



News Release

Cougar Biotechnology Presents Positive CB7630 (Abiraterone Acetate) Phase I and Phase II Data at ASCO 2008 Annual Meeting

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

Los Angeles, CA, June 2, 2008 – Cougar Biotechnology, Inc. (NASDAQ: CGRB) today announced that results from ongoing Phase I and Phase II clinical trials of Cougar's investigational drug, CB7630 (abiraterone acetate), were presented during the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO), which is currently taking place in Chicago. The data was presented today in four separate oral presentations. These presentations are further detailed below:

Identification of an androgen withdrawal responsive phenotype in castrate resistant prostate cancer (CRPC) patients treated with abiraterone acetate (COU-AA-BMA)

The COU-AA-BMA clinical trial of CB7630 was conducted at the University of Texas MD Anderson Cancer Center. In the trial, CB7630 in combination with low-dose prednisone was administered orally, once daily, to patients with castration resistant prostate cancer (CRPC), who had progressive disease despite treatment with LHRH analogues and multiple other therapies. Of the 24 patients who were accrued in the trial, all had radiological evidence of metastatic disease, with 22 patients (92%) having evidence of bone metastases (greater than or equal to 10 lesions), 4 patients (17%) having liver metastases and 8 patients (33%) having lymph node metastases. Seventeen patients (71%) had received prior treatment with ketoconazole and/or diethylstilbesterol and 19 patients (79%) had received prior treatment with chemotherapy with 13 patients (54%) having received two or more prior chemotherapy regimens before entering the trial.

In her oral presentation, Dr. Eleni Efstathiou from the MD Anderson Cancer Center presented data on the 23 evaluable patients treated in the trial. Of the 23 evaluable patients from the trial, 11 patients (48%) experienced a confirmed decline in prostate specific antigen (PSA) levels of greater than 50% and 4 patients (17%) experienced PSA declines of greater than 90%. Seventeen patients (74%) are still on study and have been receiving treatment with CB7630 and prednisone for a median duration of 6+ months. More specifically, 5 patients have been on study for over 2 months, 6 patients have been on study for over 6 months and 6 patients have been on study for over 8 months. Of the 23 evaluable patients, 10 patients (43%) experienced an improvement in ECOG performance status (PS) while receiving the combination of CB7630 and prednisone, with 5 patients improving from PS 1 to PS 0, and 5 patients improving from PS 2 to PS 1.

Of the 12 evaluable patients with bone metastases, after 6 months of treatment, 3 patients (25%) showed an improvement in their bone scan and 9 patients (75%) showed a stable bone scan. Also, of the 4 evaluable patients with measurable tumor lesions (as measured by RECIST), 3 out of 3 patients with lymph node metastases showed stable disease after 6 months of treatment with CB7630 and prednisone and 1 out of 2 evaluable patients with liver metastases demonstrated a partial radiological response (as measured by the RECIST criteria).

Both serum and microenvironment (bone marrow) testosterone levels were measured before and after treatment with CB7630. A decline in both serum and bone marrow testosterone levels to below detectable levels was seen in all patients in the trial. Higher baseline bone marrow testosterone levels appeared to correlate with response to CB7630 ($p=0.06$).

Impact of prior ketoconazole therapy on response proportion to abiraterone acetate, a 17-alpha hydroxylase C17,20-lyase inhibitor in castration resistant prostate cancer (CRPC) (COU-AA-002)

The Phase I dose ranging trial (COU-AA-002) was conducted at the University of California, San Francisco Comprehensive Cancer Center with Dr. Charles J. Ryan, Assistant Clinical Professor of Medicine, as the principal investigator. CB7630 was administered once daily to chemotherapy-naïve patients with CRPC, who had progressive disease despite treatment with LHRH analogues and multiple other hormonal therapies.

