ELAN CORP PLC
Form 6-K
January 03, 2003

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the period ended January 2, 2003

Elan Corporation, plc
(Translation of registrant's name into English)

Lincoln House, Lincoln Place, Dublin 2, Ireland
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover 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/

elan BIOGEN

MEDIA CONTACTS:
Elan -- Sunny Uberoi 212-994-8206
Biogen -- Tim Hunt 617-914-6524
Ketchum -- Amy Losak 646-935-3917
INVESTOR CONTACTS:
ELAN -- Jack Howarth (U.S.) 212-407-5740
Elan -- Emer Reynolds (Europe) 353-1-709-4000
Biogen -- Elizabeth Woo 617-679-2822

ANTEGREN(R)(natalizumab) CLINICAL STUDY RESULTS PUBLISHED IN NEW ENGLAND JOURNAL OF MEDICINE SHOW PROMISING DATA ON DISEASE REMISSION

AND QUALITY OF LIFE FOR PATIENTS WITH CROHN'S DISEASE

Antegren Phase II Results in Multiple Sclerosis
Published in Same Issue of Journal;
Novel Mechanism of Action Shows Promise in Two Diseases

Dublin, Ireland and Cambridge, MA, January 2, 2003 -- Elan Corporation, plc (NYSE: ELN) ("Elan") and Biogen, Inc. (NASDAQ: BGEN) ("Biogen") announce the publication of two clinical study reports on ANTEGREN(R) (natalizumab) in today's issue of the New England Journal of Medicine. Natalizumab, a humanized monoclonal antibody, showed promising results on disease remission and improved quality of life for patients with Crohn's disease in an investigational study, according to results published today. Crohn's disease, a chronic, progressive and immune-related inflammatory disease of the gastrointestinal tract, can cause a range of debilitating symptoms such as severe diarrhea, crampy abdominal pain and malnutrition. Current treatment options for the disease are limited.

Crohn's Disease Study Design and Results

The randomized, double-blind, placebo-controlled, parallel group, Phase II study of 248 patients with Crohn's disease presented in the New England Journal of Medicine was conducted in eight countries at 35 clinical trial sites. Patients were randomized to one of four treatment groups: single 3 mg/kg natalizumab infusion followed by placebo (n=68); two 3 mg/kg natalizumab infusions at four-week intervals (n=66); two 6 mg/kg natalizumab infusions at four-week intervals (n=51), or placebo (n=63) and all groups were observed for at least 12 weeks following the first infusion. Patients with moderate-to-severe active Crohns' disease (Crohn's Disease Activity Index ("CDAI") scores of 220 to 450) were included in the study. The primary measure of effectiveness was clinical remission: a score of less than 150 on the CDAI. Clinical response was defined as a decrease of at least 70 points in the CDAI from baseline. Additional efficacy measures included quality of life assessments, as determined by the Inflammatory Bowel Disease Questionnaire ("IBDQ").

Although the primary endpoint of remission at 6 weeks in the 6 mg/kg dose group compared to placebo was not statistically significant, both groups that received 2 doses of natalizumab had higher rates of clinical remission (a score of less than 150 points on the CDAI score) than the placebo group at multiple time points. The highest rate of remission was in the 3 mg/kg dose group at 6 weeks, with 44% of the natalizumab treated patients in clinical remission (n=29) versus 27% in the placebo group (n=17). A significant difference in clinical responses (decrease of > 70 points in the CDAI score) was noted as early as week 2 and was

maintained through week 12 with a maximal response of 71% in the dual 3 mg/kg dose group (n=47) versus 38% in the placebo group (n=24).

Secondary outcomes included improvements in quality of life as determined by the IBDQ. At week 6, improvements in IBDQ scores were seen across all three natalizumab treated groups, with the highest difference occurring in the dual 6 mg/kg dose group (32 point improvement in IBDQ score from baseline (n=51) versus

15 point improvement in placebo (n=63)).

Natalizumab was generally well-tolerated in patients with active Crohn's disease throughout the study. The most common adverse events reported were headache and abdominal pain. There were no notable differences among treatment groups in the number of patients reporting side effects.

