

Ipsen and Biomunex announce exclusive global licensing agreement for first-in-class MAIT cell engager in immuno-oncology

- » Ipsen secures exclusive global rights to develop, manufacture and commercialize BMX-502, a pre-clinical novel T cell engager (TCE) with first-in-class potential
- » BMX-502 is a bispecific antibody engaging MAIT cells, a subset of non-conventional T cells, and targeting the clinically validated tumor antigen GPC3 to kill cancer cells

PARIS, FRANCE; 03 December 2024 - Ipsen (Euronext: IPN; ADR: IPSEY) and Biomunex Pharmaceuticals today announced an exclusive global licensing agreement for BMX-502. BMX-502 is a bispecific antibody that engages and activates a subset of cytotoxic T cells called Mucosal-Associated Invariant T cells (MAIT cells) and targets the GPC3 tumor antigen, to kill cancer cells. GPC3 is a clinically validated target, highly expressed across several cancer types.¹ MAIT cells are present throughout the body, highly enriched in many specific tissues of the body, particularly in mucosal and barrier tissues. BMX-502 offers a promising approach to treating tumors in these tissues.^{2,3}

Developed using Biomunex's proprietary BiXAb technology, BMX-502 selectively engages MAIT cells and leverages their unique properties to maximize anti-tumor activity. MAIT engagers should overcome some of the limitations of current pan-T cell engager therapies, including activation of regulatory T cells and cytokine release syndrome, side effects that are difficult to manage for patients and represent a significant burden on the healthcare system.⁴ MAIT engagers have the potential to provide a more robust therapeutic window compared to classical pan-T cell engagers in specific tumor types.

"As we continue to grow Ipsen's pipeline using a science-first approach to partnering across the ecosystem, we believe BMX-502 is a strong addition with first-in-class potential in solid tumors," said Mary Jane Hinrichs, SVP and Head of Early Development at Ipsen. "This new MAIT-engager program will complement our existing TCE portfolio as we harness the next-generation of T cell engagers to overcome treatment challenges, including dose-limiting toxicity, to bring transformational new medicines to people living with solid tumors around the world."

"This agreement with such an innovative oncology company as Ipsen is proof of the relevance of MAIT-engager approach of Biomunex, the first company worldwide to have identified the high therapeutic potential of MAIT cells in cancer treatment. It also represents the demonstration of the added-value of our best-in-class BiXAb platform to rapidly generate innovative and promising bispecific antibodies. We are convinced that our MAIT engagers will represent a new step forward in the development of disruptive immuno-therapies for the treatment of cancer. We look forward to initiating and supporting the development of BMX-502 alongside Ipsen," added Dr. Pierre-Emmanuel Gerard, founder, President and CEO of Biomunex.

Under the terms of the agreement, Biomunex will complete the IND-enabling package. Ipsen will assume responsibility for Phase I preparation activities, including submission of the Investigational New Drug (IND) application, and all subsequent clinical-development and global commercialization activities. Biomunex is eligible to receive up to \$610 million, including upfront, contingent upon successful development, regulatory and commercial milestones, in addition to tiered global royalties on sales.

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About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience.

Our pipeline is fueled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 80 countries.

Ipsen 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.

About Biomunex Pharmaceuticals

Biomunex Pharmaceuticals is a biopharmaceutical company based in Paris (France) and Cambridge, MA, USA, led by an international and experienced team. Biomunex specializes in the discovery and development of breakthrough immunotherapeutic approaches, based on solid data and proven biological and clinical evidence, to address unmet medical needs in oncology.

Biomunex has created and developed BiXAb[®], a robust, “Plug and Play”, next-generation bi- and multi-specific antibody technology platform, using a proprietary computational modeling approach, with a very robust IP and patent portfolio. The BiXAb platform allows the generation of bispecific antibodies from any pair of monoclonal antibodies in a simple, fast and cost-effective manner.

Biomunex is the first company worldwide developing MAIT engagers, an immuno-oncology approach that allows, through bispecific antibodies from its BiXAb platform, to specifically target and engage MAIT cells, to kill cancer cells, for the treatment of solid tumors.

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Disclaimers and/or 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 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](https://www.ipsen.com).

References

¹ [Guo et al. Glypican-3: A New Target for Diagnosis and Treatment of Hepatocellular Carcinoma. *Journal of Cancer* 2020. 11\(8\): 2008-2021.](#) Last accessed: November 2024

² [Godfrey et al. The biology and functional importance of MAIT cells. *Nature Immunology*. 2019. 20:110-1128](#) Last accessed: November 2024

³ [Petley et al. MAIT cells regulate NK cell-mediated tumor activity. 2021 *Nature Communications* 12:4746](#) last accessed November 2024

⁴ Biomunex Presentation, AACR 2024. Available here: <https://www.biomunex.com/wp-content/uploads/2024/05/Poster-AACR-2024-FINALIZED.pdf> . Last accessed November 2024