ESOCAP REPORTS POSITIVE TOPLINE RESULTS FROM ACESO PHASE II TRIAL INVESTIGATING ESO-101 IN EOSINOPHILIC ESOPHAGITIS

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- **ESO-101, EsoCap's lead product candidate, consists of a capsule with a rolled-up, thin mucoadhesive film with the anti-inflammatory corticosteroid, mometasone furoate**
- **EsoCap's novel targeted delivery platform increases mucosal contact time and drug deposition in the esophagus**
- **The ACESO trial met the primary endpoint, demonstrating efficacy by histologic response and a very favorable safety and tolerability profile**

EsoCap AG, the Swiss biotech company dedicated to improving the lives of patients with serious diseases of the upper gastrointestinal tract, announced today that the ACESO Phase II study comparing ESO-101 to placebo for the treatment of eosinophilic esophagitis has met its primary endpoint by significantly reducing the peak eosinophil count in the histological assessment of esophageal biopsies.

The ACESO study is a randomized, placebo-controlled, double-blind Phase II study to evaluate the efficacy, tolerability and safety of ESO-101 in patients with active eosinophilic esophagitis (EoE). Forty-three adult patients with EoE and a peak eosinophil count of ≥15 eosinophils per high-power field (hpf) were enrolled in five European countries. Patients were randomized in a 2:1 ratio and treated for 28 days. EoE is an increasingly recognized, chronic, local, immune-mediated esophageal disease characterized clinically by symptoms associated with esophageal dysfunction, including dysphagia, food impaction, heartburn and vomiting, and histologically by eosinophil-dominated inflammation.

The results of the study showed that the primary endpoint was met with a statistically significant reduction of the peak eosinophil count (p=0.0318) compared to placebo. The study also showed that ESO-101 demonstrated a highly favorable safety and tolerability profile. 7.1 % (n=2) of patients who received ESO-101 treatment and 26.7 % (n=4) in the placebo group reported mild to moderate adverse events related to the investigational product; no drug related serious adverse events were reported. There were no instances of candidiasis, a type of fungal infection commonly associated with corticosteroid-based topical products. The unique EsoCap drug delivery system was shown to be easy for patients to swallow. Upon drinking the capsule through a specially designed drinking cup, the film unrolls and adheres to the patient's esophageal mucosa, where it slowly dissolves and releases mometasone furoate.

"Eosinophilic esophagitis is a chronic disease with few therapeutic options. This limitation in treatment is due to the unique anatomical and functional characteristics of the esophagus, which result in an extremely short transit time within the esophageal tract. A higher efficacy of topical corticosteroids has been shown to be directly related to the duration of mucosal contact time, but the methods for topical delivery of drugs to the esophagus have remained a challenge," said **Dr. Alfredo J. Lucendo, Department of Gastroenterology, Hospital General de Tomelloso, Spain, and coordinating principal investigator of the ACESO trial**. "We are pleased that the results of the ACESO study confirm that ESO-101, which is specifically designed to increase contact time with the mucosa, can achieve a statistically

significant histologic response compared to placebo, providing the important benefits of an esophageal-specific drug for patients with EoE."

"The ACESO study represents an important milestone in the development of our unique application platform for the treatment of esophageal diseases. With our lead product ESO-101, we have demonstrated that the EsoCap system can provide long-lasting, targeted topical delivery of the glucocorticosteroid mometasone furoate. Following the successful results of this Phase II study, we now plan to initiate a Phase III program in eosinophilic esophagitis," said **Isabelle Racamier, CEO of EsoCap**. "Our technology is extremely flexible. Multiple relevant agents, including biologics and other innovative substances, can be incorporated into the film, making our platform suitable for drug delivery in a variety of clinical indications, including reflux disease, Barrett's disease and esophageal cancer - all areas of high unmet medical need."

The detailed results from the ACESO study, including secondary endpoint data, will be submitted for presentation at a future scientific conference.

About eosinophilic esophagitis

Eosinophilic esophagitis (EoE) is an increasingly recognized, chronic, local immune-mediated esophageal disease, characterized clinically by symptoms related to esophageal dysfunction and histologically by eosinophil-predominant inflammation. The symptoms of EoE include swallowing disorders, food impaction, vomiting, and heartburn. EoE is the leading cause of dysphagia and food impaction in children and young adults.

The only treatment options for the condition are extremely strict diets, off-label treatment with steroids or proton pump inhibitors, or an orodispersible budesonide tablet available only in limited territories. These treatment options remain suboptimal for the vast majority of affected patients. Recently, a monoclonal antibody targeting Th2 cytokines was approved to treat EoE in a limited treatment-resistant patient population. Currently, about 500,000 patients worldwide suffer from this disease. The prevalence of EoE is over 6 in 10,000. The current incidence is estimated at about 5 cases per 100,000. The incidence of EoE increases with age and peaks at 30-50 years of age.

About ACESO

The ACESO trial is a multicenter, randomized, double-blinded, placebo-controlled clinical Phase II trial evaluating the efficacy, tolerability, and safety of ESO-101 in adult patients with active EoE. Patients are treated once daily for 28 days.

The trial's primary objective is to evaluate efficacy based on histological response. Secondary objectives include efficacy based on 1) histological response and clinical symptoms, 2) clinical response assessed by patient-reported outcomes, and 3) endoscopic response; patient-reported treatment satisfaction; as well as evaluation of tolerability and safety.

About ESO-101

The EsoCap system is a unique drug delivery system for the upper gastrointestinal tract, consisting of a capsule holder containing a hard gelatin capsule, with a rolled, thin mucoadhesive film, a sinker, and a soluble retainer. The capsule holder is screwed onto the lid of a drinking cup to facilitate swallowing while drinking from the cup. Upon swallowing, the film unrolls and sticks to the esophageal mucosa, where it dissolves, with a contact time of 15 minutes[1,2], significantly longer than the mucosal contact time of

pharmaceutical dosage forms, such as orodispersible tablets (less than one minute)[3].

The use of mometasone furoate as a swallowed aerosol formulation has been studied previously in several trials assessing its effect on EoE in adults. In these trials, mometasone furoate was shown to significantly decrease esophageal eosinophilic inflammation and improve clinical symptoms.

ESO-101 was designed as a locoregional, esophagus-adjusted drug formulation and novel delivery system to optimize mucosal contact time and maximize esophageal deposition of mometasone furoate. ESO-101 has the potential to provide significant clinical benefits to EoE patients.

About EsoCap

EsoCap AG is a privately funded company based in Basel, Switzerland.

EsoCap's vision is to improve the lives of patients with serious diseases of the upper gastrointestinal tract through development of a unique and innovative topical drug delivery platform.

Effective topical treatment of the esophagus is extremely difficult to achieve with the current standard of care, due to the ultra-short drug contact time of 45 seconds from the mouth to the stomach. Lead candidate ESO-101 has received Orphan Drug Designation from the U.S. Food & Drug Administration (FDA) for the treatment of EoE and is in clinical development for this indication.

EsoCap has developed a unique, proprietary drug delivery platform enabling the efficient topical application of drug substances for the local treatment of diseases of the upper gastrointestinal tract. EsoCap has a strong and broad intellectual property position.

For more information, please visit www.esocapbiotech.com and follow EsoCap on LinkedIn and Twitter.

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