Of the 30 evaluable patients, 19 patients (63%) had received prior treatment with ketoconazole, a drug that is currently widely used off-label as a secondary hormonal therapy. Furthermore, 16 (84%) of the 19 patients previously experienced a greater than 50% decline in PSA while receiving ketoconazole. Fifteen (79%) of these 19 patients had discontinued ketoconazole use due to progressive disease and 4 (21%) of the 19 patients had discontinued ketoconazole use due to toxicity.

Of the 30 evaluable patients in this Phase I trial, 27 patients (90%) experienced a decline in PSA levels while receiving CB7630, with 16 of 30 patients (53%) experiencing a greater than 50% decline in PSA levels. Additionally, 10 (53%) of the 19 patients who had previously received ketoconazole experienced a 50% or greater decline in PSA while receiving CB7630. Moreover, 9 (56%) of the 16 patients who had previously responded to ketoconazole also experienced a greater than 50% decline in PSA while being treated with CB7630 and 1 (33%) of the 3 patients who had no response to ketoconazole experienced a greater than 50% decline in PSA while being treated with CB7630.

Preliminary phase II results of abiraterone acetate in patients with castration resistant metastatic prostate cancer after failure of docetaxel-based chemotherapy (COU-AA-004)

During his oral 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 55 patients have been enrolled in the trial at 8 different centers.

In his oral presentation, Dr. Danila provided an update on the 38 patients in this Phase II trial who have been treated at Memorial Sloan-Kettering Cancer Center. Of the 38 patients who were evaluable, 10 patients (26%) had visceral disease, 16 patients (43%) had bone and soft tissue metastases, 10 patients (26%) had bone metastases only and 2 patients (5%) had soft tissue metastases only. Additionally, 22 patients (58%) had received four or more prior lines of hormonal therapy and 17 patients (45%) had been previously treated with ketoconazole, a drug that is currently used off-label as a secondary hormonal therapy. All of the patients had failed treatment with docetaxel and 12 patients (32%) had received at least two prior chemotherapy regimens before entering the trial.

Of the 38 patients who have been treated in the Phase II trial, CB7630 was well tolerated with only minimal toxicity in this post-docetaxel population. Seventeen patients (45%) experienced a confirmed decline in PSA levels of greater than 50%. Of the 21 patients who had not received prior treatment with ketoconazole, 12 patients (57%) experienced a confirmed decline in PSA levels of greater than 50%. Furthermore, of the 17 patients who had been previously treated with ketoconazole, 5 patients (29%) experienced a confirmed decline in PSA levels of greater than 50%.

After 12 weeks of treatment, of the 24 patients with lesions that were evaluable by bone scan, 14 patients had lesions that were stable. Of the 18 patients in the trial with evidence of lymph node metastases that were evaluable by CT scan, 1 patient was shown to have lesions that decreased in size and 12 patients had lesions that were stable. Of the 8 patients in the trial with evidence of visceral metastases that were evaluable by CT scan, 1 patient was shown to have lesions that decreased in size and 4 patients had lesions that were stable. Currently, 8 patients in the Phase II trial continue to receive treatment with CB7630 in combination with prednisone. This includes 6 patients who had not received prior treatment with ketoconazole and 2 patients who had previously been treated with ketoconazole. All of these patients have been on study for over 25 weeks.

Anti-tumor activity of abiraterone acetate (AA), a CYP17 inhibitor of androgen synthesis, in chemotherapy naïve and docetaxel pre-treated castration resistant prostate cancer (CRPC) (COU-AA-001 and COU-AA-003)

During his oral presentation, Dr. Johann S. DeBono from The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust in the United Kingdom presented data from two ongoing clinical trials of CB7630. These trials include a Phase I/II trial of CB7630 in patients with hormone refractory, chemotherapy naïve prostate cancer (COU-AA-001) and a Phase II trial of CB7630 in patients with advanced prostate cancer who have failed androgen deprivation and docetaxel-based chemotherapy (COU-AA-003).

