Biodexa Looks To Prevent Or Delay The Worst Outcomes For Adolescents And Young Adults With Devastating Precancerous Condition

Registrational phase 3 clinical trials of Biodexa's (NASDAQ:BDRX) candidate eRapa are expected to start first quarter next year.

The candidate was developed with private funds and acquired by Biodexa, its second portfolio expansion in less than six months, and is supported by a $17 million grant from the State of Texas.

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Individuals with hundreds of tiny precancerous polyps growing in their lower GI tract face serious trouble.

The condition, called Familial Adenomatous Polyposis, or FAP, is caused by a single gene mutation and is generally diagnosed in teenage years -- a few polyps appear at first and are surgically removed.

But as the disease progresses - and it always does -- the lining of the lower GI tract becomes blanketed with hundreds and even thousands of tiny polyps - too numerous for surgical removal.

There are extremely limited options for FAP patients, and if untreated, it leads to colorectal cancer 100% of the time. Without any FDA approved drugs, the only treatment option today is the removal of the colon and/or rectum, resulting in the lifelong use of a colostomy bag.

But hope could be on the horizon.

Biodexa Pharmaceuticals (NASDAQ:BDRX), an acquisition-focused biopharmaceutical company, recently acquired exclusive worldwide rights to eRapa™, a phase 3-ready candidate for slowing or preventing the growth of aggressive FAP precancerous polyps in the GI tract.

eRapa was acquired from Emtora Biosciences, which developed the candidate with funding from the Cancer Prevention and Research Institute of Texas. The institute is also supporting eRapa's phase 3 program with an additional $17 million grant. The potentially registrational phase 3 trial is expected to start in the first quarter of next year.

Data from a phase 2 study in FAP will be presented at podium presentations at two leading scientific conferences later this quarter. eRapa was studied in 30 FAP patients, with the primary endpoint being overall polyp burden at six months compared with baseline. The current standard of care is limited to frequent surveillance and surgery.

The acquisition marks Biodexa's second within the past six months and expands its development portfolio to three pharmaceutical compounds covering seven indications, six of which are in the clinic. Four have received Orphan Drug Designations from the FDA.

Although potentially suitable for several indications, including bladder and prostate cancers, eRapa is being initially developed for treating precancerous FAP, the polyps that presage cancer of the colon and/or rectum in approximately 100,000 individuals in the U.S. and Europe. FAP most typically results in surgical removal of the colon and/or rectum. The procedures rid the body of polyps that are on track to become cancerous and reduce the risk of metastasis to other organs. The surgeries can be challenging and always result in the lifelong use of a colostomy bag.

Phase 3 Trial Of eRapa

In announcing eRapa's acquisition, Stephen Stamp, CEO and CFO of Biodexa said, "Acquiring a phase 3 ready asset, particularly one supported by $17 million of non-dilutive grant funding, significantly advances Biodexa's oncology pipeline and adds numerous valuation catalysts for our stakeholders. We are delighted to be working with the Emtora team which has excelled in bringing eRapa close to the end of phase 2 in Non-muscle Invasive Bladder Cancer and to the beginning of a phase 3 trial in FAP, a devastating disease for which there is currently no approved pharmacological agent for altering its progression. Left untreated, it almost always leads to incredibly invasive surgery and a major deterioration in the quality of life."

Stephen Dufilho, executive chairman of Emtora said, "The transaction with Biodexa is the culmination of a decade-long effort to advance our potentially game-changing eRapa to a registrational phase 3 trial and ultimately to patients in need…We look forward to working with the Biodexa team as we embark upon this next chapter."

Data from an ongoing phase 2 study of eRapa in non-muscle invasive bladder cancer is expected to be read out in Q2 2025. This study is supported by a $3 million grant from the National Cancer Institute, a part of the National Institutes of Health.

eRapa's addition to Biodexa's portfolio further strengthens its position as an innovator in the industry. If clinical trials continue to show success, eRapa would be on track to be the first pharmaceutical intervention for FAP. Therapeutic solutions like eRapa will be key to improving the quality of life for thousands of patients.

With the addition of eRapa to its portfolio, Biodexa expects an expansion of news flow in the months and quarters ahead.

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