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Orexigen(R) Therapeutics Announces Completion of Enrollment in Second of Four Phase III Clinical Trials for Contrave(R)

--Phase III Clinical Program Remains on Schedule for Anticipated NDA Filing in Late 2009--

SAN DIEGO, Apr 22, 2008 (BUSINESS WIRE) -- Orexigen(R) Therapeutics, Inc. (Nasdaq: OREX), a biopharmaceutical company focused on the treatment of central nervous system disorders, including obesity, today announced completion of enrollment in NB-301, the largest of its Phase III clinical trials, for Contrave(R), its lead obesity product candidate. This represents completion of enrollment in the second of four Phase III trials of Contrave.

The NB-301 clinical trial is a placebo-controlled, 56-week study intended to analyze the efficacy, safety and tolerability of two doses of Contrave in generally healthy obese patients. This trial is taking place at 34 centers nationwide and has randomized approximately 1742 patients.

"Completion of enrollment in NB-301 is a key step in advancing the Contrave program toward a planned FDA submission in late 2009," said Orexigen President and CEO, Gary Tollefson, M.D., Ph.D. "Our final two Phase III clinical trials are enrolling as expected. Continued achievement of our Phase III milestones would not be possible without the dedication and hard work of the entire Contrave development team."

In November, Orexigen announced that enrollment was complete in the first of its four Phase III clinical trials, NB-302. This is a 56-week placebo-controlled study designed to analyze the efficacy, safety and tolerability of Contrave when combined with an intensive behavior modification protocol. This trial is taking place at nine centers nationwide and has enrolled approximately 790 patients.

As a part of Orexigen's Phase III clinical trial program for Contrave, the Company has two additional ongoing trials. In May 2007, Orexigen initiated enrollment in NB-304, a 56-week study designed to analyze the efficacy, safety and tolerability of Contrave in obese subjects with Type II diabetes. In December 2007, Orexigen initiated enrollment in NB-303, a 56-week study in generally healthy obese patients designed to analyze the efficacy, safety and tolerability of Contrave at the expected standard dose with the opportunity for patients who do not respond after 28 weeks of therapy to switch to a higher dose.

Contrave is a proprietary fixed dose combination of bupropion SR and the Company's novel formulation of naltrexone SR in a single tablet. Orexigen chose these two constituent drugs based on preclinical data that suggested that they could both initiate and sustain weight loss. In a Phase IIb clinical trial, Contrave demonstrated weight loss from baseline body weight, absent a significant diet or exercise intervention that ranged from 8.0% to 10.7% at 48 weeks across three Contrave dosage groups among patients who completed the trial.

About Orexigen Therapeutics

Orexigen(R) Therapeutics, Inc. is a biopharmaceutical company focused on the development of pharmaceutical product candidates for the treatment of central nervous system disorders, including obesity. Orexigen's lead combination product candidates targeted for obesity are Contrave(R), which is in Phase III clinical trials, and Empatic(TM), which is in the later stages of Phase II clinical development. Both product candidates are designed to take advantage of the company's understanding of how the brain appears to regulate appetite and energy expenditure, as well as the mechanisms that come into play to limit weight loss over time. Each product candidate is designed to act on a specific group of neurons in the central nervous system with the goal of achieving appetite suppression and sustained weight loss. Further information about the company can be found at <http://www.Orexigen.com>.

Forward-Looking Statements

Orexigen cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed," "projects" and similar expressions are intended to identify forward-looking statements. These statements are based on the Company's current beliefs and expectations. These forward-looking statements include statements regarding the completion of the Company's Contrave(R) Phase III clinical trials and the timing of its submission of an

NDA with the FDA, the efficacy and safety of Contrave, and the potential to obtain regulatory approval for, and effectively treat obesity with, Contrave. The inclusion of forward-looking statements should not be regarded as a representation by Orexigen that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in the Orexigen business, including, without limitation: the progress and timing of the Company's Contrave clinical trials or the development of Contrave; the potential for adverse safety findings relating to Contrave to delay or prevent regulatory filings; and its licensors may not be able to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its product candidates; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Orexigen undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

SOURCE: Orexigen(R) Therapeutics, Inc.

Orexigen

Graham Cooper, 858-436-8600

or

Media:

BioCom Partners

Stephen Gendel, 212-918-4650

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