



PRESS RELEASE

Ipsen and IRLAB enter exclusive worldwide licensing agreement aimed to improve the lives of people living with Parkinson's disease

- Ipsen obtains the exclusive worldwide rights to develop and commercialize the investigational treatment mesdopetam which is based on a novel mechanism of action
- Mesdopetam, an oral dopamine D3-receptor antagonist, has completed Phase Ib and IIa clinical programs which showed promising improvements for people living with Parkinson's disease experiencing levodopa-induced dyskinesia (LID) in clinically relevant endpoints
- IRLAB will continue to be responsible for the ongoing Phase IIb trial.¹ Ipsen will initiate Phase III preparatory activities, and is responsible for all remaining clinical development and worldwide commercialization
- IRLAB is eligible to receive up to \$363m, including a \$28m upfront payment and up to \$335m in potential development, regulatory and sales-based milestones, plus tiered low double-digit royalties on worldwide net sales

PARIS, FRANCE and GOTHENBURG, SWEDEN, 15 July 2021 – Ipsen (Euronext: IPN; ADR: IPSEY) and IRLAB (Nasdaq Stockholm; IRLAB A) today announced the signing of a licensing agreement, providing Ipsen exclusive worldwide development and commercial rights to mesdopetam, a novel dopamine D3-receptor antagonist. Mesdopetam is being assessed in Phase IIb clinical trials as a potential treatment option for people living with Parkinson's disease (PD) experiencing levodopa-induced dyskinesia (LID). It is estimated that approximately 40-50 percent of people living with PD will experience LID after five years of initiating dopamine replacement therapy. LID currently has limited treatment options.^{2,3,4} Mesdopetam is also in early development for Parkinson's Disease Psychosis (PDP), which is a common symptom of PD; around 50 percent of people with PD eventually develop such symptoms over the course of their disease.⁵

PD is a common, progressive neurodegenerative condition affecting more than 10 million people worldwide.⁶ PD affects nerve cells in the brain that control movement and affects patients differently; the most common motor symptoms however are tremor, muscle rigidity and slowness of movement. People living with PD also experience other problems not related to movement including anxiety, pain and depression.⁷ Symptoms of PD are most commonly managed by medicines, such as levodopa that aim to compensate for the loss of dopaminergic neurons. A common side effect of levodopa is dyskinesia, involuntary and erratic movements of the face, arms, legs or trunk.⁸ For many people, dyskinesias can be so severe that they interfere with normal functioning.⁹ Mesdopetam has also shown antipsychotic properties in preclinical studies.

Dr Howard Mayer, Executive Vice President and Head of Research and Development, Ipsen, said *"We are excited to enter this licensing agreement with IRLAB. By working in partnership, we aim to bring investigational mesdopetam to people living with Parkinson's disease experiencing levodopa-induced dyskinesia. We are delighted to strengthen our pipeline and deepen our commitment to the neuroscience community around the world, including to patients living with this debilitating neurodegenerative disorder."*

Dr Nicholas Waters, CEO of IRLAB, said *"We believe in the potential of investigational mesdopetam for people with Parkinson's disease experiencing dyskinesia or psychosis. We have purposefully worked to find a partner to pursue the late-stage clinical development of mesdopetam to commercialization and launch on a global market. Ipsen shares the broad vision for mesdopetam and the commitment to people with neurological disorders. We are very excited to enter the final steps of the journey to market in collaboration with Ipsen. Additionally, we are proud of the accomplishment this important collaboration represents. The agreement and partnership with Ipsen is a validation of our proprietary discovery platform, ISP, and our drug development efforts. This deal is one of the larger deals struck in the Swedish biotech space in decades, which is a merit for all of us at IRLAB and to those who have supported the mesdopetam project to reach this milestone."*

Under the terms of the agreement, IRLAB will be eligible to receive up to \$363m, including an upfront cash payment of \$28m and up to \$335m in development, regulatory and commercial milestones. IRLAB is also eligible to receive tiered low double-digit royalties on worldwide net sales of mesdopetam. The transaction does not impact Ipsen's financial guidance for 2021.

This information is information that IRLAB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 15 July 2021, 18:20 CET.

