

## **Salvat Laboratories announces submission of New Drug Application to the U.S. FDA for Clobetasol Nanoemulsion for treating inflammation and pain after ocular surgery**

**October 2022** - [Salvat Laboratories](#), the international company which developed and owns the globally commercialized products Otovel and Cetraxal, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the approval of the first ocular corticosteroid formulated in a nanoemulsion for inflammation and pain in post-ocular surgery patients.

### **Clinical Trials**

This submission comes after two successful phase III clinical trials conducted between 2020 and 2021. This new and pioneering corticosteroid in ophthalmology, clobetasol, was tested in more than 400 patients in the United States in over 40 different specialized centers, demonstrating the efficacy and safety of this innovative approach. Read more about the clinical trials [here](#)

### **Innovation in the Industry**

Salvat has developed IMPACT-SVT®, a patented nanoemulsion drug delivery technology that improves drug penetration and bio-adhesion, providing excellent comfort.

IMPACT-SVT® made it possible to develop SVT-15473 using clobetasol; this “superpotent” corticosteroid has never been used before as eye drops. Its presentation in single-dose vials offers **superior advantages** over other established alternatives that are readily available. In addition to its **efficacy and safety**, clinical trials have shown that it has very low impact on intraocular pressure, unlike many other corticosteroids.

After a standard 14-day course of treatment, the therapy has proven to have no rebound effect in the following 2 weeks, hence it **doesn't require a gradual decrease in dosage towards the end of treatment**. There is no need to shake the product before use, as the nanoemulsion ensures even drug concentration in every drop. Our exclusive nanoemulsion formulation (emulsion with drops of nanometric size) provides additional comfort to the patient. It also features better coverage of the ocular surface, **more effective absorption, and no blurred vision or discomfort after application**.

Designed with Blow-Fill-Seal technology, an advanced, sterile, and automated single-dose vials manufacturing system, the new drug will be produced on the manufacturing line of **Salvat USA Inc.** in Miami (Florida), and at Salvat's manufacturing site **Pharmaloop S.L.** in Alcalá de Henares (Madrid).

### **Significance for Salvat Laboratories**

Salvat Laboratories has invested over 20 million euros into this project, and this NDA submission is a big step in its goal of becoming a key player in ophthalmology. This is a great achievement for the company: “I am beyond thrilled to have submitted our FDA application for the future launch of this new corticosteroid. Once authorized, post-ocular surgery patients will see their treatment improve significantly. Additionally, the rest of the projects that are currently underway reinforce our ophthalmology line as one of our main areas of research and development and **strengthen the company's strategy to position itself as one of the main players in the field of ophthalmology worldwide in the coming years.**” says Alberto Bueno, Salvat's CEO.

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**Salvat Laboratories**

Since its founding in 1955, **Salvat Laboratories**, an independent privately held company owned by the Peris family, has been working to improve people's quality of life through innovation and the development of medicines and healthcare products with high added value.

**Salvat**, with its own sales structure in Spain and Portugal and commercial partners throughout the rest of the world, has a subsidiary in the United States, **Salvat USA, Inc.**, through which it manages its international expansion.

**Salvat's** growing production capacity includes a sterile liquid production line (BFS) located in the USA to supply the American market, and the expansion of its subsidiary Pharmalooop, to service the rest of the world.

**Salvat** currently distributes its drugs in more than 60 countries and is in the process of registering in 30 more.

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