Orexigen@ Announces Agreement From the FDA on a Special Protocol Assessment for the Contrave@ Outcomes Trial

The Associated Press

/FROM PR NEWSWIRE DALLAS 888-776-3971/

STK NASDAQ-NMS:OREX

IN HEA MTC PHA

SU TRI FDA PDT

TO BUSINESS, HEALTH, AND MEDICAL EDITORS:

Orexigen@ Announces Agreement From the FDA on a Special Protocol

Assessment for the Contrave@ Outcomes Trial

SAN DIEGO, Feb. 6, 2012 /PRNewswire/ -- Orexigen@ Therapeutics, Inc.

(Nasdaq: OREX) today announced that it has reached agreement with the

U.S. Food and Drug Administration (FDA) on a Special Protocol

Assessment (SPA) for the Contrave@ outcomes trial. On January 31,

2011, the Company received a Complete Response Letter to its New Drug

Application (NDA) noting a single approval deficiency related to

cardiovascular safety, requiring Orexigen to conduct a randomized,

double-blind, placebo-controlled cardiovascular outcomes trial prior

to approval. The objective of the trial is to demonstrate that

Contrave does not unacceptably increase the risk of major adverse

cardiovascular events (MACE).The Company plans to initiate the

Contrave outcomes trial late in the second quarter of 2012.

"We are pleased to receive agreement on the SPA from the FDA after

just one cycle of review," said Michael Narachi, President and CEO of Orexigen. "A few months ago, we received detailed written correspondence from the FDA's Director of the Office of New Drugs that identified a clear and feasible path forward for this important potential obesity therapy. We believe the rapid progress we have since made with the FDA's Division of Metabolic and Endocrinologic Products on the detailed protocol and plans for analysis is further indication of the alignment we have reached within the FDA on the requirements for resubmission of the Contrave NDA."

As previously outlined, approximately 10,000 patients will be enrolled in this streamlined trial which is focused on capturing infrequent MACE events. An interim analysis and NDA resubmission is planned once approximately 87 MACE events have occurred, which is anticipated to be less than two years from the start of the trial. If marketing approval is received for Contrave, the trial will continue toward the final analysis in the post-approval setting.

The Company plans to provide more details on the trial design and protocol on its fourth-quarter and year-end 2011 conference call in early March.

About Special Protocol Assessments

A Special Protocol Assessment is a written agreement with the FDA on the details of the design and planned analysis for a clinical trial. It is intended to form the basis for a marketing application and may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of new public health concerns.

About Orexigen Therapeutics

Orexigen Therapeutics, Inc. is a biopharmaceutical company focused on the treatment of obesity. Contrave@ has completed Phase 3 clinical trials for which a New Drug Application has been submitted and reviewed by the FDA, and the Company's other product candidate, EmpaticT, has completed Phase 2 clinical trials. Further information about the Company can be found at 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" 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 Special Protocol Assessment, the timing of a resubmission of the Contrave NDA, the feasibility of the Contrave outcomes trial, the timing for initiation of enrollment for the Contrave outcomes trial in the second quarter of 2012, the timing expected for the interim analysis of the trial and potential NDA resubmission, the speed of enrollment for the Contrave outcomes trial, and the potential for, and timing of, approval for 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 SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if Oreixgen fails to comply with the agreed upon trial protocol, Orexigen may not be able to initiate and conduct the Contrave outcomes trial and the progress and timing thereof; Orexigen's ability to demonstrate in the Contrave outcomes trial that the risk of major adverse cardiovascular events in overweight and obese subjects treated with Contrave does not adversely affect the product candidate's benefit-risk profile; the potential that earlier clinical trials may not be predictive of future results in the Contrave outcomes trial; the potential for early termination of the collaboration agreement between Orexigen and Takeda; the costs and time required to complete additional clinical, non-clinical or other requirements prior to any resubmission of an NDA; the therapeutic and commercial value of Contrave; Orexigen's ability to attract and retain key personnel; Orexigen's ability to maintain sufficient capital; and other risks described in the Company's 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, and Orexigen undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further

information regarding these and other risks is included under the

heading "Risk Factors" in Orexigen's most recent Quarterly Report on

Form 10-Q, filed with the Securities Exchange Commission on November

8, 2011 and available from the SEC's website (www.sec.gov) and on

Orexigen's website (www.orexigen.com) under the heading "Investor

Relations." 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.

Corporate Contacts: Orexigen

Investors Media

Jay Hagan Denise Powell

Chief Business Officer WCG

(858) 875-8673 (510) 703-9491

SOURCE Orexigen Therapeutics, Inc.

-0- 02/06/2012

/Web Site: http://www.orexigen.com

(NASDAQ-NMS:OREX) /

CO: Orexigen Therapeutics, Inc.

ST: California

IN: HEA MTC PHA

SU: TRI FDA PDT

PRN

-- LA47858 --

0000 02/06/2012 13:00:00 EDT http://www.prnewswire.com

Source URL (retrieved on *07/10/2014 - 2:56pm*):
http://www.mdtmag.com/news/2012/02/orexigen-announces-agreement-fda-special-protocol-assessment-contrave-outcomes-trial?qt-video_of_the_day=0