ESOCAP ANNOUNCES FIRST PATIENT ENROLLED IN PHASE II EOSINOPHILIC ESOPHAGITIS TRIAL

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- **Randomized, placebo-controlled, double-blind Phase II trial to treat 42 patients ongoing in four European countries with ESO-101**
- **ESO-101, EsoCap's lead product candidate, consists of a capsule with a rolled, thin mucoadhesive film, loaded with the anti-inflammatory corticosteroid, mometasone furoate**
- **In a previous trial, EsoCap's proprietary and unique targeted application technology for the upper gastrointestinal tract was shown to dramatically increase mucosal contact time and was well accepted**

EsoCap AG, the Swiss biotech company dedicated to improving the lives of patients with serious diseases of the upper gastrointestinal tract, reports the first patient in the Phase II ACESO trial has been dosed. The randomized, placebo-controlled, double-blind trial will evaluate the efficacy, tolerability and safety of ESO-101 in 42 adult patients with active eosinophilic esophagitis (EoE), in four European countries. Patients will be randomized 2:1 and will be treated for 28 days.

EsoCap's novel targeted application platform is designed to increase mucosal contact time and esophageal drug deposition. The EsoCap technology consists of a capsule containing a thin mucoadhesive film loaded with an active pharmaceutical ingredient (API).

The first product candidate, ESO-101, is loaded with mometasone furoate, an anti-inflammatory corticosteroid and well-known active substance approved as a topical treatment for asthma and skin conditions, and is thus well suited as a locoregional treatment for EoE. Upon drinking the capsule from a specially designed drinking cup, the film unrolls and sticks to the patient's esophageal mucosa, where it dissolves slowly, while releasing mometasone furoate.

"The start of our ACESO trial marks an important milestone in the development of our unique application platform to treat esophageal diseases. The EsoCap system has proven fully functional and was shown to be well accepted in a previous trial conducted in healthy volunteers. With our lead product, ESO-101, we now aim to provide long-lasting targeted topical delivery of the glucocorticosteroid mometasone furoate", said **Isabelle Racamier, EsoCap AG CEO**. "We are looking forward to the results of the trial in the first half of 2022, and these will guide the future pivotal program and our strategic development options. Our technology offers maximum flexibility as multiple relevant drug substances, including biologics and other innovative compounds, can be incorporated into the film, making our drug delivery platform suitable for several clinical indications, including Barrett's disease and reflux disease, two areas of high unmet medical need."

"Eosinophilic esophagitis is a chronic disease with very limited treatment options. Due to the anatomical and functional characteristics of the esophagus, including an ultra-short esophageal transit time, effective topical treatment of the esophagus is extremely difficult to achieve", explained **Dr. Alfredo J. Lucendo, Department of Gastroenterology, Hospital General de Tomelloso, Spain, and coordinating principal investigator of the ACESO trial.** "Based on the knowledge that a drug's efficacy correlates directly to the contact time between the drug and the esophageal mucosa, we are confident that ESO-101 has the potential to enhance esophageal release and deposition of a drug and thus offer substantial benefits to patients suffering from EoE."

EsoCap

About eosinophilic esophagitis

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. 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.

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 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.esocap-biotech.com and follow EsoCap on LinkedIn and Twitter.

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