ESOCAP COMPLETES PATIENT RECRUITMENT IN ACESO PHASE II TRIAL IN EOSINOPHILIC ESOPHAGITIS

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- **EsoCap's novel targeted delivery platform is designed to increase mucosal contact time and drug deposition in the esophagus**
- **ESO-101, EsoCap's lead product candidate, consists of a capsule with a rolled-up, thin mucoadhesive film filled with the anti-inflammatory corticosteroid, mometasone furoate**
- **Topline results from ACESO study expected in late 2023**

EsoCap AG, the Swiss biotech company dedicated to improving the lives of patients with serious diseases of the upper gastrointestinal tract, reports the completion of patient recruitment in the Phase II ACESO trial. The randomized, placebo-controlled, double-blind study is evaluating the efficacy, tolerability and safety of ESO-101 in 43 adult patients with active eosinophilic esophagitis (EoE) in five European countries. Patients have been randomized 2:1 and are being treated for 28 days. EoE is a rare, chronic, local immune-mediated esophageal disease, characterized clinically by symptoms related to esophageal dysfunction including swallowing disorders, food impaction, heartburn and vomiting, and histologically by eosinophil-predominant inflammation.

The first product candidate, ESO-101, is loaded with mometasone furoate, an anti-inflammatory corticosteroid and well-known active pharmaceutical ingredient (API) that is approved for the topical treatment of asthma and skin conditions, making it well suited as a loco-regional treatment for EoE. 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, releasing mometasone furoate. The objectives of the ACESCO Phase II trial are to evaluate the efficacy of ESO-101 based on histological response and clinical symptoms.

"Reaching completion of patient enrollment reflects the high level of interest in our clinical development program. We look forward to upcoming data readouts, which will guide our future strategic development plans," said **Isabelle Racamier, Chief Executive Officer.** "Our technology is highly flexible. Multiple relevant agents, including biologics and other innovative compounds, can be incorporated into the film, making our drug delivery platform suitable for several clinical indications, including reflux disease, Barrett's disease and esophageal cancer – all areas of high unmet medical need."

"Eosinophilic esophagitis is a chronic disease with few therapeutic options. This limitation in treatment arises from the distinctive anatomical and functional attributes of the esophagus, which result in an exceedingly brief transit period within the esophageal tract. As a result, achieving effective topical treatment for the esophagus presents a significant challenge," explained **Dr. Alfredo J. Lucendo, Department of Gastroenterology, Hospital General de Tomelloso, Spain, and coordinating principal investigator of the ACESO trial**. "We are confident that ESO-101 holds the promise via increased mucosal contact time of enhancing the efficacy of drugs within the esophagus, thereby providing significant advantages to individuals suffering from EoE."

In a previous study in healthy volunteers, EsoCap's proprietary and unique targeted delivery technology for the upper gastrointestinal tract was shown to significantly

increase contact time with the mucosa and was well tolerated.

About eosinophilic esophagitis

Eosinophilic Eosinophilic esophagitis (EoE), is a rare, 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 off-label 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 has been approved to treat EoE in a limited treatment resistant patient population. Currently, about half a million patients worldwide suffer from this disease. The prevalence of EoE is about 5 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.

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 histological response and clinical symptoms, efficacy based on clinical response assessed by patient-reported outcomes, efficacy based on 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 up to 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.

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 one to two 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 allowing 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.

EsoCap

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