

CELLTECH GROUP PLC
Form 6-K
April 23, 2003

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a - 16 or 15d - 16 of

the Securities Exchange Act of 1934

For the month of **April, 2003**

Commission File Number: **1-10817**

CELLTECH GROUP PLC

(Translation of registrant's name into English)

208 Bath Road, Slough, Berkshire SL1 3WE ENGLAND

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

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(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____).

Enclosure: Celltech Relaunches Dipentum(R) In U.S

Celltech Relaunches Dipentum(R) In U.S

Dedicated Gastroenterology Sales Force To Promote
Dipentum's Clinical Benefits To Physicians In January 2003

ROCHESTER, N.Y., Jan. 9 /PRNewswire-FirstCall/ -- Celltech Pharmaceuticals, a leading biotechnology company and emerging leader in gastroenterology, announces the relaunch of Dipentum(R) (olsalazine sodium capsules) in the U.S. market. Dipentum is indicated for the maintenance of remission of ulcerative colitis (UC) in patients intolerant of sulfasalazine.

"Ulcerative colitis is a chronic, debilitating condition that can be difficult to treat. Often, successful treatments in some patients may not be effective in others," said Dr. Dan Present, Clinical Professor of Gastroenterology, Mt. Sinai School of Medicine. "Patients need a drug that works for them and is easy to take. I've seen the benefit of taking a second look at effective therapies in the 5-ASA class that may have been overlooked in the past, and Dipentum may be such an example."

Celltech licensed the U.S. marketing rights for Dipentum from Pharmacia Corporation in July 2002. The drug was approved by the United States Food and Drug Administration in 1990, although the product has not been actively supported or detailed to physicians since 1996. "We believe that Dipentum's benefits may have been ignored by physicians," said Simon Hatch, Director, Clinical Development, Celltech Group. "The 5-ASA class will remain a primary treatment for ulcerative colitis, yet the product may have been underutilized due to a lack of information. We believe that there may be a large population of ulcerative colitis patients who could benefit from its use." Dipentum combines proven efficacy with convenient dosing and tolerability. Clinical trials have proven that Dipentum (500 mg BID) is as effective as sulfasalazine (1000 mg BID) in maintaining remission of the disease (n= 164, n=322).(1,2) Dipentum targets the key action site of UC by delivering 98 to 99 percent of the drug's active ingredient directly to the colon to help reduce inflammation. Unlike some other drugs in the class, Dipentum's mechanism of action is not dependent on pH levels in the body.

Patients find Dipentum convenient to take with a manageable side effect profile. Dipentum is taken in 2 capsules twice a day with meals, a patient- friendly lifestyle reminder that helps increase adherence. In two clinical trials (n=47, n=100), the tolerability of Dipentum (500 mg BID with meals) was similar to Asacol(R) (mesalamine) (1.2g per day in divided doses(3))(4,5). The most frequent adverse reaction to Dipentum is secretory diarrhea, which appears to be dose-related and may be reduced by administration with food. Dipentum does not contain sulfa, so there is no sulfa-related intolerance.

Dipentum is contraindicated in patients with hypersensitivity to salicylates. In controlled clinical trials, the incidence of adverse reactions with Dipentum therapy was comparable to placebo with the exception of diarrhea, abdominal pain, and rash/itching. The incidence of diarrhea in controlled studies was 11.1 percent with Dipentum vs. 6.7 percent with placebo.

"Dipentum is a proven therapy that may benefit many ulcerative colitis patients," said Michael Yasick, Head, Gastroenterology Business Unit for Celltech. "With a new, dedicated gastroenterology sales force and proper marketing and educational support, our goal is to help healthcare professionals understand the true clinical profile of the drug, and help physicians and patients understand how to maximize its therapeutic benefits."

Currently, Celltech is building a specialized gastroenterology sales force to support Dipentum and other emerging gastrointestinal therapies. The sales force will focus on building relationships with physicians and key thought leaders and will market the product with samples, patient starter kits and consumer educational materials.

"It is well appreciated that ulcerative colitis is a complex, chronic disease with many treatment challenges," said Dr. Norman LaFrance, Sr. Vice President - Medical & Regulatory Affairs, Celltech Pharmaceuticals. "For decades, the 5-ASA drugs have been the cornerstone of successful treatments in UC, but some dosage regimens can be a burden for patients."

"We have heard the medical community and patients comment about the importance of different options in the 5-ASA class," added LaFrance. "These options have been successful and appreciated in some patients, but overlooked in others. As a result, Celltech is committed to providing important medical information and education, including dosing and tolerability, and to ensure that the medical community understands how Dipentum and the 5-ASA class of drugs can address the needs of UC patients."

About Ulcerative Colitis

The Crohn's and Colitis Foundation of America estimates that approximately one million Americans suffer from inflammatory bowel disease, such as ulcerative colitis.

Ulcerative colitis attacks the large intestine (colon), causing painful diarrhea and bleeding. It can lead to numerous complications,

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including colon cancer. While medications control most symptoms, the only cure is surgical removal of the colon. Symptoms range from mild to severe, including:

- Persistent diarrhea
- Abdominal pain
- Rectal bleeding
- Fever
- Weight loss
- Skin or eye irritations
- Delayed growth and sexual maturation in children

Most patients with mild or moderate ulcerative colitis are first treated with 5-ASA agents, a combination of the drugs sulfonamide, sulfapyridine and salicylate that helps control inflammation. Sulfasalazine is the most commonly used of these drugs. Patients who do not tolerate sulfasalazine may respond to other 5-ASA agents, such as Dipentum, which is indicated for the maintenance of remission of ulcerative colitis in patients intolerant of sulfasalazine.

About Celltech Group

Celltech Group plc (NYSE: CLL; LSE: CCH) is one of Europe's largest biotechnology companies, with an extensive late stage development pipeline and a profitable, cash-generative pharmaceutical business. Celltech also possesses drug discovery capabilities of exceptional strength, including a leading position in antibody engineering. More details can be found at www.celltechgroup.com.

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Please see accompanying full prescribing information.

(1) Ireland A, Mason CH, Jewell DP. Controlled trial comparing olsalazine and sulphasalazine for the maintenance treatment of ulcerative colitis. *Gut*. 1988; 29:835-837.

(2) Nilsson A, Danielsson A., Lofberg R, et al. Olsalazine versus sulphasalazine for relapse prevention in ulcerative colitis: a multicenter study. *Am J Gastroenterol*. 1995;90:381-387.

(3) The dose of Asacol administered in these trials was lower than the labeled maintenance dose of 1.6 g per day.

(4) Rao SS, Cann PA, Holdsworth CD. Clinical experience of the tolerance of mesalazine and olsalazine in patients intolerant of sulphasalazine. *Scand J Gastroenterol*. 1987; 22:332-336.

(5) Courtney MG, Nunes DP, Bergin CF, et al. Randomised comparison of olsalazine and mesalazine in prevention of relapses in ulcerative colitis. *Lancet*. 1992; 339:1279-1281. SOURCE Celltech Group plc

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLC

CELLTECH GROUP

(Registrant)

ALLEN

Officer

By: /s/ PETER

Peter Allen
Chief Financial

Dated: 23 April, 2003