"These results may hold promise of a future treatment option for the one million people worldwide suffering from Crohn's disease," said Subrata Ghosh, MD, lead author, consultant gastroenterologist, Imperial College London, Hammersmith Hospital, UK. "Natalizumab targets the underlying problem in Crohn's disease in a unique way and may provide a meaningful alternative to currently available Crohn's disease therapies."

Natalizumab: First in New SAM Inhibitor Class

Natalizumab is the first in a new class of drugs known as SAM (selective adhesion molecule) inhibitors. In Crohn's disease, immune cells migrate into the inflamed gastrointestinal tract and once there, they amplify the inflammatory process; in multiple sclerosis ("MS"), this same

process occurs but on the myelin sheaths (insulation) on the nerve cells in the brain. Adhesion molecules on the surface of the immune cells play an important role in this migration. Natalizumab binds to a specific adhesion molecule on the immune cell surface known as alpha-4 integrin. By binding to alpah-4 integrin, natalizumab is thought to inhibit immune cells from leaving the bloodstream and prevent them from migrating into the inflamed gut tissue in Crohn's disease or the brain tissue in MS.

Natalizumab, a drug in development by Elan and Biogen, is also being studied in Phase III trials for the treatment of MS and may have potential in other immune-related inflammatory diseases. The Phase II study results evaluating the effects of natalizumab in reducing new inflammatory brain lesions and clinical relapses in patients with relapsing forms of MS were also published in this week's issue of The New England Journal of Medicine.

"The data published in these studies are very important in our understanding of immune-mediated diseases like Crohn's and MS. By selectively blocking the ability of immune cells to migrate to areas of chronic inflammation we may be able to alter the course of underlying disease," said Stephen Hanauer, MD, professor of medicine and clinical pharmacology, Director, section of Gastroenterology and Nutrition, University of Chicago Hospitals and Health System.

Progression of Phase III Development Program: Largest-Ever Trial in Crohn's Disease Fully Enrolled
---

Four Phase III trials further evaluating the safety and efficacy of natalizumab in both Crohn's disease and MS are underway. There are two trials in Crohn's disease: ENACT-1 (Evaluation of Natalizumab in Active Crohn's Disease Trial-1), the largest-ever study in Crohn's disease conducted to date, is now fully

enrolled with more than 850 patients and will evaluate clinical response and ability to induce remission; ENACT-2 (Evaluation of Natalizumab As Continuous Therapy-2) will evaluate duration of effect. Investigators expect ENACT-2 to be fully enrolled shortly.

The two MS trials, both fully enrolled, will evaluate natalizumab in patients with relapsing-remitting forms of the disease. AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) will evaluate the ability of natalizumab to slow the rate of disability in MS and reduce the rate of clinical relapses; SENTINEL (safety and efficacy of natalizumab in combination with AVONEX(R) (Interferon beta-1a) in patients with relapsing-remitting MS) will determine if the combination of natalizumab and AVONEX is more effective than treatment with AVONEX alone in slowing rate of disability and reducing rate of clinical relapses.

Elan is focused on the discovery, development, manufacturing, selling and marketing of novel therapeutic products in neurology, pain management and autoimmune diseases. Elan shares trade on the New York, London and Dublin Stock Exchanges.

Biogen is the world's oldest independent biotechnology company and a leader in biologics research, development and manufacturing. A pioneer in leading edge research in immunology, neurobiology and oncology, Biogen brings novel therapies to improve patients' lives around the world through its global marketing capabilities. For press releases and additional information about the company, please visit http://www.biogen.com.

In addition to historical information, this press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to statements regarding the potential for Antegren as a therapeutic product and the progression of Phase III trials. These statements are based on the companies' current beliefs and expectations as to such future outcomes. Drug development involves a high degree of risk. Success in early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that problems or delays may arise during clinical trials or in the course of development, testing or manufacturing of the product, that results in later stage or larger trials may be different than those seen in earlier stage trials or that the product may not show therapeutic effect or an acceptable safety profile in subsequent trials or may not meet applicable regulatory standards. For more detailed information on the risks and uncertainties associated with Elan and Biogen's drug development and other activities see each company's periodic reports filed with the SEC. Elan and Biogen assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

###

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.

ELAN CORPORATION, plc

By: /s/ William F. Daniel

William F. Daniel
Company Secretary

Date: January 3, 2003