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The US Food and Drug Administration (US FDA) has approved AbbVie's DUOPA (carbidopa and levodopa) enteral suspension for the treatment of motor fluctuations for people with advanced Parkinson's disease. DUOPA is administered using a small, portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally-placed tube.

DUOPA was approved by the FDA as an orphan drug, a designation granted to products intended for the treatment of rare diseases or conditions affecting fewer than 200,000 patients in the US.

"There is unmet need for treatment options for patients with advanced Parkinson's disease. As the disease advances, it can be difficult to control motor features. In clinical trials, DUOPA was shown to significantly reduce the amount of off time advanced Parkinson's disease patients experienced," said Dr C Warren Olanow, professor, Department of Neurology and Department of Neuroscience, Mount Sinai School of Medicine, and lead investigator of the DUOPA pivotal trial.

DUOPA provides patients with the same active ingredients as orally-administered carbidopa and levodopa immediate release, but is delivered in a suspension that goes directly into the small intestine via a tube placed by a percutaneous endoscopic gastrostomy procedure with jejunal extension (PEG-J). This type of administration is intended to bypass the stomach.

"The FDA approval of DUOPA is another significant milestone for AbbVie's pipeline. This advancement is important for patients with advanced Parkinson's disease and their care teams, as it provides a new therapeutic option to help manage

motor symptoms," said Dr Michael Severino, executive vice president, R&D and chief scientific officer, AbbVie.