Biodexa Moves Into Phase 3 With eRapa For FAP With First Patients Enrolled

On Track To Be First Mover In $7Bn Addressable Market With No Current Therapeutic Options

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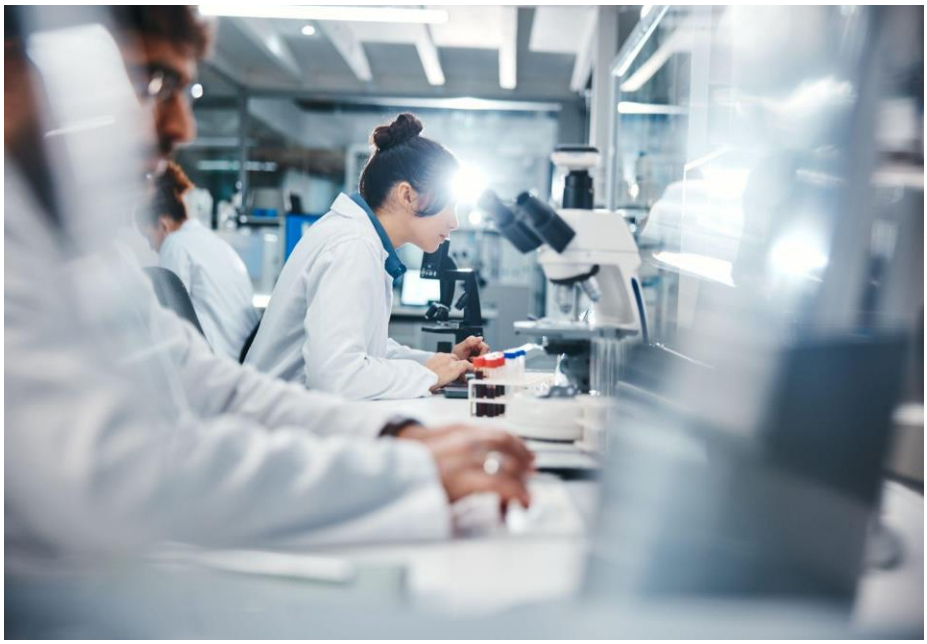

Biodexa Pharmaceuticals PLC. (NASDAQ: BDRX), a late clinical-stage biopharmaceutical company developing a pipeline of innovative products for the treatment of diseases with unmet medical needs, has launched its registrational Phase 3 trial of eRapa – its proprietary encapsulated form of rapamycin being developed for the treatment of familial adenomatous polyposis (FAP), a debilitating disease of the lower GI tract.

Multiple Key Milestones So Far in 2025

The company just enrolled the first patients in the Phase 3 trial. Earlier this year, its collaboration partner, **Rapamycin Holdings, Inc.**, which does business as **Emtora Biosciences**, was awarded an additional $3 million grant by the Cancer Prevention & Research Institute of Texas bringing the total non-dilutive funding for the Phase 3 trial to $20 million. Together with the match already paid into escrow by Biodexa, the Phase 3 trial is basically funded. The company also recorded two other important milestones earlier this year: Fast Track status from the U.S. Food and Drug Administration and Orphan Drug designation from the European Commission.

All three milestones put the company in a clear leadership position in advancing a drug that could bring relief to people suffering from this largely genetic disease.

A Rare Disease But A $7Bn Addressable Market

FAP causes hundreds or thousands of precancerous polyps to grow throughout the lower 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 rectum removed. If left untreated, there is a near 100% chance the patient will develop colorectal cancer.

Biodexa Pharmaceuticals (BDRX)	
ADS price	$5.65
ADSs outstanding	619,523
Market capitalization	$3.5 M

There are reported prevalences of FAP of one in 5,000 to 10,000 population in the U.S. and one in 11,300 to 37,600 population in Europe. Based on the lowest estimates of prevalence of 1/10,000 and 1/37,600 in the US and Europe, respectively, the adult populations in each territory of approximately 258 million and 358 million and the median annual cost of approved non-biologic orphan drugs in the US of $206,176, the combined US / European addressable market for eRapa in FAP is approximately $7.3Bn.

eRapa Could Have First Mover Advantage

Treating FAP has proven difficult over the years. While **Pfizer Inc.'s** (NYSE: PFE) Celecoxib (Celebrex), a Cox-2 inhibitor, was approved to reduce the number of polyps for FAP about eight years ago, it failed a post approval study and the label was pulled. **Recursion Pharmaceuticals, Inc.** (NASDAQ: RXRX) is developing REC-4881 and **Tempest Therapeutics Inc** (NASDAQ: TPST) is developing TPST-1495, both for FAP and both are in Phase 2. Biodexa, with compelling Phase 2 data in hand, is already in Phase 3 and could have first mover advantage in a significant market. Orphan drug designation provides market exclusivity for eRapa of 7 years and 10 years from launch in the U.S. and Europe, respectively.

Phase 3 Trial Fueled By Additional Grant On Back Of Compelling Phase 2 Data

Biodexa's Phase 3 trial is a double-blind, placebo-controlled trial in 168 patients, randomized 2:1 drug to placebo. It is expected that the study will be conducted in approximately 30 clinical sites across the U.S. and Europe. The U.S. component of the study is being managed by LumaBridge, and the European component by Precision for Medicine LLC.

The Phase 3 trial advanced after Biodexa completed a Phase 2 trial that demonstrated a 17% median decrease in overall polyp burden and an overall non-progression rate of 75% at 12 months. In cohort 2, which deployed the dosage regimen selected for the Phase 3 trial, the median decrease in polyp burden was 29% with a non-progression rate of 89% at 12 months.

Following that study Biodexa held a Type C meeting with FDA that included a discussion of the statistical plan, the safety database and, most importantly, a composite endpoint for the Phase 3 study. FDA representatives from both the gastroenterology and oncology divisions provided valuable input into the proposed program.

On the back of the Phase 2 data, the Cancer Prevention & Research Institute of Texas (CPRIT) initially awarded a $17 million grant to support the Phase 3 program. This was increased to $20 million with the most recent award. Overall, CPRIT has awarded $2.9 billion in grants to Texas research institutions and organizations focused on treating and preventing cancer. CPRIT funding has advanced scientific and clinical knowledge and provided 7.4 million life-saving cancer prevention and early detection services reaching Texans from all 254 counties.

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