

CELLTECH GROUP PLC
Form 6-K
January 06, 2004

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 **January, 2004**

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 ☒

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

Enclosure: CDP870 Phase III Trials dated 06 January 2004

6 January 2004

CELLTECH GROUP PLC

INITIATION OF CDP870 PHASE III TRIALS IN CROHN'S DISEASE

Celltech Group plc (LSE: CCH; NYSE: CLL) today announces that it commenced dosing of patients in the first of two pivotal Phase III studies ("PRECISE-1") for CDP870 in Crohn's disease on 23 December 2003, following its U.S. investigator meeting held on 22 November. The second pivotal study ("PRECISE-2 ") is scheduled to start in January 2004, with regulatory submissions planned for 2005. Celltech intends to market CDP870 in Crohn's disease using its gastroenterology focused sales force in the US and specialist focused sales forces in Europe.

CDP870 utilises Celltech's proprietary PEGylated antibody fragment technology to target TNF-alpha, a key mediator of inflammation common to a number of conditions, including Crohn's disease, rheumatoid arthritis and psoriasis. CDP870 is a Fab' fragment of a humanised anti-TNF-alpha antibody in which PEG is site-specifically attached to increase circulating half-life whilst maintaining binding activity. CDP870 is administered by subcutaneous injection.

Dr. Goran Ando, Chief Executive Officer of Celltech, commented: "There remains a huge unmet need in the treatment of Crohn's disease. We believe that CDP870 has significant potential to bring substantial benefits to Crohn's disease patients, and have initiated a comprehensive and innovative programme designed to demonstrate the particular advantages of this new treatment. Celltech is committed to developing new, innovative approaches in order to provide exceptional care for patients with inflammatory bowel disease. This commitment is exemplified both by our investment in our product pipeline and by our creation of highly specialised sales and marketing resources to fully support the commercialisation of these products."

Celltech's PRECISE (Pegylated antibody fRagment Evaluation In Crohn's dIsease: Safety and Efficacy) programme is a large, international Phase III registration programme involving over 1,300 patients, which will assess the impact of CDP870 on induction and maintenance of clinical response in patients with moderate to severe Crohn's disease.

Rodger DeRose, President and Chief Executive Officer of the Crohn's and Colitis Foundation of America (CCFA), commented: "We are extremely pleased that Celltech is moving CDP870 into Phase III trials. Over half a million Americans suffer from Crohn's Disease, dramatically impacting their ability to lead normal healthy lives. Recent technological advancements are offering new hope for these patients, and potential new treatments such as CDP870 may offer physicians who care for Crohn's Disease patient valuable alternatives in their approach to this challenging disease. Crohn's Disease patients or their families wishing to obtain further information on Crohn's Disease or specific information about ongoing clinical trials are encouraged to visit the CCFA website at www.ccfa.org"

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Celltech Group plc (LSE: CCH; NYSE: CLL) is one of Europe's largest biotechnology companies, with an extensive late stage development pipeline, funded by its 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.

Notes for Editors

Celltech's antibody fragment technologies

Celltech has developed a proprietary system of engineering and manufacturing fragments of antibodies that are able to bind to a target protein. These antibody fragments have the benefit of being manufactured in a microbial production system, rather than mammalian production systems typically used for production of whole antibodies, and exclude the antibody constant region ("Fc region"), which can in some cases lead to undesirable or unpredictable side effects. These antibody fragments are chemically modified by site-specific attachment of a polymer, polyethylene glycol ("PEG"). The resulting PEGylated antibody fragments retain both the binding activity and circulating half-life of the parent antibody, with the resulting increase in solubility facilitating dosing by subcutaneous injection.

Celltech desires to take advantage of the 'Safe Harbor' provisions of the US Private Securities Litigation Reform Act of 1995, with respect to forward-looking statements contained within this document. In particular certain statements with regard to the anticipated timing of clinical trials and regulatory filings with CDP870 in Crohn's disease, and the ability of Celltech to successfully develop and commercialise CDP870 in Crohn's disease, are all forward-looking in nature. By their nature forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. In addition to factors set forth elsewhere in this document, the following factors, although not exhaustive, could cause actual results to differ materially from those the Company expects: unanticipated difficulties in the design or implementation of clinical trials, studies and investigations, results from clinical trials, studies and investigations that are inconsistent with previous results and the Company's expectations, failure to obtain and maintain required approvals for products from governmental authorities, unavailability of raw materials or other interruptions in production or product distribution both internal and external, unexpected difficulties in the scale-up of production to viable commercial levels, unexpected fluctuations in production yields for development products or marketed products, inability of the Company to market existing and new products effectively, the failure of the Company's development, manufacturing and marketing partners to perform their contractual obligations and the risk of substantial product liability claims. Other factors that could affect these forward-looking statements are described in the Company's reports filed with the US Securities and Exchange Commission. The forward-looking statements included in this document represent the Company's best judgment as of the date hereof based in part on preliminary information and certain assumptions which management believes to be reasonable. The Company disclaims any obligation to update these forward-looking statements.

END

SIGNATURES

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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

By: /s/ PETER

Officer

Peter Allen
Chief Financial

Dated: 06 January, 2004