigm as first line BCG therapy, with the advantage that it can be prepared, handled and disposed of easily and safely. The efficacy, duration of response and safety data from MCNA's pivotal Phase 3 trial was recently published² in The Journal of Urology. The FDA has set February 27, 2016 as its review goal date for MCNA's potential approval. MCNA offers a new therapeutic option for high risk NMIBC patients and, if approved, will represent the first new therapeutic approved for these patients in the United States since 1989.

About non-muscle invasive bladder cancer (NMIBC)

Treatment options for high risk NMIBC patients who fail first line BCG treatment are extremely limited and treatment guidelines in most countries around the world call for radical cystectomy, which entails a surgical removal of the bladder and adjacent organs and glands. Bladder removal is a complex surgery associated with at least 28% to 45% surgical complications and up to 8% mortality, in addition to negatively impacting multiple aspects of quality of life. Patients who refuse or are not medically fit to undergo bladder removal face an increased risk of progression to muscle-invasive disease, likely leading to metastases and death.

About Telesta Therapeutics Inc.

Telesta Therapeutics Inc. is a late stage therapeutics company with near term commercial potential focused on the manufacturing, marketing and licensing/acquisition of proprietary and innovative therapies for the global health market. The Company's primary goal is to develop and commercialize products that advance human health and increase shareholder value. For more information, please visit www.telestatherapeutics.com.

About Ipsen

Ipsen is a global specialty-driven biotechnological group with total sales exceeding €1.2 billion in 2014. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in 30 countries. 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 urology-oncology. Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, bladder cancer or neuroendocrine tumors. Ipsen also has a significant presence in primary care. 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, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis, France; Slough/Oxford, UK; Cambridge, US). In 2014, R&D expenditure totaled close to €187 million, representing about 15% of Group sales. The Group has more than 4,500 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

² [http://www.jurology.com/article/S0022-5347\(14\)04590-X/abstract](http://www.jurology.com/article/S0022-5347(14)04590-X/abstract)

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

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. 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 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:

Telesta Therapeutics Inc.

Donald Olds, Chief Operating Officer
Telesta Therapeutics Inc.
Telephone: (514) 394-7921
Donald.Olds@telestatherapeutics.com

Ipsen:

Media

Didier Véron
Senior Vice-Président, Public Affairs
and Communication
Tel.: +33 (0)1 58 33 51 16
Fax: +33 (0)1 58 33 50 58
E-mail: didier.veron@ipsen.com

Brigitte Le Guennec
Corporate External Communication Manager
Tel.: +33 (0)1 58 33 51 17
Fax: +33 (0)1 58 33 50 58
E-mail : brigitte.le.guennec@ipsen.com

Financial Community

Stéphane Durant des Aulnois
VP Investor Relations
Tel.: +33 (0)1 58 33 60 09
Fax: +33 (0)1 58 33 50 63
E-mail: stephane.durant.des.aulnois@ipsen.com

Côme de La Tour du Pin
Investor Relations Manager
Tel.: +33 (0)1 58 33 53 31
Fax: +33 (0)1 58 33 50 63
E-mail: come.de.la.tour.du.pin@ipsen.com