DEXYCU® (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

The company’s two most recently launched products both utilize sustained-release intracellular drug delivery systems that provide a strong value proposition for both physicians and patients,” says Nancy Luker, President and CEO of EyePoint Pharmaceuticals.

“Nobody should have to risk going blind because they don’t have access to vital medications,” says Luker.

“From a clinical standpoint, we feel that ophthalmology still has many opportunities for companies like ours because of the numerous unmet needs within the spectrum of subspecialties, such as ocular surface disease, chronic noninfectious uveitis, and retinal diseases. In other words, from anterior to posterior, we are interested in novel products across the spectrum of ophthalmological specialties.”

“YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.”

“Looking ahead, EyePoint is also envisioning ways their proprietary technologies might be utilized to intervene in the management of other ophthalmic diseases. EyePoint’s proprietary Duraset™ technology allows for the sustained-release delivery of small molecules for up to 3 years with a single injection. Similarly, the proprietary Verisome® Technology allows for sustained release of small molecules in a suspension that can release over 1 to 6 months with a single injection.”

“In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure. In rare cases, YUTIQ has been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Steroid-related Effects: Use of corticosteroids including YUTIQ® may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection. Risk of Implant Migration: Patients in whom the posterior capsule of the lens is absent or has a tear at risk of implant migration into the anterior chamber.”

In summary, YUTIQ provides an opportunity to help physicians and patients address unmet needs in the marketplace.

“From anterior to posterior, we are interested in novel products across the spectrum of ophthalmology specialties.”

Dario Paggianino, MD, Senior Vice President and Chief Medical Officer of EyePoint, who has been with the company through its rebranding, says this move will certainly allow EyePoint to have more movement within the space.

“Previously, the company was about creating innovative technology but allowing other people to handle the commercialization,” says Paggianino. “But, our transformation to become a fully-flagged commercial company, while still retaining that R&D commitment, will allow us to further leverage the two drug-delivery technologies that we already have while also being committed to a progressive future.”

Looking ahead, EyePoint is also envisioning ways their proprietary technologies might be utilized to intervene in the management of other ophthalmic diseases. EyePoint’s proprietary Duraset™ technology allows for the sustained-release delivery of small molecules for up to 3 years with a single injection. Similarly, the proprietary Verisome® Technology allows for sustained release of small molecules in a suspension that can release over 1 to 6 months with a single injection. Utilizing these breakthrough technologies, the company is focused on finding new ways to make our first-in-class drug-delivery technologies fit within the overall profile of focusing on large disease states with unmet needs and considering innovative ways to better manage these diseases, says Jones. “But we are also actively looking for other products that will fit within our pipeline, as well as other technologies that may allow us to bring to market other trailblazing products.”

Paggianino agrees that EyePoint remains open to leading the way in the future. “We are committed to ophthalmology in two ways,” adds Paggianino. “First, we are committed with our commercial profile of focusing on large disease states with unmet needs. Second, we are open to developing new products that are innovative and important to physicians and patients because they solve an unmet medical need.”

Paggianino believes that this could take the company in many exciting directions going forward. “From a clinical standpoint, we feel that ophthalmology still has many opportunities for companies like ours because of the numerous unmet needs within the spectrum of subspecialties, such as ocular surface disease, chronic non-infectious uveitis, and retinal diseases. In other words, from anterior to posterior, we are interested in novel products across the spectrum of ophthalmic specialties.”

INDICATIONS AND USAGE

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

INCREASING DRUG DELIVERY OPTIONS TO MEET URGENT NEEDS

Looking ahead, EyePoint is also envisioning ways their proprietary technologies might be utilized to address unmet needs in the spectrum of ophthalmic diseases.
6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The following adverse events rates are derived from three clinical trials in which 339 patients received the 0.17 microgram dose of DEXYCU. The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and infs. Other adverse reactions occurring in 1-5% of subjects included: corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, visual field defect, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia, and anaphylactic reaction.

6.2 Lactation

Systematically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. There is no information regarding the presence of injected DEXYCU in human milk, the effects on breastfed infants, or the effects on milk production to inform risks of DEXYCU to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for DEXYCU and any potential adverse effects on the breastfed child from DEXYCU.

6.3 Cataract Progression

Corticosteroids in phakic patients may promote the development of posterior subcapsular cataracts.

6.4 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

• Infection Exacerbation
• Increase in Intraocular Pressure

The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts.

1. Includes cataract, cataract subcapsular and cataractous opacities in study eyes that were phakic at baseline. 113 of the 226 YUTIQ study eyes were phakic at baseline; 56 of 94 sham-controlled study eyes were phakic at baseline.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids including YUTIQ include cataract formation and subsequent cataract surgery, elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, secondary open-angle glaucoma, pathologies including herpes simplex, and perforation of the globe associated with infectious agents. Studies 1 and 2 were multicenter, randomized, sham-controlled trials in which patients with non-infectious inflammatory diseases of the anterior segment of the eye were treated once with either YUTIQ or sham injection, and then received standard care for the duration of the study. Patients in study 2 were treated with YUTIQ or sham injection. Table 1 summarizes adverse reactions reported in ≥ 2% of subjects randomly assigned to YUTIQ or sham injection. Table 2 summarizes adverse reactions observed in ≥ 3% of patients for both treatments. Table 3 summarizes adverse reactions observed in ≥ 3% of patients for both treatments and for the two different applicators used in study 3.

5.3. Risk of Implant

Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

6. ADVERSE REACTIONS

6.1. Clinical Trials Experience

6.2. Lactation

6.3. Cataract Progression

6.4. ADVERSE REACTIONS

ADVERSE REACTIONS

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

<table>
<thead>
<tr>
<th></th>
<th>YUTIQ (≥226 Eyes)</th>
<th>YUTIQ (N=94 Eyes)</th>
<th>Sham Injection (N=214 Eyes)</th>
<th>Sham Injection (N=94 Eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunctival Hyperemia</td>
<td>57 (25%)</td>
<td>37 (21%)</td>
<td>7 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Eye Pruritus</td>
<td>66 (30%)</td>
<td>27 (15%)</td>
<td>19 (9%)</td>
<td>10 (6%)</td>
</tr>
<tr>
<td>Vitreous Floaters</td>
<td>64 (29%)</td>
<td>23 (13%)</td>
<td>20 (9%)</td>
<td>8 (5%)</td>
</tr>
<tr>
<td>Vitreous Haze</td>
<td>74 (33%)</td>
<td>19 (11%)</td>
<td>3 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Posterior Capsule Opacification</td>
<td>63 (29%)</td>
<td>20 (11%)</td>
<td>14 (7%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>75 (34%)</td>
<td>15 (9%)</td>
<td>21 (10%)</td>
<td>7 (4%)</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>132 (60%)</td>
<td>36 (20%)</td>
<td>23 (11%)</td>
<td>12 (7%)</td>
</tr>
<tr>
<td>Visual Acuity Reduced</td>
<td>141 (64%)</td>
<td>36 (20%)</td>
<td>21 (11%)</td>
<td>9 (5%)</td>
</tr>
</tbody>
</table>

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