The Victus Receives Clearance for Enhanced Patient Interface Kit

The Victus Femtosecond Laser Platform (Bausch + Lomb) has received 510(k) clearance from the FDA for an enhanced patient interface kit, according to a news release. The interface features a smaller-diameter suction clip. The modification reportedly allows easier opening and closing of the clip to help facilitate more efficient placement in patients with narrow fissures and smaller eye openings.

Additional features of the enhanced patient interface kit, which is intended to improve the performance of the suction ring as well as laser operation function, include a colored skirt on the suction clip to assist surgeons in achieving optimal centration to avoid tilt and optimize the inner working diameter of the suction ring. Multiple suction ports along the inside of the ring were incorporated to assist surgeons in obtaining optimal control of the eye throughout the Victus Femtosecond laser procedure. Also, an enhanced contoured handle gives surgeons a comfortable grip and improved control of the suction clip, including an easy lock/unlock feature.

Earlier this year, the Victus received 510(k) clearance from the FDA for an advanced swept source optical coherence tomography imaging system and updated software that allows customized treatment planning for improved efficiency and patient flow during surgical procedures. The platform has additional CE Marks, including corneal incisions, penetrating keratoplasty, and the creation of intrastromal channel incisions for intracorneal ring segments.

Shire Acquires Foresight Biotherapeutics

Shire has acquired privately held Foresight Biotherapeutics for $300 million, according to a news release. With the acquisition, Shire gains the global rights to FST-100 (topical ophthalmic drops combining 0.6% povidone-iodine and 0.1% dexamethasone), a therapy in late-stage development for the treatment of infectious conjunctivitis. Shire will evaluate an appropriate regulatory filing strategy for additional markets outside the United States. If approved by regulatory agencies, FST-100 has the potential to become the first agent to treat both viral and bacterial conjunctivitis, the company said.

The phase 2 proof-of-concept efficacy and safety clinical trial program for FST-100 involved two studies in adenoviral conjunctivitis—one three-armed study and another two-armed pilot study. Although the two-armed study showed a trend toward efficacy, there were too few subjects testing positive for a viral presence for the study to deliver meaningful results, and the results were not statistically significant.

In the three-armed study, patients were randomized to receive FST-100, 0.6% povidone-iodine, or vehicle four times daily for 5 days. According to the company, patients treated with FST-100 showed a statistically significant improvement in rates of clinical cure and viral eradication versus vehicle at day 6 (30.6% vs 6.4%, \( P = .0033 \)). In the same trial, there was a trend toward clinical significance for FST-100 versus 0.6% povidone-iodine (30.6% vs 18.0%, \( P = .1432 \)). The most common treatment emergent adverse events were corneal infiltrates (19%), punctate keratitis (22.4%), and eyelid edema (12.1%).

The phase 2 clinical data formed the basis of a meeting with the FDA, in which Foresight Biotherapeutics discussed the path forward to conduct a phase 3 clinical development program for FST-100 as a potential treatment for adenoviral conjunctivitis. Upon close of the transaction, Shire will take responsibility for the final development and implementation for the phase 3 clinical program for FST-100, which will also include investigation for the treatment of bacterial conjunctivitis. Foresight Biotherapeutics conducted preclinical experiments evaluating the bacterial killing speed of FST-100 against pathogens that may cause bacterial conjunctivitis, and the resulting data reportedly support further exploration.

**PEARLS FROM THE DEEP**

By Cynthia Matossian, MD

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Cynthia Matossian, MD, is the founder and CEO of Matossian Eye Associates. She acknowledged no financial interest in Merchant Advocate. Dr. Matossian may be reached at cmatossian@matossianeye.com.