



PRESS RELEASE

Ipsen updates on QM-1114 regulatory process

PARIS, FRANCE, 3 October 2023 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that its partner Galderma has confirmed receipt from the FDA of a Complete Response Letter related to its Biologics License Application for liquid botulinum toxin type A (QM-1114), noting certain deficiencies related to chemical, manufacturing and controls (CMC) processes.

Furthermore, on 28 September 2023, the Arbitral Tribunal of the International Chamber of Commerce (ICC) issued a final decision on arbitration proceedings that Galderma initiated against Ipsen. This dispute was initiated in July 2021 following a difference of opinion on the regulatory submission strategy for QM-1114 related to the potency-assay testing method used in the release of commercial batches of QM-1114 in the United States, Canada and Australia.

The result of this arbitration is that any regulatory applications for QM-1114 in the partnership territories submitted by Galderma shall be assigned to Ipsen as the owner of the intellectual property and marketing authorization of QM-1114. Galderma remains responsible for development, regulatory filing strategy, manufacturing and commercialization. As such, the Tribunal declared that Galderma has the right to decide on QM-1114's regulatory strategy.

On 27 July 2023, Ipsen confirmed that it had notified Galderma of its decision to terminate the Parties' joint R&D collaboration entered into in July 2014 related to the parties' respective neurotoxin programs, including the development of IPN10200 (longer-acting neurotoxin).

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About Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With total sales of €3.0bn in FY 2022, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, 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 around 5,300 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 Dysport

Dysport®, Ipsen's botulinum toxin type A, is a neuromuscular blocking toxin which acts to block acetylcholine release at motor nerve ends and reduces muscular spasm. It was initially developed for the treatment of movement disorders such as cervical dystonia, blepharospasm, hemifacial spasms and spasticity affecting the upper and/or lower limbs in adults and children aged 2 years or older. Dysport® has marketing authorizations in more than 90 countries worldwide. The product is currently referred to as Dysport® for medical and aesthetic markets, and as Azzalure® in aesthetic indications in the E.U.

Alluzience®, Ipsen's botulinum toxin type A is a neuromuscular blocking toxin in liquid formulation, indicated for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at maximum frown in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.

About QM-1114 (relabotulinumtoxinA)

QM-1114, is an investigational liquid formulation botulinum toxin A (supported by READY-1 / READY-2 / READY-3 / READY-4 Phase III trials sponsored by Galderma), seeking registration for the improvement of both glabellar and lateral canthal lines in adult patients.

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Ipsen's forward-looking statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen'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 Ipsen'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 Ipsen'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 Ipsen. 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 medicine 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. Ipsen must face or might face competition from generic medicine 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 Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical 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 medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine 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

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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 healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen'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 Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen 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 Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen 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. Ipsen'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 Ipsen's latest Universal Registration Document, available on ipsen.com.