

PRESS RELEASE



# Ipsen and 3BP announce First Patient Dosed in Phase I/II study for first-in-class radionuclide (IPN01087)

**Paris (France), 20 November 2018 –** Ipsen (Euronext: IPN; ADR: IPSEY) and 3BP today announced the first patient has been dosed in a Phase I/II study for the first-in-class radionuclide <sup>177</sup>Lu-IPN01087 (formerly known as 3BP-227). IPN01087 is a compound that targets cancer cells in patients with advanced solid tumors which express the Neurotensin Receptor Subtype 1 (NTSR1).

The key objective of the Phase I dose-escalation trial (EUDRACT Number 2017-001263-20) is to evaluate the safety and activity, as well as to identify the optimum systemically-administered dose of radiation to treat patients with any of the following solid tumors expressing NTSR1: pancreatic ductal adenocarcinoma, colorectal cancer, gastric cancer, gastrointestinal stromal tumors, Ewing sarcoma and squamous cell carcinoma of the head and neck.

Alexandre Lebeaut, Executive Vice President, R&D and Chief Scientific Officer, Ipsen, said: "Ipsen is committed to bringing to cancer patients innovative systemic radiation therapy with targeted radiopharmaceuticals. We are pleased to report progress of the development of IPN01087 in this Phase I/II study. Our targeted theranostic approach – which we are advancing in partnership with 3B Pharmaceuticals- provides a novel and exciting potential therapeutic solution for unmet medical needs across a number of solid tumours."

"This is a great milestone for IPN01087 and for 3B Pharmaceuticals," said **Dr. Ulrich Reineke**, **Managing Director of 3BP**. "We are pleased that the compound is in clinical trials and we remain passionate about systemic radiation therapy and its potential to improve patients' lives."

#### About IPN01087

IPN01087 is a novel diagnostic and therapeutic (theranostic) product focused on the neurotensin receptor 1 (NTSR1), a protein that is overexpressed in ductal pancreatic adenocarcinoma and potentially other cancers expressing neurotensin receptors, such as colorectal cancer, gastric cancer, gastrointestinal stromal tumors, Ewing sarcoma and squamous cell carcinoma of the head and neck. IPN01087 is a small molecule DOTA-conjugated NTSR1 antagonist (formerly known as 3BP-227) labelled with the radioisotope lutetium-177 (<sup>177</sup>Lu). A theranostic approach using molecular imaging to identify potential responders will potentially allow more effective treatment of highly underserved patient populations.

#### About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €1.9 billion in 2017, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,400 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit <u>www.ipsen.com</u>.

#### About 3BP

3B Pharmaceuticals GmbH (3BP) is a German biotechnology company developing a pipeline of targeted radiopharmaceuticals to serve major unmet therapeutic and diagnostic needs of patients with cancer. All development candidates are exclusively derived from internal discovery efforts and aimed at theranostic combinations based on the same targeting molecule.

As a leader in peptide discovery and optimization, 3B Pharmaceuticals GmbH (3BP) has built a technology platform extending from hit identification to early clinical development. Technologies are applied to both collaborative R&D and inhouse projects.

3BP was founded in 2008 by a team of renowned experts in peptide drug discovery and nuclear medicine from Berlin, Berne and Basel. Following a buyout of Jerini AG's R&D assets the company became operative in 2009 and is based in the southeast of Berlin.

#### **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 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. 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. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2017 Registration Document available on its website (www.ipsen.com).

#### For further information :

#### <u>Ipsen</u>

Media Ian Weatherhead Vice President, Corporate External Communications +44 (0) 1753 627733 ian.weatherhead@ipsen.com

Fanny Allaire Director, Corporate External Communications +33 (0) 1 58 33 58 96 Fanny.allaire@ipsen.com Financial Community Eugenia Litz Vice President, Investor Relations +44 (0) 1753 627721 eugenia.litz@ipsen.com

### **3B Pharmaceuticals**

## Dr. Jan Michel

Director Finance & Corporate Development Tel: +49 30 63924317 Mob: +49 176 15151101 E-mail: jan.michel@3b-pharma.com

## Myriam Koutchinsky

Investor Relations Manager +33 (0)1 58 33 51 04 myriam.koutchinsky@ipsen.com