

Press Release

Orexigen(R) Therapeutics and Takeda Enter Into Partnership to Commercialize Contrave(R) in North America

SAN DIEGO and OSAKA, Japan, Sept 02, 2010 /PRNewswire via COMTEX/ --Orexigen(R) Therapeutics, Inc. (Nasdaq: OREX) and Takeda Pharmaceutical Company Limited (TSE: 4502), today announced that they have entered into an exclusive partnership to develop and commercialize Contrave(R) (naltrexone SR/bupropion SR), Orexigen's investigational drug for the treatment of obesity, in the United States, Canada and Mexico.

Contrave is a combination therapy believed to address both biological and behavioral drivers of obesity. The central pathways targeted by this treatment are involved in controlling the balance of food intake and metabolism, and regulating reward-based eating behavior. Orexigen submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Contrave on March 31, 2010 and the Prescription Drug User Fee Act (PDUFA) action date has been set for January 31, 2011.

Under the terms of the agreement, Orexigen will receive an upfront cash payment of \$50 million from Takeda, and Takeda will obtain an exclusive marketing right from Orexigen in the United States, Mexico and Canada while Orexigen retains the right to co-promote with Takeda in the United States. Orexigen will be eligible to receive payments of over \$1 billion upon achieving certain regulatory and sales-based milestones. Assuming Contrave is commercialized, Takeda will pay tiered double-digit royalty payments on net sales in the Territory.

Under the terms of the agreement, Orexigen and Takeda will work together on ongoing development of the product, with Orexigen leading pre-approval activities, and Takeda leading post-approval activities. The parties will share in the costs of any future development of the product.

"Takeda is an ideal partner for Contrave given its proven track record in commercializing innovative medicines and its commitment to the treatment of obesity," said Michael Narachi, President and CEO of Orexigen. "We believe this is a great strategic partnership to enable our goal of a strong market entry for Contrave, if approved. It has been our belief that getting a partner involved early would be critical to a high-quality launch of Contrave, and with this partnership now in place, we are tightly focused on the regulatory review process and securing approval for Contrave."

"Contrave represents an important addition to Takeda's cardiovascular and metabolic disease franchise and we look forward to partnering with Orexigen," said Shinji Honda, President and CEO of Takeda Pharmaceuticals North America, Inc., a wholly-owned subsidiary of Takeda that has commercial responsibility for the Americas. "Takeda has deep experience in providing important medicines to treat chronic disease and Contrave will help us provide a full spectrum of treatment to patients for the management of obesity."

Approximately 75 million Americans suffer from obesity and that number is expected to rise to 103 million by 2018. Obesity is a chronic condition linked to serious medical consequences including type 2 diabetes, cardiovascular disease, cancer and depression. Despite increasing public health concerns regarding obesity, two-thirds of the U.S. adult population is overweight or obese. Although weight loss of 5-10 percent may improve overall health, including blood sugar control, high blood pressure, high cholesterol, and overall quality of life, many individuals are not able to lose weight or maintain weight loss with diet and exercise alone.

Conference Call Today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time)

The Orexigen management team will host a teleconference and webcast to discuss the partnership. The live call may be accessed by phone by calling (866) 314-5232 (domestic) or (617) 213-8052 (international), participant code 19096068. The webcast can be accessed live on the investor relations section of the Orexigen web site at <http://www.orexigen.com/>, and will be archived for 14 days following the call.

About Contrave

Contrave is an investigational combination therapy believed to address both biological and behavioral drivers of obesity. The two components of this combination therapy act in a complementary manner in the central nervous system. The central pathways targeted by this treatment are involved in controlling the balance of food intake and metabolism, and regulating reward-based eating behavior. In clinical trials, Contrave was shown to help obese patients initiate and sustain significant weight loss, improve important markers of cardiometabolic risk and increase ability to control eating.

About Orexigen Therapeutics

Orexigen Therapeutics, Inc. is a biopharmaceutical company focused on the treatment of obesity. The Company has filed an NDA with the FDA for its lead investigational product, Contrave(R). The Company's second product, Empatic(TM), has completed Phase 2 clinical development. 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, through combination therapeutic approaches. Further information about the Company can be found at <http://www.orexigen.com/>.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, 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 patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, <http://www.takeda.com/>.

About Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, insomnia, rheumatology and gastroenterology treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for diabetes, cardiovascular disease, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit <http://www.tpna.com/>.

Forward-Looking Statements Related to Orexigen

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 potential for, and timing of, approval for Contrave, the Company's belief that this product candidate may be an important therapeutic option in the treatment of obesity, the potential milestone and royalty payments under the agreement with Takeda and the potential strength of our market entry with Contrave, if approved. 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: Orexigen's dependence on Takeda for aspects of the development and commercialization of Contrave; the potential for the FDA to delay the scheduled PDUFA action date of January 31, 2011 due to the FDA's internal resource constraints or other reasons; the uncertainty of the FDA approval process and other regulatory requirements; the FDA may not agree with the Company's interpretation of efficacy and

safety results; the FDA may require Orexigen to complete additional clinical, non-clinical or other requirements prior to the approval of the Contrave NDA; the therapeutic and commercial value of Contrave; reliance on third parties to assist with the development of Contrave and the regulatory submissions related thereto; the potential for adverse safety findings relating to Contrave; 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 Quarterly Report on Form 10-Q, which was filed with the Securities Exchange Commission on August 6, 2010 and is available from the SEC's website (<http://www.sec.gov/>) and on our website (<http://www.thresholdpharm.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.

Forward-Looking Statements Related to Takeda

This press release contains forward-looking statements regarding the Company's plans, outlook, strategies, and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at this time. Forward looking statements can sometimes be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "potential," "target," "forecast," or "intend" or other similar words or expressions of the negative thereof. Certain risks and uncertainties could cause the Company's actual results to differ materially from any forward looking statements contained in this press release. These risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding the Company's business, including general economic conditions in the US and worldwide; (2) competitive pressures; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) decisions 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; and (8) integration activities with acquired companies.

SOURCE Orexigen Therapeutics, Inc.