Biodexa Announces Additional Positive Results Of Phase 2 Trial Of eRapa In Treatment Of Precancerous Polyps In The GI Tract – Now 12-Month Data

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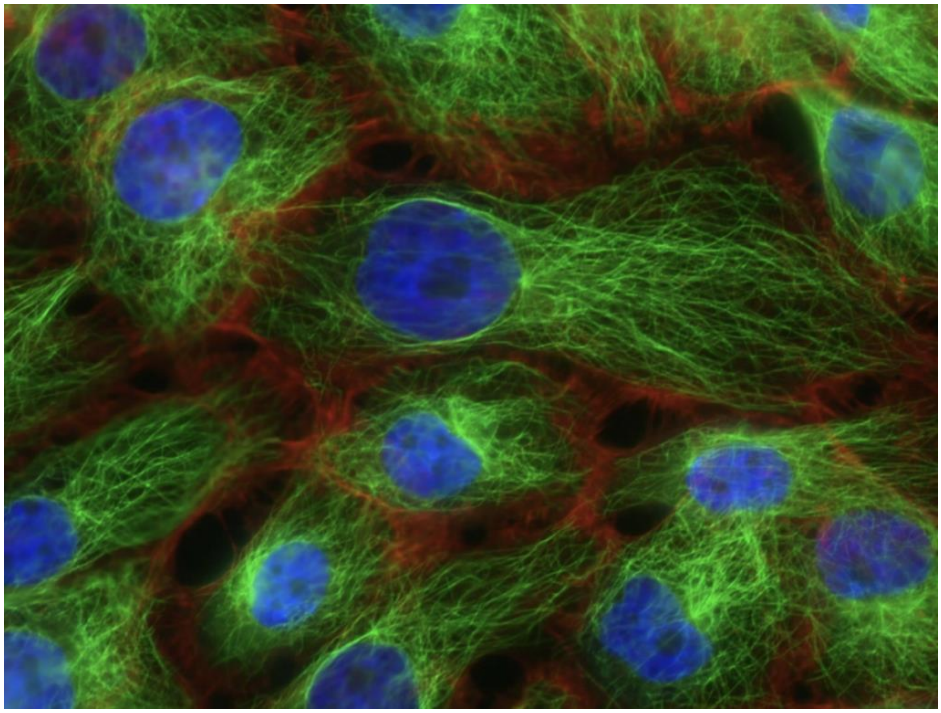

Biodexa Pharmaceuticals PLC (NASDAQ: BDRX), an acquisition-focused clinical-stage biopharmaceutical company developing a pipeline of innovative products for the treatment of diseases with unmet medical needs, seems to be making good progress with eRapa™, its drug to treat Familial Adenomatous Polyposis (FAP).

FAP is a mostly inherited condition that puts people at a much greater risk of developing colorectal cancer. Positive 12-month data from a phase 2 clinical trial were recently presented at the 2024 InSIGHT biannual meeting in Barcelona.

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 and/or rectum resected and having to carry a colostomy bag for the remainder of their lives. If left untreated, there is a 100% chance the person will develop colorectal cancer.

A Better Way Of Treating FAP

While multiple screenings and surgeries are a way of life for the more than 100,000 people worldwide who suffer from this condition, it doesn't have to remain that way.

Biodexa believes eRapa could be the first therapeutic option to treat this precancerous condition, and its data so far backs up that assessment. Results of a 12-month phase 2 clinical trial of eRapa demonstrated an overall 17% median decrease in overall polyp burden and an overall non-progression rate of 75%. Even more compelling, of patients in Cohort 2 (treated daily, alternate weeks), 89% of patients were deemed non-progressors at 12 months, with a median reduction in polyp burden of 29%. That could be gaming-changing for FAP patients if it means fewer surgeries with much-improved quality of life. The 12-month data demonstrate the longevity of the effect of eRapa.

"The promising phase 2 results, if confirmed in a registrational phase 3 study, may delay or potentially obviate the need for resection of the colon and/or rectum in FAP patients," said Stephen Stamp, CEO of Biodexa. "The six-month, and now 12-month, data together with its apparent tolerability suggest longer-term use of eRapa may be possible, with the potential to forestall resection and substantially increase the quality of life of patients with this devastating precancerous condition impacting up to 40,000 patients in the U.S. and up to 60,000 in Europe."

eRapa is 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.

Stopping It In Its Tracks

The phase 2 open-label study of 30 adults with FAP was conducted in seven U.S. centers of excellence. The median age of the trial participants was 43 years, with either an intact colon or one with a portion removed and at least ten noncancerous tumors in the rectal remnant. Patients were enrolled in three dosing cohorts, including every other day, daily every other week and daily. Although the primary endpoints were safety and tolerability of eRapa and percentage change from baseline in polyp burden at six months, patients continued to receive treatment and monitoring for 12 months, leading to the new data.

Biodexa said the dosing given to cohort 2 - daily every other week - will likely be the preferred dosage regime for its phase 3 trial, which the company is gearing up to launch soon. That study is planned to be a double-blind placebo-controlled design recruiting approximately 140 high-risk patients diagnosed with germline or phenotypic FAP.

Biodexa's phase 2 results were presented at InSIGHT by Carol Burke, M.D., a specialist gastroenterologist at the Cleveland Clinic and a leading authority in FAP. Burke is the Principal Investigator for both the phase 2 study and the upcoming phase 3 study. The phase 2 trial was partially supported by $3 million in grant funding from the Cancer Prevention and Research Institute of Texas (CPRIT). CPRIT is providing a $17 million grant for the phase 3 trial.

FAP may be rare, but for the tens of thousands of people suffering from this precancerous condition, there's got to be a better treatment. Biodexa believes it has that with eRapa. The phase 2 trial results seem to lean that way, and with a phase 3 study about to kick off, there may be hope on the horizon for FAP patients.

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