

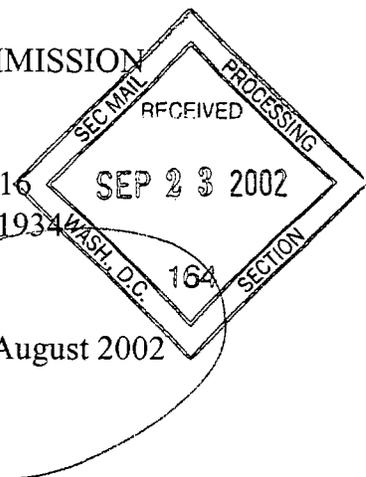


FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

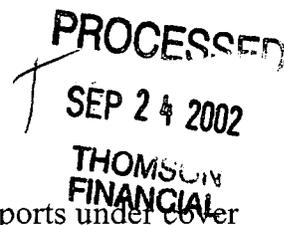
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934

Report of Foreign Issuer  
for the period of 1<sup>st</sup> August 2002 to 31<sup>st</sup> August 2002



**British Biotech plc**

Thames Court  
Watlington Road  
Oxford OX4 6LY  
England



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

Form 20F  Form 40F

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 - \_\_\_\_\_

**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.

**BRITISH BIOTECH PLC**

(Registrant)

By:  Date : 9th September 2002

Name: Tony Weir  
Title: Finance Director

9<sup>th</sup> September 2002

Company Announcements Office  
Stock Exchange  
London  
EC2N 1HP

**BY FAX: 0207 588 6057**

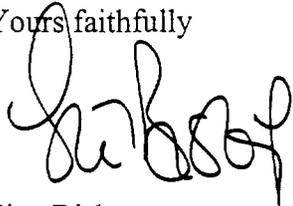
**AVS: 598587**

Dear Sir,

In accordance with paragraph 17 of the Model Code of the UKLA Listing Rules and pursuant to the terms of remuneration agreed between British Biotech plc and its subsidiaries ("British Biotech") and its Chairman, Mr Chris Hampson, it is announced that Mr Hampson, on 9<sup>th</sup> September 2002, acquired 56,476 ordinary shares in British Biotech at a price of 5.25p per share.

Following this purchase, Mr Hampson is interested in a total of 787,410 ordinary shares.

Yours faithfully



Sian Bishop  
Legal Counsel and Deputy Company Secretary

8 August, 2002

4

## **British Biotech and ImmunoGen, Inc. announce initiation of second Phase I study of BB-10901**

### **New study explores more intensive dosing regimen**

British Biotech plc (LSE: BBG, Nasdaq: BBIOY) and ImmunoGen, Inc. (Nasdaq: IMGN) announced today that patient treatment has begun in the planned second Phase I study of BB-10901, a novel anti-cancer agent targeted at small cell lung cancer that uses a humanised monoclonal antibody to deliver a highly potent chemotherapeutic agent specifically to the site of the tumour.

The study is assessing daily dosing of the product and complements a weekly dosing Phase I study currently under way in the United States. It is being conducted at the Christie Hospital in Manchester, under the direction Dr Paul Lorigan and Dr Malcolm Ranson of the Department of Medical Oncology, and at Nottingham City Hospital, under the direction of leading cancer expert Professor James Carmichael and Dr Penella Woll.

The open-label, dose-escalation study will assess the safety, tolerability, and pharmacokinetics of increasing doses of BB-10901; evidence of biological activity will also be determined. The drug will be administered daily for three successive days followed by an 18-day follow-up period. As in the US Phase I study, eligible patients have relapsed or refractory small cell lung cancer, or other tumours that express the CD56 antigen targeted by the drug's antibody component. Dosage will be increased in each new cohort of patients until dose-limiting toxicity occurs and the maximum tolerated dose is established.

The study is expected to be completed by mid-2003, with results available later that year, although timing is dependent on the rate of patient recruitment and the extent of dose escalation.

Commenting on the study, Dr Elliot Goldstein, Chief Executive of British Biotech, said: "We have made good progress in the US with our trial of this novel agent. In this study we aim to find out whether a more frequent dosing regimen can be safely employed. We expect that the data from these two Phase I studies will provide the information needed to select the optimum dosing regimen to take forward into Phase II antitumour efficacy studies."

Mitchel Sayare, PhD., Chairman and Chief Executive Officer of ImmunoGen, said: "We are pleased with the progress being made by British Biotech. The data from the US Phase I study with BB-10901 are encouraging and, combined with the data this study is expected to yield, should establish the appropriate dosing schedule for future studies with the product. This study also marks the first clinical trial to be conducted with an ImmunoGen Tumour-Activated Prodrug product in Europe."

