



## **ViroPharma Purchases Exclusive Option to Acquire Meritage Pharma**

### **- Option Creates Opportunity to Further Augment Rare Disease Development Pipeline with Novel Orphan Drug for Eosinophilic Esophagitis, a Chronic Inflammatory Disease -**

EXTON, Pa. and SAN DIEGO, Dec. 22, 2011 /PRNewswire/ -- ViroPharma Incorporated (NASDAQ: VPHM) today announced that it has entered into an exclusive option to acquire Meritage Pharma, Inc., a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE), a chronic inflammatory disorder of the esophagus.

ViroPharma has paid an initial \$7.5 million, and has agreed to provide Meritage up to an additional \$12.5 million for the development and exclusive right to purchase the company at predefined terms upon the completion of a series of clinical and regulatory deliverables. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. After receipt of final Phase 2 data and concurrence with the U.S. Food and Drug Administration (FDA) on an acceptable clinical endpoint for the Phase 3 program, ViroPharma will have an option to acquire Meritage at ViroPharma's discretion for \$69.9 million plus the potential for additional payments upon the achievement of certain clinical and regulatory milestones.

As described below, in an initial Phase 2 dose-ranging clinical trial in pediatric patients with EoE, OBS demonstrated a statistically significant reduction of esophageal eosinophilia. Clinical symptom assessment was confounded by the use of a multi-symptom assessment tool and high placebo response.

EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

"Our interest in Meritage is consistent with ViroPharma's intent to broaden our portfolio of development opportunities for rare and serious unmet medical needs," commented Vincent Milano, ViroPharma's president and chief executive officer.

"Eosinophilic esophagitis is an emerging, rare condition that currently has no approved therapy. This disease profoundly affects the lives of these patients, causing stomach and chest pain and affecting their ability to swallow and eat normally. Over time, this disease can lead to malnutrition, significant weight loss, and potentially esophageal damage. We look forward to working with Meritage to advance the development of oral budesonide suspension toward the goal of one day providing a solution to treat this debilitating disease."

"We look forward to collaborating with ViroPharma to develop OBS to treat this serious disease," added Elaine Phillips, president and chief executive officer, Meritage. "Our goal is to ensure that this therapy is available for EoE patients and their caregivers as soon as possible."

Oral budesonide suspension was granted Orphan Drug Designation by the FDA in June of 2011 for the treatment of patients with eosinophilic esophagitis. Orphan drug designation entitles the developer to seven years of market exclusivity in the United States upon FDA approval of oral budesonide, provided that the company continues to meet certain conditions established by the FDA. Other potential advantages of Orphan Drug Designation include protocol assistance, the potential for priority review, tax credits, and other financial incentives.

### **Phase 2 Clinical Data (PEER Study)**

A Phase 2 placebo controlled dose-ranging clinical trial in pediatric patients with EoE conducted by Meritage enrolled 82 patients with 71 completing therapy. Meritage evaluated OBS treatment by assessing histologic response (most notably the extent of esophageal eosinophilia) and clinical symptoms. Analyses of the compound primary endpoint, histologic response and reduction in clinical symptoms, showed a statistically significant response on the histological component in the medium and high dose groups compared to placebo. Meritage used a 6-domain symptom scoring tool to assess heartburn, abdominal pain, nocturnal awakening, nausea, early satiety and dysphagia/food impaction. While most of the children treated in the PEER study felt better, the multi-domain symptom tool as applied in this study was not sensitive enough to separate OBS and placebo treatment responses. OBS was well tolerated; there were no trends or unexpected signals in adverse events, clinical labs or vital signs.

## **Transaction Terms**

The development and option agreement provides ViroPharma with the exclusive right, but not an obligation, to acquire Meritage pursuant to the terms of a definitive merger agreement. ViroPharma made an initial payment of \$7.5 million on signing of the development and option agreement. ViroPharma would fund Meritage up to an additional \$12.5 million for the development and exclusive right to purchase Meritage upon achievement of several agreed upon clinical and regulatory development deliverables.

