Halozyme Announces Roche Doses First Patient in Phase 3 Clinical Trial with Subcutaneous Herceptin®

Posted on : 2009-10-22 | Author : Halozyme Therapeutics, Inc.
News Category : PressRelease

SAN DIEGO - (Business Wire) Halozyme Therapeutics, Inc. (Nasdaq:HALO) and Roche today announced dosing of the first patient in a Phase 3 registration trial using Enhanze™ technology (rHuPH20, recombinant human hyaluronidase) in a subcutaneous formulation with Roche's anticancer biologic, Herceptin (trastuzumab). This represents the first Roche product to enter a Phase 3 registration study as part of the Halozyme Roche collaboration and initiation of the clinical trial has triggered a milestone payment of $5 million to Halozyme. Herceptin is approved to treat HER2-positive breast cancer and currently is given intravenously (IV).

This innovative technology is anticipated to allow patients with HER2-positive breast cancer to administer Herceptin themselves with or without the support of a healthcare professional via a simple subcutaneous injection. Infusion-free administration with subcutaneous Herceptin means for example that patients with early breast cancer completing their one year of Herceptin therapy would have greater convenience of being able to receive treatment at their family doctor's office or at home without having to go to a hospital, a significant and welcome benefit.

"The start of this Phase 3 subcutaneous Herceptin trial is a major achievement for the Halozyme and Roche collaboration, representing the first Roche target to reach a pivotal trial. It reflects years of focus, dedication, and teamwork with the aim of providing an innovative solution for improved patient care," said Jonathan Lim, M.D., Halozyme's President and CEO. "I congratulate the alliance on the speed of progress to Phase 3."

In addition, offering Herceptin treatment outside of the hospital setting could reduce costs and potentially help to maximize the efficient use of hospital resources. Subcutaneous Herceptin would come in a ready-to-use administration device instead of an infusion-bag that needs to be prepared by a pharmacist. Physicians and nurses would conduct fewer infusions at the hospital freeing up infusion chair time for other procedures. Additional information about this Phase 3 subcutaneous Herceptin clinical trial can be found at clinicaltrials.gov and roche-trials.com.

Halozyme Roche Collaboration

In December 2006, Halozyme entered into an agreement with Roche to apply Halozyme's proprietary Enhanze technology to Roche's biological therapeutic compounds. Under the terms of the agreement, Roche made an initial payment to Halozyme for the application of its recombinant human enzyme, rHuPH20, to three pre-defined biologic targets exclusive to Roche. In December 2008, Roche selected a fourth biologic target followed by selection of a fifth target in June 2009 and has the option to exclusively develop and commercialize rHuPH20 with an additional eight potential targets. Pending the successful achievement of a series of clinical, regulatory, and sales events, Roche will pay Halozyme additional milestones as well as royalties on future product sales. Under the collaboration, Roche has access to Halozyme's expertise in developing and applying rHuPH20 to Roche biologics directed at multiple targets. Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and Roche compounds resulting from the collaboration.

About Breast Cancer

Breast cancer is the most common cancer among women worldwide.[i] Each year more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually.[ii] In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumor cells. This is known as 'HER2 positivity' and affects approximately 20-25% of women with breast cancer.

About Halozyme Therapeutics, Inc.

Halozyme is a biopharmaceutical company developing and commercializing products targeting the extracellular matrix for the endocrinology, oncology, dermatology and drug delivery markets. The company's portfolio of products and product candidates is based on intellectual property covering the family of human enzymes known as hyaluronidases and additional enzymes that affect the extracellular matrix. Halozyme's Enhanze™ technology is a novel drug delivery platform designed to increase the absorption and dispersion of biologics. The company has key partnerships with Roche to apply Enhanze technology to Roche's biological therapeutic compounds for up to 13 targets and with Baxter BioScience to apply Enhanze technology to Baxter's biological therapeutic compound, GAMMAGARD Liquid®. Halozyme's research pipeline candidates target significant areas of unmet medical need. For more information visit www.halozyme.com.

References

[i] World Health Organization, http://www.who.int/cancer/detection/breastcancer/en/

[ii] Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARCPress, Lyon, 2004. 2004

Safe Harbor Statement

In addition to historical information, the statements set forth above include forward-looking statements (including, without limitation, statements concerning, (*i)* Roche's progress under the collaboration, (*ii)* the potential achievement of various milestones, and (*iii*) the advantages of subcutaneous Herceptin) that involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. The forward-looking statements are also identified through use of the words "believe," "enable," "may," "will," "could," "intends," "estimate," "anticipate," "plan," "predict," "probable," "potential," "possible," "should," "continue," and other words of similar meaning. Actual results could differ materially from the expectations contained in forward-looking statements as a result of several factors, including regulatory approval requirements and competitive conditions. These and other factors that may result in differences are discussed in greater detail in the company's reports on Forms 10-K, 10-Q, and other filings with the Securities and Exchange Commission.

Halozyme Therapeutics, Inc.
Robert H. Uhl
Senior Director, Investor Relations
858-704-8264
ruhl@halozyme.com