

PRESS RELEASE

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Zambon Biotech announces first patient dosed in Phase 3b ADIP clinical study of IPX203 in Parkinson's disease

Zambon Biotech, a specialized biotech company part of the Zambon group that aims to build a scientifically robust and commercially viable portfolio of innovative patient-oriented drugs through the scouting, acquisition, licensing and development of new molecules, **today announced** that the **first participant with advanced Parkinson's disease has been enrolled in the European Phase 3b ADIP (IPX203 in Advanced Parkinson's disease) study**, which is planned to evaluate the efficacy and safety of **IPX203** versus immediate-release (IR) levodopa/carbidopa (LD/CD) in a regimen which has not yet been the focus of a Phase 3 trial.

IPX203 is a novel, oral modified-release formulation of LD/CD designed for the treatment of Parkinson's disease, the fastest growing neurological condition in the world according to the World Health Organization¹. IPX203 contains immediate-release granules and extended-release beads, providing both a rapid onset of action and a longer duration of benefit, sustaining the levodopa therapeutic effect for a longer period of time compared to IR LD/CD. Last year, Zambon Biotech entered into an exclusive licensing agreement with Amneal Pharmaceuticals for IPX203 in the European Union, United Kingdom, and Switzerland. Zambon submitted IPX203 to the EMA for regulatory approval in June 2025.

"Dosing the first person in our phase 3b ADIP study marks an important milestone for our company and for the people living with Parkinson's disease who urgently need new therapies that truly improve their quality of life and the therapeutic outcomes" explained **Mathias Knecht, M.D., Chief Medical Officer, Zambon Biotech**. *"We recognise the substantial need for new treatment options, and with ADIP we aim to demonstrate the potential of IPX203 to become a core therapy for people with PD and moderate to severe motor fluctuations"*.

ADIP is a phase 3b open-label, active comparator, randomized clinical trial designed to assess the efficacy and safety of IPX203 in patients with advanced PD and motor fluctuations. The study aims to compare IPX203 with standard immediate-release levodopa-carbidopa, focusing on improving ON time and reducing OFF time through personalized dosing schedules. Unlike previous trials, ADIP allows dosing intervals tailored to individual patient needs. This flexible approach is expected to enhance symptom control and overall patient outcomes. The trial will run for up to 25 weeks, including a 1-week screening, 12-week treatment, and an optional 12-week extension. It will enroll 92 patients across sites in Italy, Spain, and Poland.

"At Zambon Biotech we are fully committed to build a long-term pipeline of innovative medicines that make patients' lives better. Given our group's capabilities in commercialization and our existing footprint in neurology, particularly Parkinson's, we believe IPX203 could represent a valuable therapeutic option in Europe to improve the lives of moderate to severe Parkinson patients" said **Frank Weber, M.D, Chief Executive Officer at Zambon Biotech**.

¹ <https://www.who.int/publications/i/item/9789240050983>

About Zambon Biotech SA

Zambon Biotech SA is a specialized biotech company that aims to build a scientifically robust and commercially viable portfolio of innovative patient-oriented drugs through the scouting, acquisition, licensing and development of new molecules. Zambon Biotech is part of Zambon, a modern multinational chemical-pharmaceutical company established in 1906 in Vicenza, whose history is founded on the values of an Italian family committed to innovating cure and care to improve patients' lives. Zambon employs 2,768 people worldwide, is present in 23 countries in Europe, America and Asia, and has production facilities in Italy, Switzerland, China, Brazil and in France with its APIs and CDMO site. Thanks to its innovative, quality products commercialized in 87 countries, the group reported a revenue of 885 million euros in 2024. Alongside the three historical therapeutic areas - diseases of the respiratory system, urinary tract infections and pain treatment – Zambon pharma business is focused on developing treatments for neurodegenerative diseases such as Parkinson's or rare diseases such as cystic fibrosis, BOS, to which is linked the major 2019 acquisition of Breath Therapeutics, and NCFB. For further information on Zambon please visit www.zambon.com

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