Upon ViroPharma's receipt and review of the final Phase 2 study data and concurrence on an acceptable clinical endpoint for the Phase 3 program with FDA, ViroPharma shall have an option, exercisable in its sole discretion, to enter into the definitive merger agreement to acquire Meritage for \$69.9 million. The agreement also contemplates potential additional payments upon completion of certain clinical and regulatory milestones related to the development and approval of OBS for its initial indication.

BMO Capital Markets acted as the exclusive financial advisor to ViroPharma and Stifel Nicolaus Weisel acted as exclusive financial advisor to Meritage in connection with the transaction.

## **About Oral Budesonide Suspension**

Oral budesonide suspension, or OBS, is a proprietary formulation that is viscous and is designed to coat the esophagus with budesonide where it acts topically. Budesonide is an anti-inflammatory corticosteroid that is the active pharmaceutical ingredient in several products approved by the U.S. Food and Drug Administration (FDA), including products for the treatment of pediatric asthma, allergic rhinitis and Crohn's disease. The FDA has granted Orphan Drug Status designation to OBS for the treatment of eosinophilic esophagitis. In addition, OBS has pending patent applications, which may result in patent protection to approximately 2028.

## **About Eosinophilic Esophagitis**

Eosinophilic esophagitis (EoE) is an emerging disease that has only recently been classified as a unique condition due to a dramatic rise in the incidence and diagnosis over the last decade. Due to inflammation caused by eosinophils, EoE patients may have persistent or relapsing symptoms including dysphagia and food impaction. Other symptoms may include reflux symptoms that do not respond to proton pump inhibitor therapy, failure to thrive, difficulty sleeping and poor appetite. Long term, EoE may result in malnutrition, weight loss, and acute esophageal perforations. People living with EoE commonly have other allergic conditions such as asthma or eczema.

EoE occurs when eosinophils, a type of white blood cell involved in allergic reactions, infiltrate the surface of the esophagus. Eosinophil infiltration leads to inflammation of the esophagus and is believed to cause tissue remodeling and fibrosis if left untreated. A variety of stimuli may trigger this allergic process, including certain foods and environmental allergens. There are no approved products for the treatment of EoE. There are approximately 160,000 patients diagnosed with EoE in the U.S.

## **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. ViroPharma is developing a portfolio of therapeutics for rare and Orphan diseases including C1 esterase inhibitor deficiency, Friedreich's Ataxia, and adrenal insufficiency; and recurrent *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 and *C. difficile*-associated diarrhea (CDAD); for full U.S. prescribing information on our products, please download the package inserts at <http://www.viropharma.com/Products.aspx>; the prescribing information for other countries can be found at [www.viropharma.com](http://www.viropharma.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.viropharma.com](http://www.viropharma.com). The company encourages investors to consult these sections for more information on ViroPharma and our business.

## **About Meritage Pharma**

Meritage Pharma is committed to the development of prescription products based on safe and effective molecules for the treatment of gastrointestinal and atopic diseases. Meritage Pharma's product candidate, oral budesonide suspension, is intended for the treatment of pediatric eosinophilic esophagitis, an allergic inflammation of the gastrointestinal tract. The company was founded in March 2008 and raised its Series A financing from Domain Associates, Latterell Venture Partners and The Vertical Group. More information about Meritage Pharma is available at [www.meritagepharma.com](http://www.meritagepharma.com).

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***Disclosure Notice***

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 oral budesonide suspension (OBS) as a treatment for Eosinophilic Esophagitis (EoE) and the ability of Meritage to develop OBS and execute on its plans including clinical development activities with OBS related to EoE; whether ViroPharma ultimately will acquire Meritage; anticipated scientific progress on the OBS research program; and the relative value to ViroPharma's business of an acquisition of Meritage. There can be no assurance that the clinical program with OBS will yield positive results or support further development of OBS for EoE. The FDA may view the data regarding utilization of OBS for EoE 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. 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.

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