



ViroPharma and Halozyme Therapeutics Announce Positive Data From Initial Phase 2 Assessment of Subcutaneous Cinryze® (C1 esterase inhibitor [human]) with Hyaluronidase (rHuPH20)

EXTON, Pa., Dec. 6, 2011 /PRNewswire/ -- ViroPharma Incorporated (Nasdaq: VPHM) and Halozyme Therapeutics (Nasdaq: HALO) today announced positive top line data from ViroPharma's open-label, multiple dose Phase 2 clinical trial designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze® (C1 esterase inhibitor [human]) in combination with Halozyme's Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20), in subjects with hereditary angioedema (HAE), a rare, debilitating and potentially fatal genetic disease.

In this study, the addition of rHuPH20 led to higher maximum levels and greater systemic exposure of functional and antigenic C1 inhibitor (C1 INH) for both Cinryze doses evaluated (1000 and 2000 units) as compared to subcutaneous administration of Cinryze alone. In addition, administration of Cinryze with rHuPH20 resulted in mean functional C1 INH levels that are clinically relevant and potentially associated with protection against HAE attacks. The most commonly reported adverse events are mild local injection site reactions such as erythema and pain.

Complete data are expected to be presented at a future international scientific meeting.

"We are very encouraged by these initial data from this Phase 2 study of subcutaneous delivery of Cinryze in combination with rHuPH20, which are informative for the trial design of the upcoming Phase 2 dose ranging combination study," commented Colin Broom, MD, ViroPharma's chief scientific officer. "These preliminary data suggest that rHuPH20 enhances the delivery and absorption of Cinryze, and increases systemic exposure to C1 inhibitor relative to subcutaneous Cinryze administered alone. We believe that utilization of this cutting edge technology sets the combination apart from subcutaneous delivery of Cinryze without rHuPH20, and increases the likelihood of successful clinical development. It could improve flexibility and convenience, and potentially allow prevention-minded patients living with HAE to self administer every three or four days, just as they do today with the current IV formulation, but with a single subcutaneous injection."

This open-label multiple-dose study was conducted in 12 subjects with HAE who previously participated in the ViroPharma Phase 2 trial evaluating the pharmacokinetics of subcutaneous injections of Cinryze when given alone relative to intravenous infusion. Qualified subjects participated in a single 18-day study period, followed by a 30-day post-treatment follow-up. A 1000 U or 2000 U dose of Cinryze in combination with rHuPH20 was administered as a single subcutaneous injection, two times weekly, allowing within-subject comparison across the different methods of administration. Additional information about this Phase 2 subcutaneous Cinryze clinical trial can be found at clinicaltrials.gov.

Halozyme's proprietary rHuPH20 enzyme facilitates the absorption and dispersion of drugs or fluids that are injected under the skin. When injected under the skin, rHuPH20 transiently generates channels in tissues underlying the outer layers of the skin to increase the absorption and spread of injected drugs.

About Cinryze® (C1 esterase inhibitor [human])

Cinryze is a highly purified, pasteurized and nanofiltered plasma-derived C1 esterase inhibitor product. In the U.S., Cinryze is approved by the FDA for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE. In the E.U., the product is approved by the EMA for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE), and routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments or patients who are inadequately managed with repeated acute treatment. Cinryze is for intravenous use only.

Severe hypersensitivity reactions to Cinryze may occur. Thrombotic events have occurred in patients receiving Cinryze, and in patients receiving off-label high dose C1 inhibitor therapy. Monitor patients with known risk factors for thrombotic events. With any blood or plasma derived product, there may be a risk of transmission of infectious agents, e.g. viruses and, theoretically, the CJD agent. The risk has been reduced by screening donors for prior exposure to certain virus infections and by manufacturing steps to reduce the risk of viral transmission including pasteurization and nanofiltration.

The most common adverse reactions in clinical trials associated with Cinryze were rash, headache, nausea, erythema, phlebitis and local reactions at the injection site. Adverse events of sinusitis and upper respiratory infection also were observed in clinical trials. No drug-related serious adverse events (SAEs) were reported in clinical trials.

Please visit <http://www.viopharma.com/products/cinryze.aspx> for the full U.S. Prescribing Information; the prescribing information for other countries can be found at www.viopharma.com.

About Enhanze™ Technology

Enhanze™ technology is a proprietary drug delivery platform using Halozyme's first approved enzyme, recombinant human hyaluronidase or rHuPH20. When formulated with other injectable drugs, Enhanze technology can facilitate the subcutaneous dispersion and absorption of these drugs. Molecules as large as 200 nanometers may pass freely through the extracellular matrix, which recovers its normal density within approximately 24 hours, leading to a drug delivery platform which does not permanently alter the architecture of the skin. The principal focus of Halozyme's Enhanze technology platform is the use of rHuPH20 to facilitate subcutaneous administration for large molecule biological therapeutics, some of which currently require intravenous administration.