British Biotech acquired rights to develop and commercialise BB-10901 for Europe and Japan under a May 2000 agreement with ImmunoGen Inc., of Cambridge, Massachusetts. ImmunoGen retained commercialisation rights for the US and the rest of the world.

----ends----

**For British Biotech plc**

*This news release contains forward-looking statements that reflect the Company's current expectations regarding future events. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies and the uncertainties related to the regulatory process.*

**For ImmunoGen, Inc.**

*This press release includes forward-looking statements based on management's current expectations. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the success of the Company's research strategy; the applicability of the discoveries made therein; the difficulties inherent in the development of pharmaceuticals, including uncertainties as to the timing and results of preclinical studies; delayed achievements of milestones; reliance on collaborators; uncertainty as to whether the Company's potential products will succeed in entering human clinical trials and uncertainty as to the results of such trials; uncertainty as to whether adequate reimbursement for these products will exist from the government, private healthcare insurers and third-party payors; the uncertainties as to the extent of future government regulation of the pharmaceutical business; and other factors described in ImmunoGen's periodic filings with the Securities and Exchange Commission.*

**Enquiries:****British Biotech plc**

Dr Elliot Goldstein, Chief Executive  
Tony Weir, Finance Director

**www.britishbiotech.com**

Tel: 01865 781166

**Media contacts for British Biotech**

Georgina Briscoe, Hogarth Partnership (UK)  
Duke Coffey, GA Kraut (USA)

Tel: 020 7357 9477

Tel: 00 1 212 696 5600

**ImmunoGen Inc.**

Carol Hausner, Senior Director, Investor  
Relations and Corporate Communications

**www.immunogen.com**

Tel: 00 1 617 995 2500

**Media contact for ImmunoGen, Inc.**

Pete Holmberg, Rx Communications, LLC

Tel: 00 1 917 322 2164

**Background Notes****1. BB-10901**

BB-10901 is an immunoconjugate of the humanised monoclonal antibody, huN901, which binds to a particular protein found on the surface of certain tumour cells, and a powerful cytotoxic agent, DM1. Thus, it is designed to selectively seek out and kill certain types of cell, including those found in small cell lung cancer (SCLC) tumours. In pre-clinical studies, BB-10901 eradicated SCLC tumours. Under the same experimental conditions, other chemotherapies used to treat SCLC, such as cisplatin and etoposide produced only a temporary interruption of tumour growth. [Chari, R. V. J., et. al. Proceedings AACR, 2001, Abstract 4405; Liu, C., et.al. Proceedings AACR, 1997, Abstract 190]

Earlier this year, data from the ongoing U.S. Phase I study of BB-10901 were presented at the 2002 Annual Meeting of the American Society of Clinical Oncology (ASCO). The presentation included data on the product's pharmacokinetics and tolerability; initial evidence of biological activity was also presented. Patients in this study are now being dosed at 75 mg/m<sup>2</sup>.

## **2. ImmunoGen, Inc.**

ImmunoGen, Inc. develops innovative biopharmaceuticals for the treatment of cancer. The Company's Tumour-Activated Prodrug (TAP) technology couples highly potent cytotoxic agents with tumour-targeting antibodies to create effective new treatments for cancer with minimal damage to normal tissue. Two TAP products developed by ImmunoGen are in clinical trials – huN901-DM1/BB-10901 and cantuzumab mertansine; the latter is licensed to GlaxoSmithKline.

## **3. British Biotech**

British Biotech is a research and development stage pharmaceuticals company aiming to develop and commercialise specialist drugs for serious illnesses, principally cancer. It currently has four products in or near to patient trials, supplemented by focused drug discovery research programmes.

### **Product Portfolio**

BB-10901 – A Tumour-Activated Prodrug product, currently in Phase I/II trials in small cell lung cancer. British Biotech acquired exclusive European and Japanese development and commercialisation rights to BB-10901 from ImmunoGen Inc. (Boston, USA) in May 2000.

MG98 – A 2nd generation antisense inhibitor of DNA methyltransferase (DNMT), a nuclear enzyme implicated in uncontrolled tumour growth. British Biotech acquired exclusive European development and commercialisation rights to MG98 from MethylGene Inc. (Montreal, Canada) in February 2002.

BB-10153 – A novel thrombolytic, about to start a Phase II proof-of-principle study in heart attack patients. The study will be conducted by the Thrombolysis in Myocardial Infarction Study Group, a US-based investigative team at the forefront of clinical research into acute coronary syndromes.

