



News Release

Cougar Biotechnology Presents Positive CB7630 (Abiraterone Acetate) Phase II Data at ASCO Annual Meeting

Phase II Results Demonstrate Efficacy of CB7630 in Both Chemotherapy-Naïve and Chemotherapy-Refractory Castration-Resistant Prostate Cancer Patients

Los Angeles, CA, May 31, 2009 – Cougar Biotechnology, Inc. (NASDAQ: CGRB) announced that results from ongoing Phase II clinical trials of Cougar's investigational drug CB7630 (abiraterone acetate) were presented at the 2009 ASCO Annual Meeting that is currently taking place in Orlando, Florida. The data were released today in three poster presentations. These presentations are further detailed below:

Preliminary results of a phase II multicenter study of chemotherapy-naïve castration-resistant prostate cancer (CRPC) patients not exposed to ketoconazole, treated with abiraterone acetate plus prednisone (COU-AA-002)

A Phase II clinical trial of CB7630 (COU-AA-002) is being conducted by The Prostate Cancer Clinical Trials Consortium, a national clinical research group sponsored by the Department of Defense, with Dr. Charles J. Ryan, Associate Professor of Clinical Medicine at the University of California, San Francisco Comprehensive Cancer Center, as the principal investigator. In this Phase II trial, CB7630 in combination with prednisone is administered once daily to chemotherapy-naïve, ketoconazole-naïve patients with castration-resistant prostate cancer (CRPC), who had progressive disease despite treatment with LHRH analogues and other hormonal therapies.

In his poster discussion presentation, Dr. Ryan presented data on the 33 evaluable patients treated in the trial. After 12 weeks of treatment, 26 patients (79%) experienced a decline in prostate specific antigen (PSA) levels of greater than 30%, 24 (73%) experienced a PSA decline of greater than 50% and 10 (30%) experienced PSA declines of greater than 90%. For the 33 evaluable patients, the median time to PSA progression was 337 days (48 weeks).

Of the 33 evaluable patients, treatment with CB7630 plus prednisone resulted in radiologic disease control in 28 patients (85%) with partial responses in 9 patients (27%) and stable disease in 19 patients (58%).

A multicenter phase II study of abiraterone acetate (AA) demonstrates anti-tumor activity in docetaxel pre-treated castration-resistant prostate cancer (CRPC) patients (COU-AA-003)

The COU-AA-003 Phase II trial of CB7630 in patients with advanced prostate cancer who have failed docetaxel-based chemotherapy was conducted at numerous locations in the United States and United Kingdom. In the trial, CB7630 is administered orally, once daily, to patients with CRPC who have failed treatment with androgen deprivation therapy and failed treatment with first-line docetaxel-based chemotherapy.

Dr. Allison Reid from The Institute of Cancer Research and The Royal Marsden Hospital in the United Kingdom presented data on the 47 patients enrolled in this Phase II trial. CB7630 was well tolerated with only minimal toxicity in this post-docetaxel population. After 12 weeks of treatment, of the 47 patients treated, 24 patients (51%) experienced a decline in PSA of greater than 30%, with 19 patients (40%) demonstrating a decline in PSA levels of greater than 50%, and 6 patients (13%) demonstrating a decline in PSA levels of greater than 90%. Of the 47 evaluable patients with measurable tumor lesions, radiologic disease control was observed in 31 of the 47 patients (66%) with 6 patients (13%) experiencing confirmed partial radiological responses and 25 patients (53%) experiencing stable disease. The median time to PSA progression for the 47 patients in the trial was estimated to be 169 days (24 weeks).

Phase II multicenter study of abiraterone acetate (AA) plus prednisone therapy in docetaxel treated castration-resistant prostate cancer (CRPC) patients: impact of prior ketoconazole (COU-AA-004)

During his poster discussion presentation, Dr. Daniel Danila from Memorial Sloan-Kettering Cancer Center presented data from the ongoing Phase II trial of CB7630 in combination with prednisone in patients with advanced prostate cancer who have failed androgen deprivation and docetaxel-based chemotherapy (COU-AA-004).

