

SAN DIEGO and DEERFIELD, Ill., Nov. 11, 2013 /PRNewswire/ -- Orexigen® Therapeutics, Inc. (Nasdaq: [OREX](#)) and Takeda Pharmaceuticals U.S. A. Inc. (Takeda), today announced multiple Contrave® (naltrexone sustained release (SR)/bupropion SR) abstracts accepted for poster presentations and an oral presentation at the upcoming ObesityWeek meeting. This meeting will be held November 11-16, 2013 in Atlanta at the Georgia World Congress Center.

Details on the presentation times are as follows:

Oral Presentation: Thursday, November 14, 2013 - Abstract T-36-OR, Presentation time 3:00-4:30 EST  
, Georgia World Congress Center  
Presenter:  
Kevin D. Hall  
, Ph.D.; National Institutes of Health, NIDDK,  
Bethesda, MD  
, USA.  
Title: Dynamical Systems Modeling of Caloric Intake and Body Composition with Combination Naltrexone/Bupropion Therapy

Poster Presentation: Friday, November 15, 2013 - Abstract T-740-P, Presentation time 12:00-1:30PM EST  
, Georgia World Congress Center, Exhibit Hall A  
Presenter: Raymond A Plodkowski, MD; Scripps Clinic,

La Jolla, CA  
, USA.

Title: Early achievement of significant weight loss with naltrexone/bupropion is associated with additional weight loss at one year – an integrated analysis of four Phase 3 trials

Poster Presentation: Friday, November 15, 2013 - Abstract T-741-P, Presentation time 12:00-1:30PM EST

, Georgia World Congress Center, Exhibit Hall A

Presenter:

Susan McElroy

, MD; Research Institute, Lindner Center of HOPE,

Mason, OH

, USA.

Title: Naltrexone/bupropion is associated with early and longer-term improvement in binge eating disorder that is related to improvement in depression

**About Contrave** About Contrave (32 mg naltrexone sustained-release (SR)/360 mg bupropion SR) being evaluated for the treatment of obesity: In 2012, Orexigen enrolled more than 10,400 with approximately 8900 randomized patients in the Light Study. The primary objective of the double-blind, randomized, placebo-controlled Light Study, which Orexigen is conducting under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA), is to assess the occurrence of major adverse cardiovascular events in overweight and obese patients receiving Contrave. An interim analysis of the Light Study is anticipated by early December, enabling the potential resubmission of the Contrave New Drug Application to the FDA by year end.

In October, Orexigen submitted a Marketing Authorization Application for Contrave to the European Medicines Agency.

Orexigen has licensed North American Contrave commercial rights to Takeda Pharmaceuticals. Orexigen owns Contrave rights in Europe and throughout the rest of the world outside of North America and will seek a partner to commercialize Contrave in those territories.

**About Orexigen Therapeutics** Orexigen Therapeutics, Inc. is a biopharmaceutical company focused on the treatment of obesity. The company's lead product candidate is Contrave, which

has completed Phase 3 clinical trials and for which a NDA has been submitted and reviewed by the FDA. The company has also reached agreement with the FDA on a SPA for the Light Study, the Contrave cardiovascular outcomes trial. The company's other product candidate, Empatic, has completed Phase 2 clinical trials. Further information about the company can be found at [www.orexigen.com](http://www.orexigen.com)

**Orexigen 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," "should," "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 potential for, and timing of, the approval of a Contrave Marketing Authorization Application (MAA) in the European Union (EU); the probability of the interim analysis of the Light Study excluding a prespecified level of risk of MACE; the potential for, and timing of, resubmission of a NDA for Contrave based on interim results of the Light Study; the possibility of resubmitting the Contrave NDA with the independent DMC report on the interim analysis and without the clinical study report for the interim analysis; the safety and effectiveness of Contrave; the potential for, and timing of, the accrual and adjudication of MACE in the Light Study; the probability of overall success of the Light Study; the potential for past Contrave clinical trials to predict the outcome of future Contrave clinical trials; the potential for the FDA to continue to honor the Special Protocol Assessment, or SPA; the potential to enter into a collaborative partnership for commercialization of Contrave outside of North

America

; the potential for Takeda to commercially launch Contrave in North America

; and the use of pharmacotherapy to treat obesity. 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 materially from those expressed or implied in this release due to the risk and uncertainties inherent in the Orexigen business, including, without limitation: the possibility that the FDA determines not to initiate review of the Contrave NDA until it has received the complete study report for the interim analysis; 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 Orexigen fails to comply with the agreed upon trial protocol; Orexigen's ability to conduct the Light Study and the progress and timing thereof, including risks associated with enrolling and retaining the appropriate patients in the Light Study; Orexigen's ability to demonstrate in the Light Study that the risk of MACE in overweight and obese patients treated with Contrave does not adversely affect Contrave's benefit-risk profile; the potential that earlier clinical trials may not be predictive of future results in the Light Study; the potential for the FDA to not approve Contrave even after the resubmission with the MACE data; the potential for the Light Study to cost more than what is projected; the potential for early termination of Orexigen's North American collaboration agreement with Takeda Pharmaceutical Company Limited; the costs and time required to

complete additional clinical, non-clinical or other requirements prior to any resubmission of the Contrave NDA; the therapeutic and commercial value of Contrave; Orexigen's ability to maintain sufficient capital to fund our operations through potential approval of Contrave in 2014; the development plan for Empatic; Orexigen's ability to enter into a collaborative partnership for Empatic on acceptable terms, if at all; and other risks described in Orexigen'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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission

August 7, 2013

and its other reports, which are available from the SEC's website (

[www.sec.gov](http://www.sec.gov)

) and on Orexigen's website (

[www.orexigen.com](http://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.

**About Takeda Pharmaceuticals U.S.A., Inc.** Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan

and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine.

The company has a commercial presence covering around 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China

. Takeda is ranked 12th by global Rx sales, 14th in the BRIC countries and 18th in Europe

. Areas of focus include cardiovascular and metabolic, oncology, respiratory and immunology, central nervous system, general medicine, and vaccines.

Through the integration of Millennium Pharmaceuticals and Nycomed, Takeda has been transforming itself, broadening its therapeutic expertise and geographic outreach.

Takeda Pharmaceuticals U.S.A., Inc. is located in Deerfield, Ill., and is the U.S. marketing and sales organization of Takeda Pharmaceutical Company Limited.

Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com), and additional information about Takeda Pharmaceuticals U.S.A., Inc. is available through its website, [www.takeda.us](http://www.takeda.us).

**Takeda Forward-Looking Statements** This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan,

the United States

and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements,

investors and others should not conclude that Takeda will make additional updates or corrections.

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## Orexigen and Takeda Announce Multiple Contrave Data Presentations at the ObesityWeek Meeting in Atlanta

Written by Australian Business

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