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Colorado biotech firm's new cell therapy could eliminate the need for knee replacements

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A Louisville-based biotech company has developed a way to provide cellular therapy that could eliminate the need for patients to have total knee replacements — and the therapy can be administered within 60 minutes.

GID Bio has created technology that can isolate cells from fat tissue taken from a patient through a biopsy, said William Cimino, CEO of the company. The fat tissue then goes into a device that processes the tissue within 60 minutes.

During that process, the fat tissue breaks down into the different types of cells it consists of, such as blood cells and stromal cells. Stromal cells — cells the body uses for healing — are targeted and concentrated. After the stromal cells are concentrated, they're assayed for quality control and then a dose is created and administered back to the patient.

"We isolate between 1.1 million and 1.5 million stromal cells per gram consistently and reliably to create this therapeutic dose," Cimino said. Not only is the procedure fast, but the recovery is as well: patients are able to walk out of the office in most cases.

This type of treatment is shown to be therapeutic enough to be an effective alternative to surgery. It's proving to be especially effective for patients with osteoarthritis of the knee. Knee pain occurs because existing cells are impaired or reduced to a point where they can't repair the knee tissue. Transplanting new cells can kickstart and augment the repair process.

The company recently received full approval from the FDA for Phase 3 clinical trials to test the treatment in osteoarthritis patients with knee pain. Covid-19 put those trials on pause for a bit, but GID Bio is now getting the trials up and running. They will start with three test sites: San Antonio, New Orleans and Cedar Knolls, New Jersey. Phase 3 will consist of 124 total subjects monitored for six months with a 12-month follow-up.

The three sites will be fully operational in August. There is the possibility that additional test sites will be added on.

In addition to FDA approval for Phase 3, GID Bio was given approval for a small trial to treat patients with severe Covid-19 infections using their cell therapy technology. It was a



GID BIO

William Cimino is CEO of Louisville-based GID Bio.

compassionate care trial, a trial authorized by the FDA for an unapproved drug to be used to treat seriously ill patients for which no other treatment is available.

"The FDA can decide whether it wants to take the next step of a larger clinical trial effort under different conditions and do one that is more formalized," Cimino said.

But GID Bio has a pipeline of uses of this therapy beyond osteoarthritis patients, he said. The company has also completed clinical trials in which the treatment is applied to diabetic foot ulcers. The theory being tested in the latest trial is that the therapy can save patients with severely degraded joints from having to get surgery. In earlier trials, GID Bio saw that with patients at the worst stage of osteoarthritis, there was a 68% reduction in pain one year after the cell therapy. After two years, 90% of patients were still better off than they were before they received the treatment.

With osteoarthritis, current treatment choices include injections, drugs to reduce pain and joint replacement surgery. The latter can be extremely costly and is the largest expenditure for Medicare. Total knee replacement surgery is the No. 1 surgical procedure that is performed in U.S. hospitals with 966,000 procedures a year as of 2017.

"Cell therapy is the first potential way to treat a knee, have a decrease in pain and increase the ability to function and have a minimally invasive procedure," Cimino said. "We've and a tremendous response in the reduction of pain, and you enter the doctor's office and two hours later you leave walking on your knee."

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