About Hereditary Angioedema (HAE)

HAE is a rare, severely debilitating, life-threatening genetic disorder caused by a deficiency of C1 inhibitor, a human plasma protein. This condition is the result of a defect in the gene controlling the synthesis of C1 inhibitor. C1 inhibitor maintains the natural regulation of the contact, complement, and fibrinolytic systems, that when left unregulated, can initiate or perpetuate an attack by consuming the already low levels of endogenous C1 inhibitor in HAE patients. Patients with C1 inhibitor deficiency experience recurrent, unpredictable, debilitating, and potentially life threatening attacks of inflammation affecting the larynx, abdomen, face, extremities and urogenital tract. Patients with HAE experience approximately 20 to 100 days of incapacitation per year. There are estimated to be at least 6,500 people with HAE in the United States and at least 10,000 people in the European Union.

For more information on HAE, visit the HAEi's (International Patient Organization for C1 Inhibitor Deficiencies) website at www.haei.org and the U.S. HAE Association's website at: www.haea.org.

About ViroPharma Incorporated

ViroPharma Incorporated is an international biopharmaceutical company committed to developing and commercializing novel solutions for physician specialists to address unmet medical needs of patients living with diseases that have few if any clinical therapeutic options, including C1 esterase inhibitor deficiency, treatment of seizures in children and adolescents, adrenal insufficiency (AI), and *C. difficile* infection (CDI). Our goal is to provide rewarding careers to employees, to create new standards of care in the way serious diseases are treated, and to build international partnerships with the patients, advocates, and health care professionals we serve. ViroPharma's commercial products address diseases including hereditary angioedema (HAE), seizures in children and adolescents, and CDI; for full U.S. prescribing information on our products, please download the package inserts at <http://www.viopharma.com/Products.aspx>; the prescribing information for other countries can be found at www.viopharma.com.

ViroPharma routinely posts information, including press releases, which may be important to investors in the investor relations and media sections of our company's web site, www.viopharma.com. The company encourages investors to consult these sections for more information on ViroPharma and our business.

About Halozyme

Halozyme Therapeutics is a biopharmaceutical company developing and commercializing products targeting the extracellular matrix for the diabetes, cancer, dermatology and drug delivery markets. The Company's product portfolio is based primarily 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 absorptior and dispersion of biologics. In addition to partnerships that use Halozyme's ENHANZE™ Technology, the Company has a number of product candidates in its pipeline that target multiple areas of significant unmet medical need. For more information visit www.halozyme.com.

ViroPharma Forward Looking Statements

Certain statements in this press release contain forward-looking statements that involve a number of risks and uncertainties. Forward-looking statements provide our current expectations or forecasts of future events, including the therapeutic indication and use, safety, efficacy, tolerability and potential of Cinryze and our focus, goals, strategy, research and development programs, and ability to develop pharmaceutical products, commercialize pharmaceutical products, and execute on our plans

including clinical development activities with Cinryze related to subcutaneous administration.

The safety, pharmacokinetics and pharmacodynamics data described in this press release are preliminary and additional review of the data may reveal additional findings which may not be consistent with this press release. The data described in this press release may not be predictive of the results of future studies and there can be no assurance that that future studies with Cinryze utilizing subcutaneous administration in combination with rHuPH20 will yield positive results or support further development of Cinryze for subcutaneous administration in combination with rHuPH20. The FDA or EMA may view the data regarding subcutaneous administration of Cinryze in combination with rHuPH20 as insufficient or inconclusive, request additional data, require additional clinical studies, delay any decision past the time frames anticipated by us, limit any approved indications, or deny the approval of Cinryze for subcutaneous administration in combination with rHuPH20. These factors, and other factors, including, but not limited to those described in our annual report on Form 10-K for the year ended December 31, 2010 and quarterly reports on Form 10-Q filed with the Securities and Exchange Commission for the periods ended March 31, 2011, June 30, 2011 and September 30, 2011, could cause future results to differ materially from the expectations expressed in this press release. The forward-looking statements contained in this press release are made as of the date hereof and may become outdated over time. ViroPharma does not assume any responsibility for updating any forward-looking statements. These forward looking statements should not be relied upon as representing our assessments as of any date subsequent to the date of this press release.

Halozyme Safe Harbor Statement

In addition to historical information, the statements set forth above regarding the subcutaneous Cinryze with rHuPH20 product candidate, its possible advantages and attributes, the anticipated presentation of the complete data from the initial Phase 2 trial referenced in this press release, future clinical trials plans, including the anticipated Phase 2 dose ranging efficacy combination trial, and other statements regarding Halozyme's product candidates and potential attributes of these product candidates, 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 "expect," "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 clinical trial results, delays in development, possible adverse events associated with the use of the product candidate, regulatory delays 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.

SOURCE ViroPharma Incorporated

News Provided by Acquire Media