



Press release

GTx and Ipsen expand partnership

Paris (France) and Memphis (USA), 23 March 2010 – Ipsen (Euronext: FR0010259150; IPN) and GTx, Inc. (Nasdaq: GTXI) today announced the expansion of their partnership for the development and commercialization of toremifene 80 mg for the reduction of fractures in men with advanced prostate cancer on androgen deprivation therapy (ADT) and toremifene 20 mg for the prevention of prostate cancer in high risk patients with High Grade Prostatic Intraepithelial Neoplasia lesions (HGPIN).

Under the terms of the amended collaboration agreement, Ipsen will pay GTx up to €42 million (approximately \$58 million, based on current exchange rates) in milestone payments upon the initiation, enrollment and progression of the second toremifene 80 mg Phase III clinical trial. In return, GTx has granted Ipsen:

- The right to co-promote toremifene 80 mg in the United States or, in lieu of co-promoting in the US, the right to a double digit royalty stream on net sales of toremifene 80 mg in the U.S.
- An expansion of Ipsen's licensed territory for marketing toremifene products beyond Europe, including Australia and certain countries in North Africa, the Middle East, and Asia (excluding Japan).
- Relief from Ipsen's previous contractual obligations, notably to pay GTx potential remaining milestones related to the European approval of toremifene 80 mg.
- Royalties on Ipsen's net sales of toremifene 80 mg set at a fixed low teens rate compared to a variable rate previously.
- A first right of negotiation under certain conditions for rights to GTx-758, currently in Phase II clinical trial for the first-line treatment of men with advanced prostate cancer, in Ipsen's licensed toremifene territories.

"Once the agreement is reached with the FDA on a final study protocol required for marketing approval, we will initiate the second phase III clinical trial later this year with toremifene 80 mg to reduce fractures in men with prostate cancer on androgen deprivation therapy" said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. "We are excited to expand our toremifene clinical and commercial partnership with Ipsen."

Stéphane Thiroloix, Executive Vice President, Corporate Development, Ipsen said: "This new agreement with GTx gives us expanded market reach and rights for toremifene, in what we view as significant unmet medical needs for patients suffering from prostate cancer. It will strengthen Ipsen's franchise in hormone-dependent cancers and broaden our drug range in the oncology area."

About toremifene

Toremifene is a selective estrogen receptor modulator, or SERM, developed by GTx as a daily tablet for the treatment of the multiple estrogen related side effects of androgen deprivation therapy for advanced prostate cancer and for the prevention of prostate cancer in high risk





patients with High Grade Prostatic Intraepithelial Neoplasia lesions (HGPIN). Toremifene was designed to bind to and selectively modulate estrogen receptors depending on the tissue type.

About the second toremifene 80 mg phase III clinical trial

In 2008, based upon the successful results of a first Phase III clinical trial, GTx submitted a New Drug Application to the United States Food and Drug Administration (FDA) for toremifene 80 mg for the reduction of fractures in men with prostate cancer on ADT. In October 2009, GTx received a Complete Response Letter from the FDA requesting a second Phase III clinical trial.

In the second half of 2010, GTx plans to initiate the second international, randomized, doubleblind, placebo-controlled phase III clinical trial evaluating toremifene 80 mg in men with advanced prostate cancer on androgen deprivation therapy (ADT) who are at increased risk of fractures. The primary endpoint will be the incidence of new vertebral fractures. Additional efficacy data on bone mineral density (BMD), hot flushes and breast tenderness/pain will also be collected as well as toremifene safety/tolerance data.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. For more information on GTx, visit our website, <u>www.gtxinc.com</u>.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements based upon GTx's current expectations. Forwardlooking statements include, but are not limited to, statements relating to GTx's plans to continue to pursue the development of and marketing approval for, and the potential commercialization of, toremifene 80 mg, and the continued development and potential commercialization of GTx's other product candidates. Forward-looking statements involve risks and uncertainties. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risks (i) that GTx and its collaboration partner will not be able to commercialize their product candidates if clinical trials do not demonstrate safety and efficacy in humans, including in any additional clinical trials that GTx may conduct in connection with the NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates, including toremifene 80 mg to reduce fractures in men with prostate cancer on ADT or toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, in a timely manner or at all; (iii) that clinical trials being conducted or planned to be conducted by GTx and its collaboration partner may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) related to GTx's dependence on its collaboration partner for product candidate development and commercialization efforts; (v) related to GTx's reliance on third parties to manufacture its product candidates and to conduct its clinical trials; and (vi) that GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product candidate development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's annual report on Form 10-K filed with the SEC on March 15, 2010 contains under the heading, "Risk Factors," a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.





About Ipsen

Ipsen is a global biotechnology specialty care group with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, which significantly contribute to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. Almost 900 people are dedicated to the discovery and development of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. 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.

Forward-looking statements

The forward-looking statements, objectives, perspectives and targets contained herein are based on the Group's management strategy, current views, and assumptions regarded as reasonable by the Group. These forward-looking statements depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Such statements involve known and unknown risks and uncertainties that the Group may not be able to control or mitigate and that may cause actual results, performance or events to differ materially from those anticipated herein. Moreover, the perspectives, objectives or targets described in this document were prepared without taking into account external growth assumptions which may alter these parameters. 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 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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