

ESTEVE brings to market the first inhaled rescue treatment designed to control OFF episodes in Parkinson's disease¹

- **The company has obtained pricing and financing for an inhaled treatment for OFF periods in Parkinson's disease, which it launched on the Spanish market in mid-February 2023.**
- **The treatment consists of an inhaled levodopa that makes it possible to start improving the symptoms of the motor fluctuations associated with OFF episodes within 10 minutes after its administration and for at least 60 minutes².**

Madrid, 2 March 2023.- As of mid-February, healthcare professionals and patients now have a new treatment to counteract OFF-episode symptoms in Parkinson's disease. After having obtained pricing and reimbursement authorization for the product in December 2022, ESTEVE has now launched its commercialization.

Parkinson's is one of the most disabling diseases and the second most common neurodegenerative disease after Alzheimer's⁴. It is a progressive and chronic pathology in which patients experience increasing disability and a deterioration of their quality of life, regardless of the patient's age at diagnosis⁴. There is currently no cure for the disease, but treatments are available that can help alleviate the symptoms.

Although these treatments yield a favorable response for a certain period of time, after about 2-5 years, patients begin to notice that their symptoms reappear between treatment intervals, referred to as fluctuations or OFF episodes³. These episodes may include motor symptoms (impaired gait, stiffness, trembling, etc.) and non-motor symptoms (anxiety, disturbed sleep, pain, etc.), varying from one person to another and from one OFF period to another³. They tend to appear within two years and estimates suggest that almost 100% of patients with Parkinson's suffer OFF episodes after 10 years of carbidopa/levodopa treatment³.

"These episodes occur in practically every patient with Parkinson's and have an impact on their quality of life insofar as they interrupt their social and personal activities", explains Dr. Juan Carlos Martínez Castrillo, Head of the Neurodegenerative Diseases Unit at the Ramón y Cajal Hospital in Madrid. *"It is one of the greatest constraints on a patient's ability to lead a normal life, take exercise, socialize.... As physicians, we always stress how important it is to lead an active social life and practice sport, but the uncertainty of potentially experiencing an OFF episode at any time prevents many patients from doing so."* It is estimated that some 160,000 people suffer from Parkinson's disease in Spain⁴

Inbrija® is the first and indeed only orally inhaled therapy to be indicated for the intermittent treatment of the OFF episodes¹. Introduced in Spain by ESTEVE, this advance further strengthens the company's commitment to therapeutic innovation in the neurosciences. Levodopa, its active substance, is already well-known among neurology professionals. It begins to take effect after 10 minutes and it maintains its efficacy for at least 60 minutes². It is intended as a rescue drug and as a complement to oral treatment, ready to be inhaled when the patient becomes aware of the onset of symptoms.

A treatment for an unmet need in Parkinson's disease

"In the past, we have handled OFF episodes by adjusting each patient's oral medication dosage and doses. But not only is this an extremely laborious process, but it doesn't work when we're dealing with certain types of OFF episodes therefore an on demand therapy for the treatment of individual OFF episodes remains an important

therapeutic need at the present time to get complete control of OFFs³” Dr Martínez Castrillo tells us. “We really needed a drug that would allow patients to overcome OFF-episodes”.

This launch further strengthens ESTEVE's commitment to the field of neurology, to healthcare professionals and to people suffering from Parkinson's disease. As such, the company remains firmly committed to innovation and to delivering new treatments to improve people's lives. *“ESTEVE's goal is to continue to grow in the areas in which it specializes, especially in the field of neurology and the treatment of pain, where the company has extensive knowledge and expertise, and where it can provide exceptional value for the treatment of unmet health needs”,* affirms Dr. José María Giménez Arnau, Chief Scientific & Medical Officer at ESTEVE.

About ESTEVE

ESTEVE (www.esteve.com) is an international pharmaceutical company with headquarters in Barcelona. Its mission is to improve people's lives and it has focused on providing solutions for unmet medical needs since its foundation in 1929. ESTEVE has a major presence in Europe thanks to its affiliates in Spain, Portugal, Germany, France, the UK and Italy and its own production centers dedicated to the development and manufacture of active pharmaceutical ingredients in Spain, Mexico and China, as well as a pharmaceutical plant in Germany.

Dr. Martínez Castrillo is an advisor to ESTEVE and an expert in the field of Neurodegenerative Diseases.

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¹ European Medicines Agency. Inbrija (levodopa). Información general sobre Inbrija y sobre los motivos por los que se autoriza su uso en la UE. 2019. Disponible en: https://www.ema.europa.eu/en/documents/overview/inbrija-epar-medicine-overview_es.pdf .

² LewittPA, Hauser RA, Pahwa R, Isaacson SH, Fernandez HH, Lew M, et al. Safety and efficacy of CVT-301 (levodopa inhalation powder) on motor function during off periods in patients with Parkinson's disease: a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet Neurol.* 2019 Feb;18(2):145- 154

³Thach A, Jones E, Pappert E, Pike J, Wright J, Gillespie A. Real-world assessment of the impact of “OFF” episodes on health-related quality of life among patients with Parkinson's disease in the United States. *BMC Neurol.* 2021 Jan 30;21(1):46;

⁴ Garcés, M. Estudio sobre las enfermedades neurodegenerativas en España y su impacto económico y social. Madrid: Universidad Complutense. 2016:175.

⁵ European brain council. [Internet] Parkinson's disease (PD) Fact sheet. Disponible en: <https://www.braincouncil.eu/wp-content/uploads/2020/07/A4-Parkinsons-Disease-Fact-Sheet-Final.pdf>