BIOPHARMADIVE

DIVE BRIEF

Bayer reports positive early data for Parkinson's cell therapy

The therapy, developed by Bayer's Bluerock Therapeutics subsidiary, appeared safe and well-tolerated in a 12-person clinical trial.

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Dive Brief:

- A cell therapy for Parkinson's disease scored positive results in an early-stage clinical trial, according to an announcement Monday from its developer, Bluerock Therapeutics.
- Bluerock, a Massachusetts-based subsidiary of the German pharmaceutical giant Bayer, said its stem cell-derived therapy met the study's main goal, appearing safe and well-tolerated in the 12 patients who received it. There were two so-called serious adverse events, but each was deemed unrelated to treatment.
- The study tested a low and high dose of the therapy, known as bemdaneprocel, and found evidence across both groups that cells had engrafted and were surviving. Researchers also explored whether bemdaneprocel had any effect on Parkinson's itself. Bluerock reported that the severity of disease had gotten better one year after treatment, with patients in the high-dose group showing the greatest improvement.

Dive Insight:

Estimates hold that around half a million people in the U.S. have Parkinson's, though, due to underdiagnosis or misdiagnosis, some believe the true number is much higher. The disease causes nerve cells in the part of the brain that controls movement to die or become impaired.

Many of the medicines used to treat Parkinson's symptoms revolve around dopamine, a chemical messenger that plays a role in a variety of essential functions, including motor function. Bluerock's therapy targets this chemical as well, but in a way different from currently available treatments, as it's meant to replace the dopamine-making nerve cells that are lost in Parkinson's patients.

As part of the bemdaneprocel study, participants were asked to record when they were in "on" states, meaning their symptoms were well controlled, and "off" states, when their symptoms seemed to worsen. According to Bluerock, one year after treatment, participants in the high-dose group said they were experiencing a little over two hours more in the "on" state without troubling involuntary movements, and just under two hours less in the "off" state.

Claire Henchcliffe, one of the study's principal investigators and the chair of the neurology department of the University of California, Irvine School of Medicine called the data collected for bemdaneprocel "extremely encouraging."

"While this is a small open-label study, meeting the study's primary objective for safety and tolerability along with initial improvements seen in clinical outcomes represents a great step forward," Henchcliffe said in a statement from Bluerock. "The hope now is that these trends continue and translate into

meaningful benefit for people with Parkinson's disease in controlled clinical trials."

Bluerock said that, based on the results seen so far, it is planning a mid-stage study that should begin enrolling participants in the first half of next year.

Bluerock launched in late 2016 as part of a joint venture between Bayer and the investment firm Versant Ventures. By 2019, Bayer had agreed to buy all the startup's equity it didn't already own for $240 million upfront and potentially another $360 million, provided Bluerock's programs hit certain development milestones.

Since the acquisition, Bluerock has operated as an independent subsidiary. Bayer, meanwhile, has continued to invest in cell therapy. In 2021, its venture arm led a $105 million funding round for Senti Biosciences, a California-based biotechnology company trying to create "off-the-shelf" cellular medicines for cancer.

Bayer had also acquired rights to two experimental cell therapies developed by Atara Biotherapeutics as potential treatments for solid tumors. However, that deal has since fizzled.