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Cougar Biotechnology, Inc. (CGRB.OB) Announces Agreement with **FDA** on Special Protocol Assessment for Phase III trial of CB7630
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LOS ANGELES--(BUSINESS WIRE)--Cougar Biotechnology, Inc. (NASDAQ: CGRB - News) today announced that it reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for its planned Phase III clinical trial of the Company's lead drug candidate CB7630 (abiraterone acetate). The SPA is a written agreement between the trial's sponsor and the FDA regarding the design, endpoints, and planned statistical analysis approach of the Phase III trial to be used in support of a new drug application (NDA). The European Medicines Agency (EMEA) has also provided protocol advice consistent with that of the FDA regarding the Company's Phase III trial design.

Pursuant to the SPA, the Phase III trial will be a randomized, double-blind, placebo-controlled trial of CB7630 plus prednisone in patients with metastatic castration-resistant prostate cancer who have failed docetaxel-based chemotherapy. Similar to the patient populations in the Company's Phase II trials COU-AA-003 and COU-AA-004, patients are allowed to have received up to two prior chemotherapy regimens before entering the trial. The trial is expected to enroll approximately 1160 patients who will be randomized (2:1) to receive either CB7630 plus prednisone or placebo plus prednisone. The trial will be conducted at approximately 150 sites in North America, Europe and Australia. The primary endpoint of the trial will be overall survival. The Company expects to begin patient enrollment later this month.

Alan H. Auerbach, Chief Executive Officer and President of Cougar Biotechnology, said, "Obtaining FDA agreement on our overall Phase III trial design, patient population and endpoints represents an important milestone in the global development of CB7630 and for Cougar as a company."

Arturo Molina, M.D., M.S., FACP, Senior Vice President of Clinical Research and Development of Cougar, added, "We are pleased to be able to reach agreement with the FDA on our Phase III trial design. We look forward to commencing patient enrollment in this Phase III trial shortly."

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 II 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 clinical trial initiation dates, 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 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 in testing of CB7630 will be predictive of results in later stages of development. 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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