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EsoCap

Building a smart drug delivery technology for the esophagus

Switzerland-based EsoCap has built a novel drug delivery system that aims to provide long-lasting local therapy in the upper gastrointestinal tract and is currently being tested in a phase 2 trial.

Esophageal conditions affect ~370 million people a year worldwide. However, up to now, there have been no globally approved locally administered treatments. The esophagus is a particularly challenging environment, as swallowed drugs only remain in the area between the mouth and the stomach for a few seconds. EsoCap, a privately funded company based in Basel, Switzerland, has come up with a novel solution to increase mucosal contact time in the upper gastrointestinal tract and esophageal drug deposition. Its drug delivery platform, developed in collaboration with the University of Greifswald, Germany, is designed to provide targeted and long-lasting local therapy in the upper gastrointestinal tract.

The main feature of the EsoCap delivery system is a small capsule containing a coiled mucoadhesive film loaded with the drug. The capsule also contains a weight and a soluble thin thread. The patient places the specially designed mouthpiece, already containing the capsule, on a drinking cup filled with water. As soon as the capsule reaches the esophagus during swallowing, the film is pulled out of the capsule by the very thin thread. As a result, the mucoadhesive film unrolls as the capsule passes through the esophagus and adheres to the esophageal wall because of its adhesive property. The additional weight in the capsule speeds up the swallowing process and allows comfortable drinking. The connecting thread is made of a material that dissolves after just a few seconds (Fig. 1).

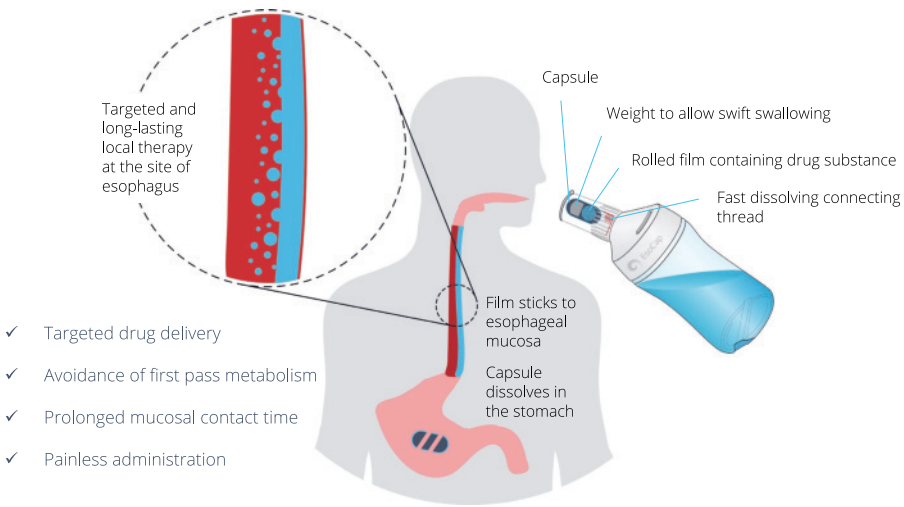

Fig. 1 | Targeted and long-lasting local therapy of the esophagus for the first time.

Moving into the clinic

For proof-of-principle, a study was conducted on healthy volunteers using MRI. In this study, MRI tracking showed that the film rolled off well and adhered to the esophagus for at least 15 minutes. According to all subjects, swallowing the capsule on consecutive days was well accepted. Currently, EsoCap is in the next phase—a phase 2 study in patients with eosinophilic esophagitis. In EsoCap's investigational product, ESO-101, the mucoadhesive film is loaded with the locally highly potent corticosteroid mometasone, which is not bioavailable and thus avoids the serious side effects of systemic corticosteroid therapy.

"The EsoCap novel smart drug delivery technology will enable targeted and long-lasting local therapy of the esophagus for the first time," said Isabelle Racamier, EsoCap CEO. "We carried out a freedom to operate analysis and found nothing similar in development, confirming the uniqueness of our technology."

For the phase 2 study, named ACESO after the Greek goddess of the healing process, EsoCap is currently recruiting 42 patients with the rare disease eosinophilic esophagitis (EoE) at 14 centers in four countries. Eosinophilic esophagitis is a chronic, inflammatory disease of the esophagus that is triggered by allergens and leads to symptoms including dysphagia and extremely painful food impactions. The only treatment options for the condition are extremely strict diets, off-label treatment with steroids, off-label proton pump inhibitors, or, in few European countries only, an orodispersible budesonide tablet.

The randomized controlled study will compare ESO-101 with a placebo. ESO-101 or the placebo will be taken daily in the evening for 28 days. Data from this trial are expected in early 2022.

"This is just the start of the story. Our technology offers maximal flexibility as multiple relevant drug substances, including biologics and further innovative compounds, can be incorporated into the film, making our drug delivery platform applicable for various clinical indications," said Racamier.

This flexibility gives EsoCap's approach potential in a range of different esophageal disorders such as gastroesophageal reflux disease (GERD), and Barrett's esophagus, a condition which may evolve into esophageal cancer. Together with EoE, EsoCap is looking at GERD and Barrett disease as priority indications, as these are areas of high unmet medical need. The company is also carrying out feasibility work in collaboration with the University of Greifswald.

Building a business strategy towards partnering

ESO-101 gained Orphan Drug Designation for eosinophilic esophagitis in the USA in 2019, and an application has been submitted in Europe. This will provide the product with between 7 and 10 years of marketing exclusivity. EsoCap has filed a patent application, with patents granted in the USA, Japan, South Africa and Russia, and expected in the EU and 12 further countries. Ring-fencing patent applications cover the capsule holder and production methods.

"We plan to demonstrate clinical feasibility in eosinophilic esophagitis with the ACESO phase 2 trial, and use the data from this, and from the other applications in our pipeline, to put together a deal with a major biopharmaceutical company following the release of data from the ACESO study," said Racamier. "Our platform will be valuable for biopharmaceutical companies already working in gastroenterology, immunology or oncology, as well as for contract manufacturers."

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