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**Meritage Pharma Reports Positive Phase 2b Data for Oral Budesonide Suspension in Pediatric Patients with Eosinophilic Esophagitis**

Data Presented at Digestive Disease Week Highlight OBS in Chronic Inflammatory Condition

**Chicago, IL (May 10, 2011)** – Meritage Pharma, Inc. announced today its proprietary oral budesonide suspension (OBS) met the primary endpoint of reduction of esophageal eosinophilia and symptoms in a Phase 2b dose-ranging clinical trial in pediatric patients with eosinophilic esophagitis (EoE), an allergic inflammatory condition of the esophagus. Results from the Pediatric Eosinophilic Esophagitis Research (PEER) study were presented by principal investigators at Digestive Disease Week (DDW) in Chicago, Illinois.

“Eosinophilic esophagitis is an emerging, orphan disease that has challenged gastroenterologists who don’t have an approved therapy for patients who experience nausea, have difficulty swallowing, and in severe cases are incapable of eating normally,” said Elaine Phillips, President and CEO of Meritage Pharma, Inc. “We have clear guidance from the FDA on the requirements of the OBS Phase 3 program and are eager to advance this therapeutic option to enable EoE patients to thrive, despite their disease.”

The double-blind, randomized, placebo-controlled 12-week PEER study evaluated three different daily doses (low, medium and high) of OBS and placebo in patients aged two to 18 with confirmed EoE. Patients were evaluated for symptoms and by standard endoscopic biopsies of the esophagus that measured the number of eosinophils (EOS) per high power field (HPF). Treatment responders were defined as patients with  $\leq 6$  EOS per HPF in all esophageal levels and  $\geq 50\%$  symptom score reduction at the end of 12 weeks of treatment.

Eighty-two patients enrolled in the study with 71 completing therapy. At end of treatment, there were statistically significant greater percentages of responders in both the medium and high dose groups compared to placebo whereas no difference was noted between the low dose and placebo groups. Subjects in the medium and high dose groups also demonstrated statistically significant histologic remission ( $\leq 1$  EOS per HPF) compared to placebo. Most of the children treated in the PEER study felt better, although the symptom response was similar in both the placebo and active treatment groups. Daily therapy with medium and high doses of OBS also resulted in a statistically significant reduction of

endoscopic findings and epithelial inflammation. OBS was well tolerated; there were no trends or unexpected signals in adverse events, clinical labs or vital signs.

Efficacy Parameter	Placebo N=18	Low Dose N=17	Medium Dose N=19	High Dose N=17
% Responders (Peak EOS $\leq$ 6/HPF + $\geq$ 50% Symptom Score Reduction)	5.6	11.8	52.6	47.1
- p-value (OBS vs Placebo)	–	0.5282	0.0092	0.0174
% Subjects with Histologic Response (Peak EOS $\leq$ 6/HPF)	5.6	23.5	52.6	94.1
- p-value (OBS vs Placebo)	–	0.1786	0.0090	0.0001
% Subjects with Histologic Remission (Peak EOS $\leq$ 1/HPF)	0	11.8	42.1	76.5
- p-value (OBS vs Placebo)	–	0.4597	0.0042	<0.0001

“The profound reduction of esophageal eosinophilia after treatment with OBS is exciting because, in my experience, patients with reduced eosinophilia will have a better long term prognosis than those without histologic response,” said Sandeep K. Gupta, M.D., Professor of Clinical Pediatrics and Clinical Medicine and Director, Pediatric Endoscopy, Division of Pediatric Gastroenterology, Hepatology and Nutrition at Riley Hospital for Children, Indiana University School of Medicine. “I want my patients to be able to return to a healthy diet because abnormal feeding patterns disrupt the lives of patients and their families. School is missed and social activities are severely restricted, affecting normal childhood development,” Dr. Gupta continued. He is also a member of the Medical Advisory Board of the [American Partnership for Eosinophilic Disorders \(APFED\)](#) and is on the Executive Committee of The International Gastrointestinal Eosinophils Researchers conSortium ([TIGERS](#)).

Margaret H. Collins, M.D., Professor of Pathology at Cincinnati Children’s Hospital Medical Center, described the esophageal epithelial pathology results from the PEER study in a poster presentation at DDW. “This topically active formulation of budesonide effectively reduces EOS and other key features of inflammation throughout the length of the esophagus. This pan-esophageal response has the potential to modify the EoE process by reducing inflammation and possibly reverse the fibrosis that, left untreated, may cause dysphagia and food impactions,” said Dr. Collins. Dr. Collins also serves on the Medical Advisory Board of APFED and is on the Executive Committee of TIGERS, as well as on the Steering Committee of the Registry for Eosinophilic Gastrointestinal Diseases ([REGID](#)).

### About Eosinophilic Esophagitis

EoE is an emerging disease that has only recently been classified as a separate condition due to a dramatic rise in the incidence and diagnosis over the last decade. EoE patients may have persistent or relapsing symptoms, which include nausea, dysphagia (problems swallowing), stomach pain, chest pain, heartburn, loss of weight and food impaction. Other symptoms may include reflux that does not respond to proton pump inhibitor therapy, failure to thrive, poor appetite, malnutrition and difficulty sleeping. People 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. EOS 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.

### **About Oral Budesonide Suspension**

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 pediatric EoE.

### **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 has raised \$30.5 million in 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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### **Forward-Looking Statements**

Meritage Pharma cautions you that statements included in this press release that are not a description of historical facts may be forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Meritage Pharma that any of its plans will be achieved. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in Meritage Pharma's business including, without limitation, statements about: difficulties or delays in developing, obtaining regulatory approval, manufacturing and commercializing its products; unexpected performance or side effects of its products that could delay or prevent development or commercialization; the scope and validity of patent protection for its products; competition from other pharmaceutical companies; and its ability to obtain additional financing to support its operations. All forward-looking statements are qualified in their entirety by this cautionary statement and Meritage Pharma undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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