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About mesdopetam

Mesdopetam (IRL790) is a dopamine D3-receptor antagonist being developed to prevent and treat levodopa-induced dyskinesias (LIDs), a severe form of troublesome involuntary movements commonly occurring in Parkinson's disease (PD). Mesdopetam is also in development for the treatment of psychosis in Parkinson's (PDP). In clinical studies, mesdopetam reduces time spent with troublesome dyskinesia and thereby increases daily 'good ON-time' in patients with Parkinson's. Preclinical studies show that mesdopetam is a potent and efficacious antidyskinetic, and that mesdopetam also has the potential to prevent the development of dyskinesia. In addition, mesdopetam has shown antipsychotic properties in preclinical studies.

About Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established Consumer Healthcare business. With Total Sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. The Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has c.5,700 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit [ipsen.com](https://www.ipsen.com).

About IRLAB

IRLAB is a Swedish research and development company that focuses on developing novel treatments in Parkinson's disease. The company's most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), have completed Phase IIa studies and are designed to treat some of the most difficult symptoms related to Parkinson's disease: involuntary movements (PD-LIDs), psychosis (PDP) and symptoms linked to cognitive decline such as impaired balance and increased risk of falls (PD-Falls). Through the proprietary research platform, ISP (the Integrative Screening Process), IRLAB discovers and develops unique drug candidates for central nervous system (CNS)-related disorders where large and growing medical needs exist. In addition to the clinical candidates, the ISP platform has also generated several CNS programs that are now in preclinical phase. IRLAB is listed on Nasdaq Stockholm Main Market. More information on www.irlab.se.

Ipsen's 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. 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 2020 Registration Document, available on ipsen.com.

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References

¹ NCT04435431 <https://clinicaltrials.gov/ct2/show/NCT04435431>

² Ahlskog JE, & Muenter MD (2001) Frequency of levodopa- related dyskinesias and motor fluctuations as estimated from the cumulative literature. *Mov Disord*, 16, 448-458

³ Holloway RG, Shoulson I, Fahn S, Kieburtz K, Lang A, Marek K, McDermott M, Seibyl J, Weiner W, Musch B, Kamp C, Welsh M, Shinaman A, Pahwa R, Barclay L, Hubble J, LeWitt P, Miyasaki J, Suchowersky O, Stacy M, Russell DS, Ford B, Hammerstad J, Riley D, Standaert D, Wooten F, Factor S, Jankovic J, Atassi F, Kurlan R, Panisset M, Rajput A, Rodnitzky R, Shults C, Petsinger G, Waters C, Pfeiffer R, Biglan K, Borchert L, Montgomery A, Sutherland L, Weeks C, DeAngelis M, Sime E, Wood S, Pantella C, Harrigan M, Fussell B, Dillon S, Alexander-Brown B, Rainey P, Tennis M, Rost-Ruffner E, Brown D, Evans S, Berry D, Hall J, Shirley T, Dobson J, Fontaine D, Pfeiffer B, Brocht A, Bennett S, Daigneault S, Hodgeman K, O'Connell C, Ross T, Richard K, & Watts A (2004) Pramipexole vs levodopa as initial treatment for Parkinson disease: A 4- year randomized controlled trial. *Arch Neurol*, 61, 1044- 1053.

⁴ Rascol O, Brooks DJ, Korczyn AD, De Deyn PP, Clarke CE, & Lang AE (2000) A five-year study of the incidence of dyskinesia in patients with early Parkinson's disease who were treated with ropinirole or levodopa. 056 Study Group. *N Engl J Med*, 342, 1484-1491.

⁵ Forsaa EB, Larsen JP, Wentzel-Larsen T, et al. A 12-year population-based study of psychosis in Parkinson's disease. *Arch Neurol*. 2010;67:996-1001

⁶ Marras, C., Beck, J. C., Bower, J. H., Roberts, E., Ritz, B., Ross, G. W., Abbott, R. D., Savica, R., Van Den Eeden, S. K., Willis, A. W., Tanner, CM, on behalf of the Parkinson's Foundation P4 Group (2018). Prevalence of Parkinson's disease across North America. *Npj Parkinson's Disease*, 4(1), 1–7

⁷ The European Parkinson's Disease Association (EPDA). About Parkinson's Disease. <https://www.epda.eu.com/about-parkinsons/what-is-parkinsons/>

⁸ American Parkinson's Disease Association. What is Dyskinesia. <https://www.apdaparkinson.org/what-is-parkinsons/treatment-medication/medication/dyskinesia/>

⁹ Parkinson's Foundation. Understanding Parkinson's, Movement Disorders, Dyskinesia.

<https://www.parkinson.org/Understanding-Parkinsons/Symptoms/Movement-Symptoms/Dyskinesia>