Promising Phase 2 Results For Biodexa's eRapa™ Indicates Hope For FAP Patients Who Otherwise Have A 100% Lifetime Risk Of Colorectal Cancer

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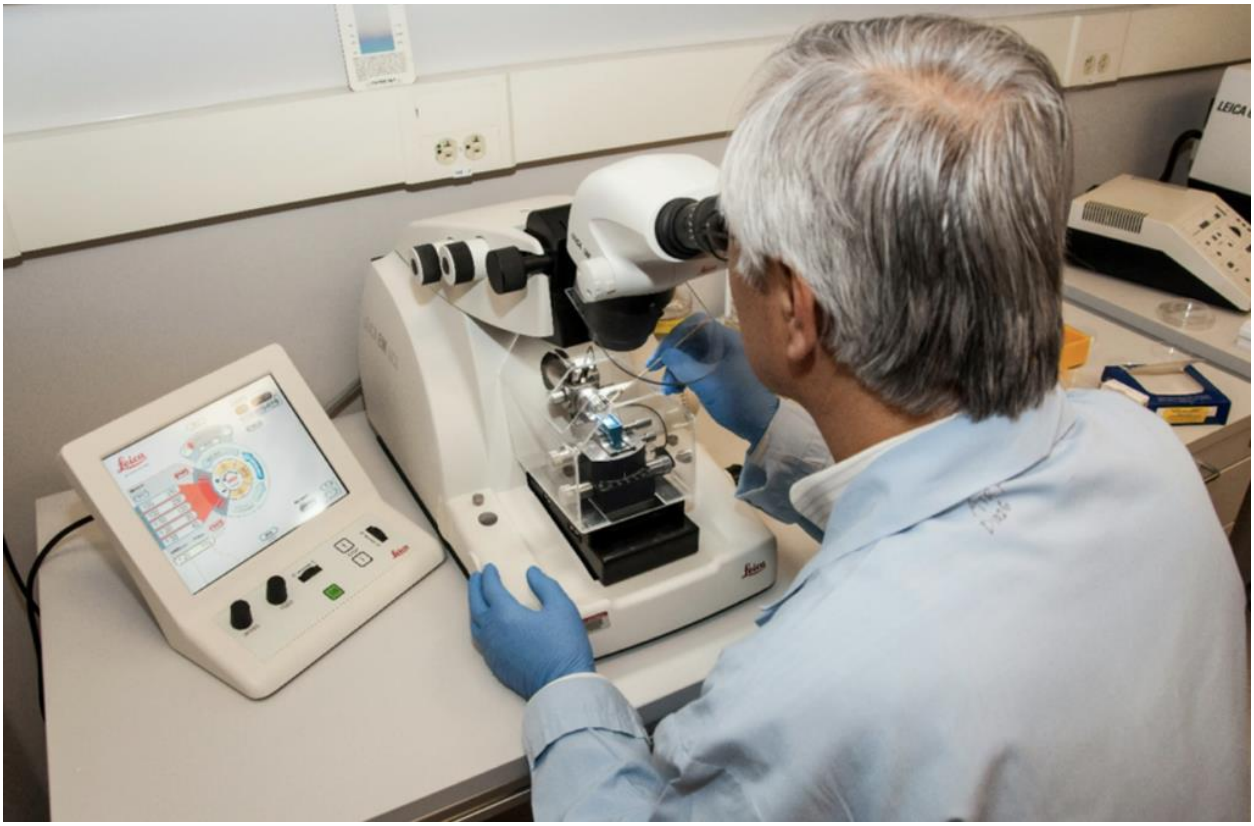
June 3, 2024



Biodexa Pharmaceuticals (NASDAQ:BDRX)) just announced promising phase 2 results for its newly in-licensed drug eRapa for treating familial adenomatous polyposis (FAP), a mainly genetic disease of the lower GI tract for which there is currently no remedy except surgical removal of the colon and/or rectum.

In a clinical trial involving 30 adult patients, three groups received the same dose of the drug but with different regimens over a period of 12 months. Safety, tolerability and changes from baseline in polyp burden (measured by the sum of polyp diameters) were evaluated using endoscopic exams.

After the first six months, eRapa appeared to be safe and well-tolerated with a statistically significant 24% reduction (p=0.04) in the total polyp burden compared with

baseline, as well as an overall 83% non-progression rate. In other words, the drug has been proven to have a high success rate at stopping the growth of polyps before they get a chance to turn into cancer.

Biodexa claims that no drug before has shown such promise in stalling the progression of this disease. The company plans to announce the 12-month results of the phase 2 trial at the InSIGHT scientific conference in Barcelona on June 19-22.

Understanding FAP

FAP is an inherited disease affecting the gastrointestinal tract. If left untreated, it causes hundreds to thousands of polyps to grow inside the colon or rectum. The condition is typically diagnosed in the early teenage years and results in a nearly 100% lifetime risk of colorectal cancer.

Treatment options are very limited, with the only current remedy for FAP being surgical removal of the colon and/or rectum, a surgery that always results in the lifelong use of a colostomy bag.

With roughly 100,000 individuals in the United States and Europe affected by FAP, there is a considerable need for an effective non-surgical intervention.

Introducing eRapa: A New Hope

In April, Biodexa acquired worldwide exclusive rights to eRapa, a drug that the company hopes will delay or prevent the need for surgery.

eRapa is a proprietary oral tablet formulation of rapamycin, which is known to play a role in regulating cellular metabolism, growth and proliferation – all crucial factors in cancer development. Using nanotechnology and pH-sensitive polymers, Biodexa has designed eRapa to address the poor bioavailability, variable pharmacokinetics and toxicity generally associated with the currently available forms of rapamycin.

The medication can also potentially be used to treat bladder and prostate cancers. Results of an ongoing phase 2 study into bladder cancer are expected to be announced in the second quarter of 2025.

Non-Dilutive Financial Backing And Next Steps

Crucially, the Cancer Prevention Research Institute of Texas (CPRIT) has awarded a $17 million grant to support the phase 3 registrational study of eRapa in FAP. The grant requires a 1 for 2 match and Biodexa recently announced that it secured $7 million, most of the required $8.5 million match, in financing through the exercise of existing warrants, which the company intends to use to advance eRapa through the final clinical stage. A phase 3 trial is expected to start in the first quarter of 2025 which, if successful, is expected to lead to applications for marketing approvals in the U.S. and Europe.

eRapa has the potential to catapult Biodexa from a clinical-stage biotech to a commercial organization, supported by non-dilutive grant funding for a devastating disease that currently has no FDA-approved drugs.

All eyes are now on the upcoming 12-month results of the phase 2 trial to be announced later this month, and the subsequent phase 3 trial next year.

Featured photo by National Cancer Institute on Unsplash.

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