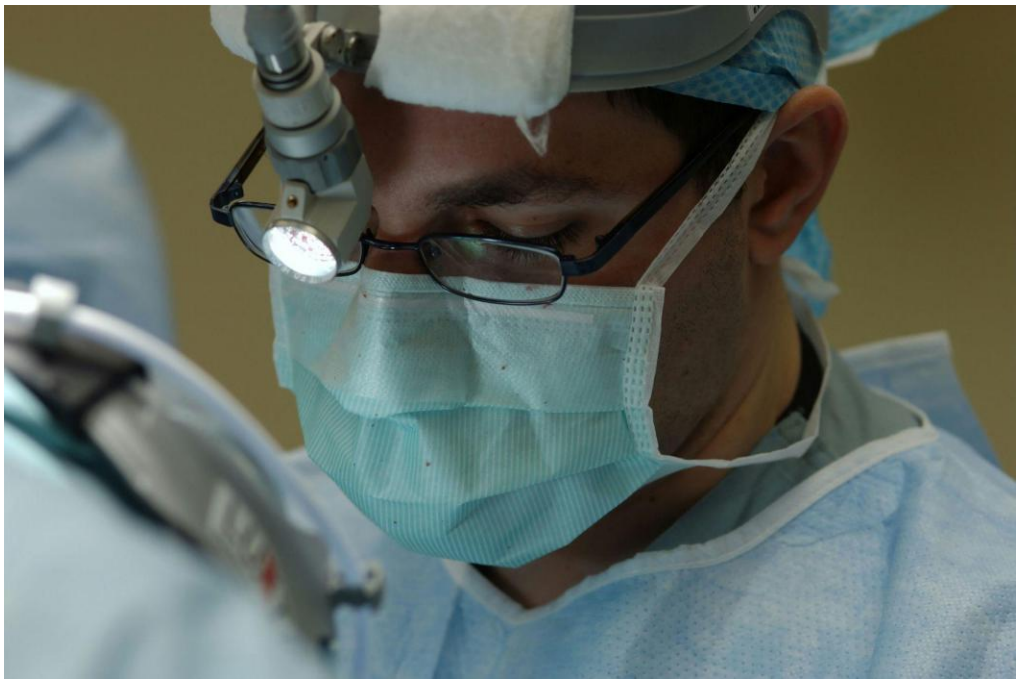
With Fast Track Designation in Hand, a Successful Protocol Discussion with FDA, and CROs in Place, Biodexa is on Track to Initiate its Funded Phase 3 Trial in FAP Next Quarter

Biodexa Pharmaceuticals PLC. (NASDAQ: BDRX), a clinical stage biopharmaceutical company developing a pipeline of innovative products for the treatment of diseases with unmet medical needs, is making progress in readying the launch of a phase 3 trial for eRapa, its proprietary encapsulated form of rapamycin being developed for the treatment of familial adenomatous polyposis (FAP).



In just the last few weeks, Biodexa received Fast Track designation from the FDA, conducted a successful Type C (pre-Phase 3 protocol finalization) meeting with the FDA and appointed a clinical research organization (CRO) to conduct the European component of its registrational Phase 3 trial. A CRO for the U.S. component was appointed earlier.

FAP is an inherited condition that puts people at a much greater risk of developing colon cancer. With FAP, hundreds or thousands of precancerous polyps grow throughout the gastrointestinal tract. There is no approved therapeutic option for treating FAP patients, for whom active surveillance and surgical resection of the colon and/or rectum remain the standard of care. People with FAP, which usually appears in the patient's mid-teens, end up eventually having their entire colon removed. If left untreated there is a high likelihood the person will develop colon or rectum cancer.

Biodexa hopes to help with eRapa, a proprietary oral tablet formulation of rapamycin, also known as sirolimus, which slows down the mTOR (mammalian Target Of Rapamycin) protein.

"Too much mTOR has been linked to cancer and has been shown to be over-expressed in FAP polyps – thereby underscoring the rationale for using an mTOR inhibitor like eRapa to treat FAP", noted Stephen Stamp, Biodexa's CEO and CFO.

Phase 3 Study Commencing Next Quarter

Biodexa, which has already received Fast Track designation by the FDA for the drug, completed a successful Phase 2 trial of eRapa, demonstrating a 17% median decrease in overall polyp burden and an overall non-progression rate of 75%. Biodexa said patients in cohort 2, the dosage regimen that will be used in Phase 3, experienced an 89% non-progression rate and 29% median reduction in polyp burden at 12 months compared with baseline.

The Phase 3 study will be a double-blind placebo-controlled design recruiting approximately 168 high-risk patients diagnosed with germline or phenotypic FAP. It is expected the study will be conducted in about 30 clinical sites across the U.S. and Europe.

That Phase 3 trial is getting closer to a launch following on the heels of what the company says was a successful Type C meeting with the FDA. During the meeting with FDA representatives from both the gastroenterology and oncology divisions, Biodexa and the FDA discussed the company's statistical plan, the safety database and a composite endpoint for the Phase 3 study. As a result of that meeting, Biodexa believes it has a clear path forward for the initiation of the U.S. Phase 3 study next quarter.

"With no approved products for FAP, we were pleased to collaborate with FDA and our U.S. CRO, LumaBridge, to define the regulatory pathway for eRapa in FAP," said Gary Shangold, MD, Chief Medical Officer of Biodexa. "Agreement on the composite endpoint, in particular, clears the path to finalize the protocol, recruit the U.S. sites and begin patient enrollment."

The Phase 3 program is substantially funded by a $17 million grant from the Cancer Prevention Research Institute of Texas, which has been matched 1:2 by Biodexa contributions of $8.5 million for a total funding of $25.5 million.

U.S. and European CROs On Board

Biodexa previously appointed **LumaBridge** to conduct the study in the U.S. and just tapped **Precision for Medicine** as the CRO to conduct the European component of the upcoming registrational Phase 3 study of eRapa in FAP.

LumaBridge was founded in 2014 to help advance the development of novel immunotherapies in the fight against cancer. Building on the founders' 3 decades of combined experience in academic and military research, LumaBridge offers full outsourced clinical trial support across the entire timeline of clinical development, including consultation on clinical development strategy, as well as special capabilities in military research. Over the 11 years since its founding, LumaBridge has made a significant impact in the advancement of immuno-oncology therapies, supporting a substantial number of trials and projects for over 30 clients.

Precision for Medicine is focused on rare diseases and has a stated mission to accelerate the pathway for complex drug development. Precision for Medicine has been conducting studies for over twenty years and according to Biodexa is known for its high-caliber, therapeutically specialized staff, experienced scientists and physicians, advanced specialty laboratories and problem-solving capabilities. Precision for Medicine has conducted 333 clinical trials in rare diseases and employs over 700 team members in Europe across 11 locations, Biodexa shared in a press release.

With thousands of new cases of FAP each year, people in Europe and America suffering from this disease need relief. Biodexa is aiming to deliver that, and with its phase 3 study about to get underway, that may happen sooner rather than later.

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