BB-83698 – A peptide deformylase inhibitor targeted at community-acquired pneumonia (hospitalised patients). In completed pre-clinical studies BB-83698 has shown high potency against a range of gram positive bacteria, including several drug-resistant strains. A Phase I clinical study in healthy volunteers, to determine the safety and pharmacokinetics of single doses of an intravenous formulation, is expected to begin in October 2002.

### **Research**

Antibiotic Programme – A research programme into the use of inhibitors of peptide deformylase and other bacterial metalloenzymes to treat infectious disease. The programme has produced several lead compounds in research and pre-clinical development, with high potency shown against drug resistant gram-positive and gram-negative pathogens.

Anti-Inflammatory Programme – Working in collaboration with Serono SA, this research programme is investigating the use of metalloenzyme inhibitors as new treatments for serious inflammatory diseases, particularly multiple sclerosis.

Cancer Programme – As part of its collaboration with MethylGene on MG98 (see above) British Biotech has an exclusive option to European development and commercialisation rights for compounds from MethylGene's research into small molecule inhibitors of DNMT.

Biodefence Research – As part of the UK Government's biodefence initiative, the Defence, Science and Technology Laboratory (DSTL) of Porton Down is investigating the utility of selected British Biotech metalloenzyme inhibitors against anthrax lethal toxin and botulin toxin.

For release: 9 August 2002

8

## **British Biotech and GeneSoft collaborate to discover and develop novel antibiotics**

### **First in class product expected in clinic by Q4 2002**

British Biotech plc (LSE: BBG, Nasdaq: BBIOY) and GeneSoft Inc. announced today that they have signed agreements for a broad-based collaboration to discover and develop novel anti-infective drugs based on British Biotech's proprietary bacterial metalloenzyme inhibitors.

Combining British Biotech's novel targets, chemistry and clinical development with GeneSoft's experience in antibiotic lead optimisation and clinical expertise, the collaboration will focus on three specific areas:

- clinical development and marketing of BB-83698, British Biotech's lead peptide deformylase (PDF) inhibitor, governed by a licence, development and commercialisation agreement;
- lead optimisation and clinical development of oral PDF inhibitors, governed by a research agreement; and
- drug discovery research exploiting British Biotech's portfolio of intellectual property and expertise in respect of other microbial metalloenzyme targets, governed by a research agreement.

GeneSoft will make an initial payment to British Biotech of US\$4 million. On commencement of a Phase I study of BB-83698, anticipated in October 2002, GeneSoft will pay British Biotech a further US\$1 million and equity representing 3.45 per cent of GeneSoft.

"GeneSoft is delighted to partner with British Biotech to discover and develop new antibiotics," said Gary Patou, MD, GeneSoft's President. "The medical community desperately needs new mechanism of action antibiotics to combat multidrug resistant bacteria. We believe that the programmes developed within British Biotech have tremendous potential to bring new antibiotics to patients."

Welcoming the agreement, British Biotech Chief Executive Dr Elliot Goldstein said: "Through this collaboration British Biotech has achieved its three key objectives of expanding the Antibiotic Programme, while sharing the costs and commercialisation rights. GeneSoft is an ideal partner for the programme. It specialises in antibiotic drug discovery and development and brings a wealth of clinical and scientific expertise in this field."

**BB-83698**

BB-83698 represents a new class of antibiotic and is targeted at hospitalised patients with community-acquired pneumonia. A Phase I clinical study in healthy volunteers, to determine safety and pharmacokinetics of single doses of an intravenous formulation, is expected to begin in October 2002.

Under the first part of the collaboration, British Biotech and GeneSoft have entered into an exclusive agreement to co-develop and commercialise BB-83698. The development costs will be shared equally by British Biotech and GeneSoft, as will the world-wide profits.

**PDF research programme**

In support of BB-83698, British Biotech and GeneSoft have entered into an exclusive research agreement, for an initial period of three years, to identify further PDF inhibitors for clinical development, including oral inhibitors for broader indications. The collaboration will allow increased resource and capabilities to be applied to the PDF programme to exploit fully the potential of this novel series of agents. British Biotech will maintain resources on this programme at current levels with GeneSoft adding resource equivalent to 170 per cent of British Biotech's. As with BB-83698, development costs and world-wide profits are shared equally.

**Other metalloenzyme targets**

GeneSoft will select from British Biotech's other anti-microbial metalloenzyme programmes, and determine the research projects that it wishes to progress. British Biotech will receive undisclosed milestone and royalty payments on the successful development and commercialisation of any products from each research project.