In the COU-AA-001 trial, CB7630 was administered orally, once daily, to chemotherapy-naïve patients with CRPC, who had progressive disease despite treatment with LHRH analogues and

multiple other hormonal therapies (median: 3 prior hormonal therapies). At the time of PSA progression on CB7630 the corticosteroid dexamethasone was added to CB7630 to see if the addition of dexamethasone could potentially overcome the resistance to CB7630. Of the 54 patients who were evaluable in both the dose escalating Phase I portion and the Phase II portion of the trial, all of the patients had radiological evidence of metastatic disease.

Of the 54 evaluable patients from the Phase I/II trial, 38 patients (70%) experienced a confirmed decline in PSA levels of greater than 50% while receiving CB7630 as a monotherapy. For the 54 evaluable patients in the trial, the median time to PSA progression while the patients were receiving CB7630 alone was estimated to be 231 days (33 weeks).

Thus far in the trial, 30 of the 54 patients have been treated with dexamethasone, in addition to CB7630, at the time of PSA progression. Nine (30%) of these 30 patients have experienced a confirmed decline in PSA levels of greater than 50% when treated with the combination of CB7630 and dexamethasone after PSA progression on CB7630 alone. For the 54 patients in the trial, including both the patients who have not yet progressed on CB7630 alone and those patients receiving the combination of CB7630 and dexamethasone after PSA progression on CB7630 alone, the median time to PSA progression was estimated to be 399 days (57 weeks).

Of the 29 evaluable patients with measurable tumor lesions, treatment with CB7630 resulted in partial radiological responses (as measured by the RECIST criteria) in 15 patients (52%), with 8 patients (28%) demonstrating ongoing stable disease as assessed by an independent radiological review blinded to outcome data. Individual patients treated with CB7630 also experienced improvement in pain and a reduction in opioid use.

The COU-AA-003 Phase II trial of CB7630 in patients with advanced prostate cancer who have failed docetaxel-based chemotherapy is being 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. To date, a total of 44 patients have been enrolled in the trial.

In his oral presentation, Dr. DeBono provided an update on the 34 patients in this Phase II trial who have been treated in the United Kingdom and have been in the study for over 3 months. Of these 34 patients, CB7630 was well tolerated with only minimal toxicity in this post-docetaxel population. Of the 34 patients treated, 24 patients (71%) experienced a decline in PSA, with 16 patients (47%) demonstrating a decline in PSA levels of greater than 50%. Of the 19 evaluable patients with measurable tumor lesions, 5 patients (26%) experienced confirmed partial radiological responses (as measured by the RECIST criteria) and 10 patients (53%) experienced ongoing stable disease. The median time to disease progression for the 34 patients in the trial was estimated to be 161 days (23 weeks).

Alan H. Auerbach, Chief Executive Officer and President of Cougar Biotechnology, said, "The data from our Phase I and Phase II trials of CB7630 presented at the ASCO Annual Meeting continue to support the potential role of the drug in the treatment of CRPC. We continue to be pleased with the strong evidence of antitumor activity in patients who were both chemotherapy naïve and chemotherapy refractory, both of which represent significant unmet medical needs in

prostate cancer. We have strong confidence in the potential of CB7630 in both of these patient populations.”

Arturo Molina, M.D., M.S., FACP, Cougar's Senior Vice President of Clinical Research and Development, added, "We are pleased to be able to present the results of these Phase I and Phase II studies at ASCO. We look forward to continuing to enroll our Phase III trial (COU-AA-301) in the post docetaxel CRPC population and look forward to initiating our second Phase III trial in the chemotherapy naïve CRPC population during the second half of 2008."

About Cougar Biotechnology

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 tested in Phase III clinical trials in prostate 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 Biotechnology 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 benefits to be derived from Cougar's drug development programs, including the potential advantages of CB7630 and its potential for use in the treatment of CRPC and in second-line hormone and chemotherapy naïve treatment settings. 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, including the uncertainty of whether results of prior clinical trials of CB7630 will be predictive of results of later stage clinical trials, including COU-AA-301. For a discussion of these and other factors, please refer to Cougar's annual report on Form 10-KSB for the year ended December 31, 2007, 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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