Orexo´s partner Endo announces positive results from interim analysis of Rapinyl ™ phase III clinical trial

Orexo´s licensing partner for Rapinyl ™ in North America announced today positive results from the previously announced, planned interim statistical analysis of a Phase III, placebo-controlled, double-blind trial of its development product, Rapinyl ™. The data from the analysis of 61 patients demonstrated that Rapinyl ™ met its primary endpoint, the Sum of Pain Intensity Difference from baseline to 30 minutes (SPID 0-30), and the results were highly statistically significant (p=0.0004). In addition, all the secondary endpoints were met. Statistically significant separation from placebo on mean pain intensity difference was seen as early as 10 minutes.

On the basis of these results and in accordance with the predetermined criteria of the interim analysis, Endo is terminating enrollment in the double-blind crossover portion of this clinical study. Enrollment is continuing in the safety portion of this trial and a second Phase III trial to meet the requirements for additional safety data. Rapinyl ™ is an oral, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl ™ is in registration phase in Europe with Orexo's partner ProStrakan. Kyowa Hakko, a licensee in Japan, is preparing for a phase III study.

“We are extremely pleased by the outcome of this analysis, which we believe demonstrates that Rapinyl ™ can be an effective treatment for breakthrough pain in cancer patients,” said David A. Lee, M.D., Ph.D., Chief Scientific Officer. “We remain confident that Rapinyl´s quick dissolution and rapid absorption profile make it a potentially attractive treatment for breakthrough cancer pain.”

Endo will conduct a thorough analysis of the data to determine the next course of action, including the possibility of filing a New Drug Application (NDA) based on these results.

Endo further noted that although this planned interim analysis was only intended to determine efficacy and not tolerability, those adverse events that were reported were consistent with what is usually observed with other opioids.

“The results from Endo Pharmaceuticals support that Rapinyl ™ can be an effective treatment for breakthrough pain in cancer patients,” said Torbjorn Bjerke, M.D., President and CEO. “It is also a confirmation of our sublingual tablet form and how well it works when immediate onset of effect is desirable”.

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TO THE EDITORS

About Orexo

Orexo is a pharmaceutical company which focuses on identifying suboptimal therapeutic characteristics of existing products and developing more efficient and effective delivery methods for them. By combining approved active substances with Orexo´s drug delivery technologies it is possible to significantly enhance their therapeutic value, such as providing quicker onset of action or ease of administration. This business model is aimed at bringing products to market faster with lower development risk and costs.

Orexo, which has its global headquarters and development laboratories in Sweden, currently operates across the world through development, licensing and distribution agreements in all major markets.

Orexo has a balanced portfolio with two products on the market, three in registration and/or late stage clinical phase, one in clinical phase I, one in formulation phase and two in early development phase.

Orexo is listed on the Nordic List at the OMX Nordic Exchange Stockholm, Mid Cap (ticker: ORX).

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About Endo
A wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc., Endo Pharmaceuticals is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com.