

CELLTECH GROUP PLC  
Form 6-K  
August 01, 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 **August, 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

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

Enclosure: Zavesca Approval

1st August 2003

**US FOOD AND DRUG ADMINISTRATION APPROVES ZAVESCA®  
- First oral treatment option for type 1 Gaucher disease -**

Celltech Group plc (LSE: CCH; NYSE: CLL) and Actelion Ltd (SWX: ATLN) today announced that the US Food and Drug Administration (FDA) has approved Zavesca® (miglustat) capsules, the first oral treatment option for type 1 Gaucher disease.

Type 1 Gaucher disease is a rare genetic lipid storage disorder affecting an estimated 10,000 individuals worldwide. It is a progressive condition that is caused by a deficiency of glucocerebrosidase, an important enzyme in the metabolism of key lipids in the body. The deficiency of this enzyme results in accumulation of excess amounts of glycosphingolipids (GSLs) in specific cells primarily in the liver, spleen and bone marrow. Such accumulation leads to liver and spleen enlargement/dysfunction, anaemia, bone disease and pain.

Current therapy includes enzyme replacement therapy (ERT), which is delivered via an intravenous infusion twice monthly.

Zavesca® is the first in a new class of drugs known as substrate reduction therapy (SRT), which reduces the amount of glycosphingolipid (GSL) production to a level which can effectively be cleared by the naturally occurring glucocerebrosidase in the cells. Zavesca® will be available to patients in the United States later this year.

**Zavesca® Indication in the US**

The FDA has approved Zavesca® for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to constraints such as allergy, hypersensitivity, or poor venous access). Women who are or may become pregnant should not take Zavesca®.

Zavesca® is approved in the European Union and is commercially available in the United Kingdom and Germany.

**Background on Actelion and Zavesca®**

Actelion is the license holder for Zavesca® worldwide, with the exception of Israel where the drug is also approved. Actelion is responsible for all regulatory and marketing activities and will book all sales of Zavesca®. The drug was originally developed by Oxford GlycoSciences (OGS), now part of the Celltech Group.

**Actelion and Celltech to further develop Zavesca®**

Through a joint steering committee, Actelion and Celltech are currently conducting clinical studies with Zavesca® for the treatment of other lipid storage disorders, such as type 3 Gaucher disease, Niemann-Pick type C, and Late Onset

Tay-Sachs.

**Contacts:**

|                     |                                      |                       |
|---------------------|--------------------------------------|-----------------------|
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Celltech Group plc (LSE: CCH; NYSE: CLL) is one of Europe's largest biotechnology companies, with an extensive 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](http://www.celltechgroup.com)

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.

PLC

CELLTECH GROUP

(Registrant)

ALLEN

By: /s/ PETER

Peter Allen  
Chief Financial

Officer

Dated: 1 August, 2003