## PRESS RELEASE





# Ipsen and GW Pharmaceuticals plc enter into agreement for Ipsen to promote and distribute Sativex<sup>®</sup> in Latin America

- The intended indication of Sativex<sup>®</sup> is the treatment of spasticity due to multiple sclerosis
  - Sativex® a companion drug to Dysport® in neurology

London (UK) and Paris (France), 14 January 2014 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical company, and GW Pharmaceuticals plc (Nasdaq: GWPH, AIM: GWP, "GW"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announce that they have entered into an exclusive agreement for Ipsen to promote and distribute Sativex<sup>®1</sup>, a sublingual cannabis extract spray intended for the treatment of spasticity due to multiple sclerosis (MS) in Latin America (excluding Mexico and the Islands of the Caribbean). GW will be responsible for commercial product supply to Ipsen.

Sativex<sup>®</sup> is already approved in 24 countries (principally in Europe) as a treatment of spasticity due to multiple sclerosis. GW Pharmaceuticals and Ipsen aim to start regulatory filings in selected countries in Latin America during 2014 for the MS spasticity indication. The rights granted to Ipsen cover spasticity due to MS and also cover the future potential cancer pain indication. Financial terms include an upfront payment to GW Pharmaceuticals, regulatory and commercial milestone payments, and a long term supply price.

**Justin Gover, Chief Executive Officer of GW**, stated: "We are pleased to have expanded our commercial distribution agreements for Sativex<sup>®</sup> to include Latin America. Ipsen is an ideal partner with both a strong presence in the region as well as international expertise in the two therapeutic areas of neurology and oncology. We look forward to working with Ipsen to achieve successful approvals and launches of Sativex<sup>®</sup> across Latin America."

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<sup>&</sup>lt;sup>1</sup> The product will be distributed under either Sativex<sup>®</sup> or any substitute trademark, if needed





Christophe Jean, Executive Vice-President, Strategy and Business Development, Ipsen stated: "Ipsen is delighted to enter into partnership with GW for Latin America, as Sativex® is a good complement to our neurology franchise portfolio in this region. Sativex® will bring added value to patients with spasticity due to multiple sclerosis. Furthermore, this partnership is fully aligned with our neurology franchise strategy focused on helping patients suffering from debilitating neurologic diseases, in particular spasticity."

#### **About Ipsen in Latin America**

Ipsen has a direct presence in Brazil and Mexico and presence via various partners in other countries such as Colombia, Argentina, Venezuela, Chile and Peru. In Brazil, in the therapeutic area of neurology, Ipsen has consolidated its leadership position with Dysport<sup>®</sup> in the public market and grown its market share in the private segment.

### About Sativex®

Sativex<sup>®</sup> is an endocannabinoid modulator made of two actives - THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol). The product was developed, and is manufactured by GW. Sativex<sup>®</sup> contains active ingredients known as 'cannabinoids' which are extracted from the plant Cannabis Sativa grown and processed under strictly controlled conditions. As part of the human endocannabinoid system (ECS), cannabinoid receptors, CB1 and CB2 receptors are found predominantly at nerve terminals where they have a role in retrograde regulation of synaptic function. THC acts as a partial agonist at both CB1 and CB2 receptors, mimicking the effects of the endocannabinoids, which may modulate the effects of neurotransmitters (e.g. reduce effects of excitatory neurotransmitters such as glutamate).

Sativex<sup>®</sup> is indicated as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other antispasticity medication and who demonstrate clinically significant improvement in spasticity-related symptoms during an initial trial of therapy<sup>i</sup>.

Sativex<sup>®</sup> is already approved in 24 countries (principally in Europe) as a treatment of spasticity due to multiple sclerosis (MS). Sativex<sup>®</sup> is also currently in a global Phase III program for the treatment of cancer pain.

Sativex<sup>®</sup> is already licensed to Otsuka Pharmaceutical Co., Ltd in the United States; to Almirall S.A. in Europe (excluding the UK) and Mexico; to Bayer in the UK and Canada; to Novartis in Australasia, Asia (excluding China and Japan), the Middle East (excluding Israel) and Africa; and to Neopharm in Israel.

#### **About spasticity**

Spasticity is a symptom defined as loss of mobility, painful spasms, stiffness and / or weakness of muscles, occurring in over 80% of MS sufferers in the course of the disease<sup>ii</sup>. Spasticity can affect many aspects of the daily lives of patients with MS and is one of the main factors contributing to their distress and disability<sup>iii</sup>.

#### **About GW Pharmaceuticals plc**

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup>, which is approved for the treatment of spasticity due to multiple sclerosis. Sativex<sup>®</sup> is also in Phase 3 clinical development as a potential treatment of pain in people with advanced cancer. GW has established a world leading position in the development of plant-derived cannabinoid therapeutics and has a deep pipeline of additional clinical-stage cannabinoid product candidates targeting epilepsy





(including an orphan pediatric epilepsy program), Type 2 diabetes, ulcerative colitis, glioma and schizophrenia. For further information, please visit www.gwpharm.com.

#### **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 2012, R&D expenditure totalled close to €250 million, representing more than 20% of Group sales. The Group has close to 4,900 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 on Ipsen, visit <a href="https://www.ipsen.com">www.ipsen.com</a>.

#### **GW Pharmaceuticals plc Forward-looking statements**

This news release may contain forward-looking statements that reflect GWs current expectations regarding future events, including statements about the terms of such agreement, the clinical benefits of Sativex® and the commercial potential of Sativex. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of the GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex® and other products by consumer and medical professionals. A further list and description of risks, uncertainties and other risks associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including its most recent Form F-1 filed with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

#### **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 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 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.

#### For further information

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SmPC (http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con084961.pdf)

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