New form of levodopa might improve parkinson's care

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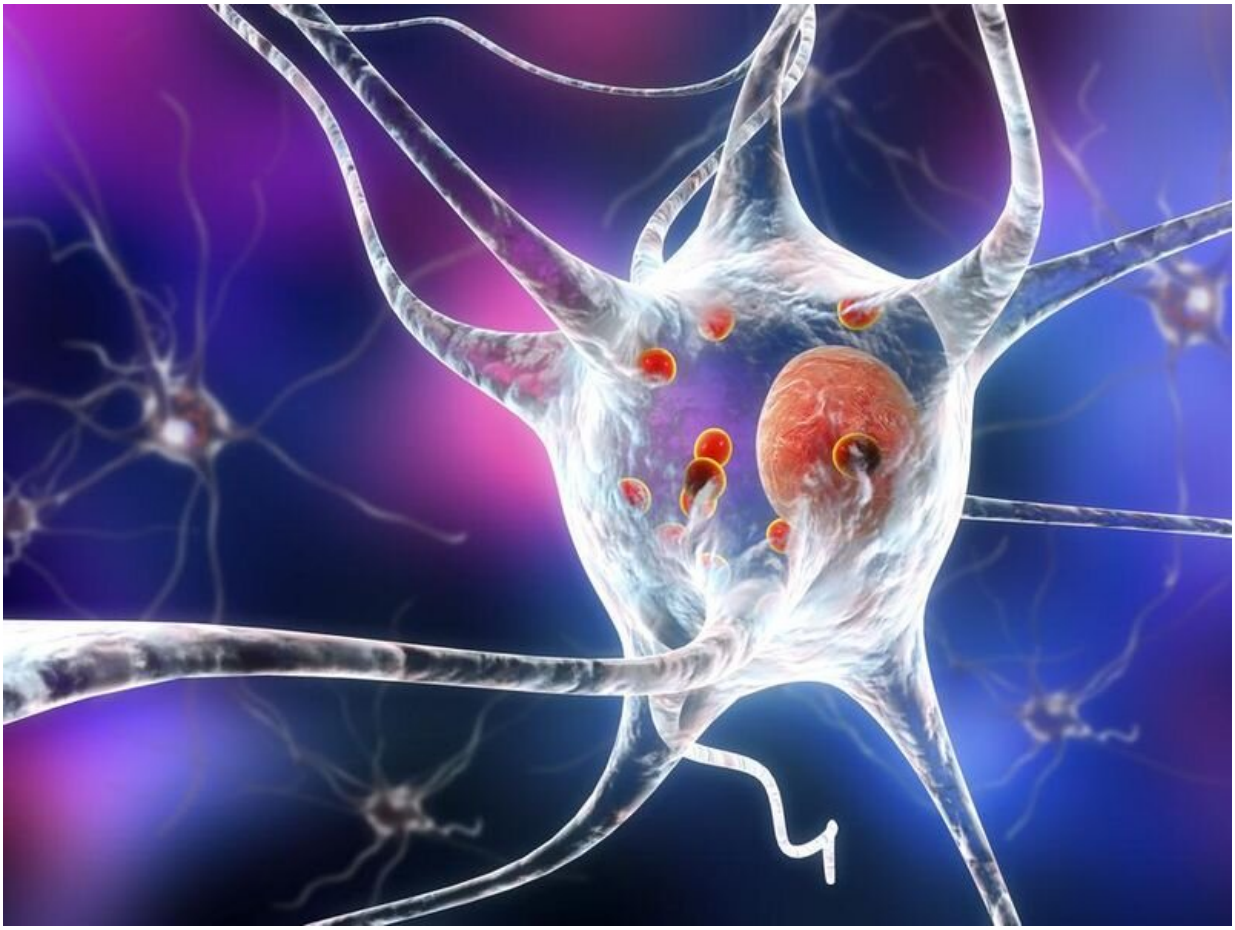

An extended-release version of a Parkinson's disease drug could provide

more stable relief for patients with the movement disorder, new clinical trial data show.

The new formulation of levodopa, called IPX203, extended the duration of patients' "on time"—the amount of time the medication is working and symptoms are lessened, researchers reported this week at the American Academy of Neurology's annual meeting, in Boston.

Three oral doses of IPX203 a day worked slightly better than five doses of standard levodopa, with patients' "on time" running about a half-hour longer, said lead researcher Dr. Alberto Espay, chair of the University of Cincinnati's department of neurology and rehabilitation medicine.

If approved, Espay expects the new formulation would be dosed with the same frequency as standard levodopa, but that it would provide more stable and sustained "on time" for patients.

"This might well be used with five doses a day, and then this will be a marked improvement," Espay said. "Most patients really don't mind. What they're worried about is not how frequently they are taking it, but how much 'off time' they still may have. They don't want to have 'off time' regardless of how many times it takes for them to dose themselves."

Parkinson's symptoms like tremors, slowness and stiffness are caused by low levels of dopamine in the brains and bodies of patients.

For decades, doctors have treated Parkinson's by giving patients levodopa, the substance produced by neurons that is converted into dopamine, Espay explained.

"If our brains aren't making enough levodopa, then we have less of the dopamine that we need for movement and emotional regulation," Espay

said. "Levodopa is to Parkinson's what insulin is to diabetes. It's actually replenishing something that the brain makes, but in these patients is making a little less than they need."

Patients take multiple doses of levodopa daily to maintain stable blood levels of dopamine that will inhibit the symptoms of Parkinson's.

The IPX203 capsule combines immediate-release granules and extended-release beads of levodopa.

The new report reflects results from a nine-month safety extension trial. It also found the three-dose regimen of IPX203 was as safe as standard levodopa.

The extended trial involved 419 patients, of whom about 16% dropped out during treatment.

The most common side effects were tremors, urinary tract infection, back pain and constipation. The majority of side effects were mild or moderate, and occurred within the first 90 days of treatment.

The U.S. Food and Drug Administration currently is reviewing IPX203, and Espay said he anticipates the new formulation could be approved by fall or early winter. IPX203 would be the second extended-release levodopa pill approved.

IPX203 would be a valuable addition to the treatment options available for Parkinson's patients, said Dr. Anna Hohler, chair of neurology at St. Elizabeth's Medical Center in Brighton, Mass.

"Our patients with Parkinson's disease potentially have some variability in their response to different manufacturers' versions of levodopa," Hohler said. "Providing them with additional options can improve their

outcomes, in terms of response to the therapy."

Further, the extended-release version could help patients enjoy more stable "on time," Hohler said.

"The more stable the dosing levels in the system—particularly with long-acting versions—the more sustained and reliable effect the patients will have. It will improve their quality of life in general," Hohler said.

Amneal Pharmaceuticals, the maker of IPX203, funded the clinical trial.

Findings presented at medical meetings should be considered preliminary until published in a peer-reviewed journal.

More information: The U.S. National Institute on Aging has more about Parkinson's disease.