

Ipsen and Foreseen Biotechnology announce exclusive global licensing agreement for antibody-drug conjugate with first-in-class potential

- » Exclusive global rights secured for development, manufacture and commercialization of FS001, completing final stages of pre-clinical development with first-in-class potential
- » FS001 targets a novel tumor associated antigen, highly expressed across a range of solid tumors, identified through the application of Foreseen's proprietary proteomic platforms
- » FS001 has demonstrated robust preclinical efficacy in multiple tumor models and exhibits a favorable preclinical safety profile

PARIS, FRANCE, 11 July 2024 - Ipsen (Euronext: IPN; ADR: IPSEY) and Foreseen Biotechnology (Foreseen) today announced an exclusive global licensing agreement for FS001, an antibody-drug conjugate (ADC) with first-in-class potential. FS001 targets a novel tumor-associated antigen that is overexpressed in many solid tumors and plays a critical role in tumor proliferation and metastasis. This novel tumor antigen was identified using Foreseen's high throughput, integrated translational proteomics, and artificial intelligence (AI)-powered screening platforms, to analyze their vast collection of well-characterized clinical tumor samples. FS001 utilized an innovative, stable and cleavable linker coupled to a potent topoisomerase I inhibitor. Preclinical efficacy of FS001 was demonstrated in multi-drug resistant cancer models. The agreement gives Ipsen exclusive worldwide rights to develop, manufacture and commercialize FS001.

"We are excited to add FS001, the second ADC Ipsen has in-licensed this year, to our growing pipeline. Using cutting-edge proteomics technology and AI-powered screening platforms the Foreseen team has uncovered a novel and clinically relevant target which could unlock the potential of ADCs for even more people living with hard-to-treat forms of cancer," said Mary Jane Hinrichs, SVP and Head of Early Development at Ipsen. "As we prepare for the initiation of a Phase I clinical trial, we will evaluate FS001 in selected solid tumor types, which we hope will deliver critical new treatments for people living with cancer around the world."

"Our strategic partnership with Ipsen provides a strong endorsement to our high throughput integrated translational proteomics platform approach to discover and develop innovative therapeutic products with first-in-class potential", said Catherine Wong, Founder and Chairman of Foreseen. "We are pleased to be collaborating with Ipsen to advance FS001 globally, harnessing Ipsen's robust track record in accelerating the clinical development and commercialization of innovative therapeutics. We believe FS001 has the potential to treat multiple cancers as a single agent or in combination with standard of care."

Foreseen Biotechnology is eligible to receive up to \$1.03bn comprising upfront, development, regulatory and commercial milestone payments, and tiered royalties on global sales, contingent upon successful development and regulatory approvals. Under the terms of the agreement, Ipsen will assume responsibility for Phase I preparation activities, including submission of the Investigational New Drug (IND) application, and all subsequent clinical-development, manufacturing, and global commercialization activities.

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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 ipсен.com.

About Foreseen Biotechnology

We are an emerging biotechnology company that pioneered a high throughput integrated translational proteomics platform powered by AI-based data analytical system to accelerate discovery of novel targets for therapeutics and diagnostics that are clinically relevant. We are building a pipeline of novel product candidates for the diagnosis and treatment of cancer, inflammatory/autoimmune diseases and neurological disorders. Foreseen Biotechnology is incubated by Nest.Bio Ventures.

About Antibody-Drug Conjugates (ADCs)

ADCs are comprised of three main components: the antibody, a payload and a linker. The antibody selectively targets an identified tumor antigen. Payloads are the pharmaceutically active component to treat the cancer, attached to the antibody via a chemical linker. The linker connects the antibody and the payload and reduces the amount of payload that reaches non-tumor tissue.¹

About FS001

FS001 is a potential first-in-class ADC with demonstrated preclinical efficacy in multiple solid tumors as well as a favorable safety profile with wide therapeutic window in animal studies. FS001 is comprised of (i) Foreseen's proprietary antibody that specifically binds to a novel target identified using the company's high throughput integrated translational proteomics platform and (ii) an innovative linker-payload with excellent pharmaceutical features developed by Shanghai Escugen Biotechnology Co. Ltd. FS001 is in the final stages of pre-clinical development.

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Ipsen 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 E. Jabbour, S. Paul, H. Kantarjian. The clinical development of antibody-drug conjugates - lessons from leukemia. *Nature Reviews Clinical Oncology*. 2021. 18: 418-433. Available here: <https://www.nature.com/articles/s41571-021-00484-2>