CELLTECH GROUP PLC
Form 6-K
June 23, 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 **June, 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 X 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 X

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

Enclosure: FDA Approval

For immediate release

23 June 2004

CELLTECH GROUP PLC

CELLTECH ANNOUNCES U.S. FDA APPROVAL FOR 12-HOUR CODEPREX™

- First codeine cough suppressant to be dosed every 12 hours -

Celltech Group plc (LSE: CCH; NYSE: CLL) announces that the U.S. Food and Drug Administration ("FDA") has approved Codeprex™ (codeine polistirex/ chlorpheniramine polistirex) Extended-Release Suspension CIII for cough relief. Codeprex™ uses Celltech's proprietary Pennkinetic® extended-release drug delivery technology to provide 12-hour dosing. Codeprex™ is the first codeine-based cough suppressant to provide 12-hour dosing and offers patients the convenience of less frequent dosing compared to other codeine cough suppressants, in particular by avoiding the need for middle of the night dosing.

Codeprex™ is indicated for the temporary relief of cough - as may occur with the common cold or inhaled irritants - and for the temporary relief of: runny nose, sneezing, itching of the nose or throat; and itchy watery eyes due to hay fever, other upper respiratory allergies, or allergic rhinitis. Codeprex™ is expected to be available in retail pharmacies by the fourth quarter.

"Celltech is introducing Codeprex™ in order to offer a 12-hour dosing option for patients requiring a prescription codeine cough suppressant, " said Dan Greenleaf, president, US operations, Celltech Pharmaceuticals. "The approval of Codeprex™ extends our leadership in the cough/cold market, which can be in part attributed to Celltech's proprietary Pennkinetic® technology. It is the foundation for a full range of antitussives developed by Celltech to meet individual patient needs."

Celltech also manufactures Tussionex® (hydrocodone polistirex/chlorpheniramine polistirex) Extended-Release Suspension CIII, the number one prescribed hydrocodone antitussive, and Delsym® Extended-Release Suspension, an over-the-counter (OTC) dextromethorphan antitussive that provides 12-hour cough relief. Delsym®'s efficacy has helped position it as the number two brand in the cough suppressant category, and the number one brand in pediatric dollar sales.

Codeprex™ is contraindicated in persons with sensitivity to codeine or chlorpheniramine. Codeprex™ should be used with caution in patients with persistent or chronic cough, as occurs with smoking, asthma or emphysema, or with cough accompanied by excessive phlegm. Caution is also advised when prescribing to patients with narrow-angle glaucoma or prostatic hypertrophy. The possibility of tolerance and/or dependence, particularly in patients with a history of drug abuse, should be considered. Common side effects may include drowsiness, confusion, dizziness, nausea, constipation, dry mouth, headache, and allergic reactions.

Tussionex® is contraindicated in the presence of known allergy to hydrocodone or chlorpheniramine. The most common adverse reactions associated with Tussionex ® are sedation, drowsiness, and mental clouding, which may impair the mental and/or physical abilities required for potentially hazardous tasks. The possibility of tolerance and/or dependence, particularly in patients with a history of drug dependence, should be considered.

Codeprex™ and Tussionex® are not recommended for use in children under six years of age.

Please see enclosed full-prescribing information for Codeprex™ and Tussionex ®.

Codeprex: http://www.celltechgroup.com/Products/PI/LR428_COL.pdf

Tussionex: http://www.celltechgroup.com/Products/PI/Tussionex_LR242A.pdf

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Celltech Group plc (LSE: CCH; NYSE: CLL) is one of Europe's largest biotechnology companies, with an innovative 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

Codeprex, Tussionex, Delsym and Pennkinetic are trademarks of Celltech.

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 timing of launch of Codeprex™ are 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: pricing and product initiatives of the Company's competitors, including the introduction of branded competition or generic substitution for the Company's products, failure to 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, fluctuations in currency exchange rates, inability of the Company to market new products effectively, 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 judgement 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

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.

CELLTECH GROUP PLC

(Registrant)

By: /s/ PETER ALLEN

Peter Allen
Chief Financial Officer

Dated: 23 June, 2004