The COU-AA-004 Phase II trial is being conducted at numerous locations in the United States and United Kingdom. In the trial, CB7630 in combination with prednisone is administered orally, once daily, to patients with CRPC who have failed treatment with androgen deprivation therapy and have failed treatment with first-line docetaxel-based chemotherapy. To date, a total of 58 patients have been enrolled in the trial at 8 different centers.

Of the 58 patients, 13 patients (22%) had visceral disease, 26 patients (45%) had bone and soft tissue metastases, 11 patients (19%) had bone metastases only and 8 patients (14%) had soft tissue metastases only. Additionally, 27 patients (47%) had been previously treated with ketoconazole, a drug that is currently used off-label as a secondary hormonal therapy.

The combination of CB7630 plus prednisone was well tolerated with only minimal toxicity in this post-docetaxel population. After 12 weeks of treatment, 20 patients (34%) experienced a confirmed decline in PSA levels of greater than 50%. Of the 31 patients who had not received prior treatment with ketoconazole, 13 patients (42%) experienced a confirmed decline in PSA levels of greater than 50%. Furthermore, of the 27 patients who had been previously treated with ketoconazole, 7 patients (26%) experienced a confirmed decline in PSA levels of greater than 50%.

Of the 18 evaluable patients with measurable tumor lesions, 3 patients (17%) experienced confirmed partial radiological responses (as measured by the RECIST criteria) and 11 patients (61%) experienced ongoing stable disease. For the 31 patients who had not received prior treatment with ketoconazole, the median time to PSA progression was estimated to be 198 days (28 weeks). Furthermore, for the 27 patients who had been previously treated with ketoconazole, the median time to PSA progression was estimated to be 99 days (14 weeks).

Alan H. Auerbach, Chief Executive Officer and President of Cougar Biotechnology, said, "We are pleased to present data from these clinical trials at the ASCO Annual Meeting. CB7630 continues to show strong evidence of antitumor activity in patients with chemotherapy-naïve disease as well as in patients with chemotherapy-refractory disease. These populations not only represent significant unmet medical needs in prostate cancer but also are representative of the patient populations being studied in our ongoing Phase III trials (COU-AA-301 and COU-AA-302)."

Arturo Molina, M.D., M.S., FACP, Chief Medical Officer and Executive Vice President of Clinical Research and Development of Cougar, added, "We are pleased to present the multi-center results of these Phase II studies, which continue to support the potential roles of CB7630 both as a second-line hormonal therapy for patients with advanced prostate cancer who fail first-line hormonal treatment and as a second-line therapy for patients with advanced prostate cancer who fail docetaxel-based chemotherapy. These patient groups continue to represent patient populations that are underserved with current treatments."

About Cougar Biotechnology, Inc.

Cougar Biotechnology, Inc. is a Los Angeles-based biotechnology company established to in-license and develop clinical stage drugs, with a specific focus on the field of oncology. Cougar's oncology portfolio includes CB7630, a targeted inhibitor of the 17-alpha hydroxylase/c17,20 lyase enzyme, which is currently being studied in two Phase III clinical trials in prostate cancer and a Phase I/II trial in breast cancer; CB3304, an inhibitor of microtubule dynamics, which is currently in a Phase I trial in multiple myeloma; and CB1089, an analog of vitamin D, which has been clinically tested in a number of solid tumor types.

Further information about Cougar can be found at www.cougarbiotechnology.com.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include, without limitation, statements related to the potential advantages of CB7630 and its potential for use in the treatment of advanced prostate cancer. Such statements involve risks and uncertainties that could cause Cougar's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in clinical trials, and drug development and commercialization. For a discussion of these and other factors, please refer to Cougar's annual report on Form 10-K for the year ended December 31, 2008, as well as other subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Cougar undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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