----ends----

**Enquiries:****British Biotech plc**

Dr Elliot Goldstein, Chief Executive Officer  
Tony Weir, Finance Director

[www.britishbiotech.com](http://www.britishbiotech.com)

Tel: 01865 781166

**Media contacts for British Biotech**

Georgina Briscoe, Hogarth Partnership (UK)  
Duke Coffey, GA Kraut (USA)

Tel: 020 7357 9477

Tel: 00 1 212 696 5600

**GeneSoft Inc.**

David Singer, Chairman and Chief Executive Officer

[www.genesoft.com](http://www.genesoft.com)

Tel: 00 1 650 837 1900

**Media contact for GeneSoft Inc.**

Joanne DelRosario

Tel: 00 1 650 837 1800

*This news release contains forward-looking statements that reflect the Company's current expectations regarding future events. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies and the uncertainties related to the regulatory process.*

## **Background Notes**

### **1. The need for new antibiotics**

One of the key contributors to morbidity and mortality due to bacterial infections is the increasing prevalence of drug-resistant bacteria. The combination of a limited number of targets, widespread use of prophylactic therapy, empirical treatment with broad-spectrum agents, and the natural evolution of bacteria, has contributed to a resurgence of antibiotic resistance and the creation of a major public health problem. New structural classes of antibiotics that target alternative, essential bacterial processes are likely to make significant inroads into the anti-infectives market.

Bacterial genomes contain a number of metalloenzymes, several of which are believed to be essential to survival, and bacterial polypeptide deformylase (PDF) is now widely recognised as an attractive target for antibacterial chemotherapy (Giglione *et al*, 2001 *Molecular Microbiology*, vol 36, 1197-205). Deformylation is a crucial step in bacterial protein biosynthesis and the PDF enzyme is essential for bacterial growth, with the gene encoding PDF (*def*) found to be present in all sequenced pathogenic bacterial genomes.

In research and pre-clinical studies, British Biotech's PDF inhibitors have shown a microbiological activity profile suitable for respiratory tract pathogens and high potency against antibiotic-resistant organisms. BB-83698, the company's lead PDF inhibitor compound, has now completed the toxicology studies necessary to allow human dosing and a Phase I clinical study in healthy volunteers, to determine the safety and pharmacokinetics of single doses of an intravenous formulation, is expected to begin in October 2002.

### **2. GeneSoft Inc**

GeneSoft is a privately held biopharmaceutical company headquartered in South San Francisco, California. GeneSoft was founded in 1998 by Peter Dervan, Ph.D. and others based on proprietary chemistry technology licensed from the California Institute of Technology. GeneSoft has been using its proprietary technology to discover and develop novel anti-infective products, and currently has a portfolio of lead compounds in late pre-clinical studies. Since its founding, GeneSoft has raised over \$60 million in equity capital from investors in the United States, Europe and Asia.

For more information please visit [www.genesoft.com](http://www.genesoft.com)

### **3. British Biotech**

British Biotech is a research and development stage pharmaceuticals company aiming to develop and commercialise specialist drugs for serious illnesses, principally cancer. It currently has four products in or near to patient trials, supplemented by focused, collaborative drug discovery research programmes.

#### **Product Portfolio**

BB-10901 – A Tumour-Activated Prodrug product, currently in Phase I/II trials in small cell lung cancer. British Biotech acquired exclusive European and Japanese development and commercialisation rights to BB-10901 from ImmunoGen Inc. (Boston, USA) in May 2000.

MG98 – A 2nd generation antisense inhibitor of DNA methyltransferase (DNMT), a nuclear enzyme implicated in uncontrolled tumour growth. British Biotech acquired exclusive European development and commercialisation rights to MG98 from MethylGene Inc. (Montreal, Canada) in February 2002.

BB-10153 – A novel thrombolytic, about to start a Phase II proof-of-principle study in heart attack patients. The study will be conducted by the Thrombolysis in Myocardial Infarction Study Group, a US-based investigative team at the forefront of clinical research into acute coronary syndromes.

BB-83698 – A peptide deformylase inhibitor targeted at community-acquired pneumonia (hospitalised patients). (See above.)

### **Research**

**Antibiotic Programme** – Now working in collaboration with Genesoft, this research programme is focused on the development of bacterial metalloenzyme inhibitors as novel anti-infective drugs (see above).

**Anti-Inflammatory Programme** – In collaboration with Serono SA, this research programme is investigating the use of metalloenzyme inhibitors as new treatments for serious inflammatory diseases, particularly multiple sclerosis.

**Cancer Programme** – As part of the collaboration with MethylGene on MG98 (see above) British Biotech has an exclusive option to European development and commercialisation rights for compounds from MethylGene's research into small molecule inhibitors of DNMT.

**Biodefence Research** – As part of the UK Government's biodefence initiative, the Defence, Science and Technology Laboratory (DSTL) of Porton Down is investigating the utility of selected British Biotech metalloenzyme inhibitors against anthrax lethal toxin and botulin toxin.