NewsRoom

6/7/01 PR Newswire 00:00:00

PR Newswire
Copyright (c) 2001 PR Newswire. All rights reserved.

June 7, 2001

Initial Phase I Solid Tumor Data on Celgene's Lead Imid(TM), Revimid(TM)

WARREN, N.J., June 7 PRNewswire

Celgene Corporation (Nasdaq: CELG)
announced today preliminary results of its initial Phase I safety trial of REVIMID(TM), Celgene's lead Immunomodulatory Drug (IMiD(TM)) for the treatment of solid tumors. The protocol conducted by Professor Angus Dalgleish of the Division of Oncology at the St. Georges Medical School in London, enrolled 20 cancer patients. Of those enrolled, 13 had metastatic melanoma, 2 pancreatic cancer, 2 non-small cell lung cancer, 2 breast cancer and one metastatic renal cancer. After four weeks of therapy, patients were evaluated for safety and those whose highly progressive cancers had stabilized or decreased in size were entered onto continuing therapy on a named patient basis at the discretion of both Dr. Dalgleish and the patient.

Therapy consisted of consecutive one week treatments with 5 mg, 10 mg, 25 mg and 50 mg per day. REVIMID was well tolerated with the only adverse event noted being numbness in one hand in the renal cancer patient. No laboratory abnormalities were noted in this study that titrated patients to 50 mg a day dose. Sedation was not an observed side effect in these patients. Thirteen patients were entered into continuing therapy on a named patient basis. Eight of these had metastatic melanoma and six of the eight had evidence of disease regression. Both patients with pancreatic cancer had symptomatic improvement; one of whom had a decline in the CA 19.9 pancreatic cancer marker
"We are encouraged at both REVIMID's tolerability and the initial results that indicate that the drug may be active in treating melanoma," said Professor Dalgleish. "Based on these results we have expanded the trial by adding 60 patients and are increasing the dose".

In May, Celgene reported positive findings in preliminary results of REVIMID (CDC501), Celgene's lead Immunomodulatory Drug (IMiD(TM)) for the treatment of multiple myeloma.

"Based on these results in both solid tumors and multiple myeloma, Celgene will focus resources towards pursuing an aggressive regulatory and clinical

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

strategy," said Sol Barer, Ph.D. Celgene's President and Chief Operating Officer.

IMiDs are novel, small-molecule, orally available analogs of thalidomide that are designed to be more potent and potentially have a superior safety profile than the parent compound. Celgene's IMiDs have significantly greater immunological activity than thalidomide in in vitro studies. IMiDs were reported in the November 1, 2000 issue of BLOOD to enhance T-cell proliferation and interleukin (IL)-2 production. In the same report, IMiDs were also shown to be potent inhibitors of inflammatory cytokines that include TNF-alpha and IL-1beta while stimulating the anti-inflammatory cytokine IL-10. IMiDs, including Celgene's current lead clinical candidate REVIMID are covered by issued and pending patents in the U.S. and internationally.

Malignant Metastatic Melanoma
Malignant metastatic melanoma is a cancer predominantly of skin but may occur as a primary tumor in other locations including mucous membrane and the retina. U.S. incidence of melanoma of the skin has increased 4% annually over the past 30 years due to increased exposure to ultraviolet radiation from the sun. Prognosis is affected by tumor stage and anatomic location of the lesion. Thickness and/or level of invasion of the melanoma are the most important local determinants of prognosis, while nodal or widespread metastatic disease portends an even poorer prognosis.

The American Cancer Society estimates that 47,000 cases were diagnosed in the United States in 2000, of which 9,000 were metastatic. Currently, 90% of patients with metastatic disease die, with a median survival of 9 - 12 months, while death resulting from less advanced disease is still significant.

Celgene Corporation, headquartered in Warren, New Jersey, is an independent biopharmaceutical company engaged in the discovery, development and commercialization of small molecule drugs for cancer and immunological diseases.

This release contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or other expectations implied by these forward-looking statements. These factors include results of current or pending research and development activities, actions by the FDA and other regulatory authorities, and those factors detailed in the Company's filings with the Securities and Exchange Commission such as 10K, 10Q and 8K reports.

MAKE YOUR OPINION COUNT -- Click Here
http://tbutton.prnewswire.com/prn/11690X41210181

SOURCE Celgene Corporation
CONTACT: Robert J. Hugin, Senior Vice President & CFO of Celgene Corporation,

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

732-271-4102
Web site: http://www.celgene.com

---- Index References ----

Company: CELGENE CORP

News Subject: (Health & Family (1HE30); Economics & Trade (1EC26))

Industry: (Growth Factors & Cytokines (1GR66); Healthcare (1HE06); Pharmaceuticals Regulatory (1PH03); Pharmaceuticals & Biotechnology (1PH13); Internal Medicine (1IN54); Healthcare Practice Specialties (1HE49); Pharmaceuticals Research & Development (1PH57); Cancer Drugs (1CA21); Oncology & Hematology (1ON95))

Region: (Europe (1EU83); USA (1US73); Americas (1AM92); North America (1NO39))

Language: EN

Other Indexing: (AMERICAN CANCER SOCIETY; CELGENE; CELGENE CORP; DALGLEISH; FDA; GEORGES MEDICAL SCHOOL; MALIGNANT METASTATIC MELANOMA MALIGNANT; NASDAQ: CELG; REVIMID; SECURITIES AND EXCHANGE COMMISSIONSUCH; SOLID TUMOR DATA) (AngusDalgleish; Celgene; Celgenewill; D. Celgene; IMiDs; Nolaboratory; Phase; Robert J. Hugin; Sedation; Sol Barer)

Word Count: 979

End of Document

© 2018 Thomson Reuters. No claim to original U.S. Government Works.

NewsRoom

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.