

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

November 2020

NEW DRUG INFORMATION

- **Eysuvis™ (loteprednol etabonate 0.25%):** The U.S. Food and Drug Administration (FDA) approved Eysuvis for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease (DED). Approximately 80% of people living with DED suffer from episodic flares which Eysuvis is hoping to alleviate as the first short-term treatment for dry eye flares. The FDA granted approval to Eysuvis based on three Phase 3 trials that demonstrated significant improvements in both the signs and symptoms of DED. Statistical significance was observed in two of the three Phase 3 trials for the symptom endpoints of ocular discomfort severity in both the overall intent-to-treat (ITT) population and in a predefined subgroup of ITT patients with more severe ocular discomfort at baseline.¹ Eysuvis appears safe and well tolerated when dosed four times a day for two to four weeks. Kala expects to launch Eysuvis before year-end with pricing to follow.
- **Sesquient™ (fosphenytoin sodium for injection):** Sedor Pharmaceuticals' Sesquient was approved by the FDA for the treatment of status epilepticus (SE) in adults and pediatric patients. Sesquient is ready to dilute and is stable at room temperature, making it efficient for administration in emergency rooms, intensive care units, first responder vehicles and long-term care facilities where serial seizures are most commonly treated.² Benzodiazepines are first-line treatment for SE, however 33% of patients experience benzodiazepine-refractory SE for which Parke Davis' Cerebryx® (fosphenytoin) or Sesquient are the only FDA-approved treatments.³ Unlike Sesquient, Cerebryx requires refrigerated storage which can create a delay in treatment for patients in need. Launch and pricing are pending.
- **Sutab® (sodium sulfate, magnesium sulfate, and potassium chloride) tablets:** Sebela Pharmaceuticals has received FDA approval for Sutab for colonoscopy preparation, as an alternative to liquid-based colonoscopy solution. Sutab is an osmotic laxative. Patients instructed to take Sutab may consume a low residue breakfast followed by only clear liquids until post colonoscopy. The full colonoscopy preparation is administered as two doses of twelve oral tablets. Sutab was submitted through the 505(b)(2) pathway using Braintree's Suprep® Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution as a reference product. Sutab was approved based on two pivotal trials that demonstrated 92% of patients achieved successful bowel cleansing with Sutab. Additionally, 91% of Sutab treated patients when surveyed rated Sutab as very easy to tolerable to consume.⁴ Sutab launch and price are pending.

GENERIC DRUG INFORMATION

- **Vascepa® (iscosapent cap):** Hikma launched their generic version of Amarin's Vascepa for the treatment of hypertriglyceridemia or dyslipidemia. Hikma forfeited its eligibility for 180-day marketing exclusivity. Multiple manufacturers are set to launch in 2020. Vascepa generated \$847 million in U.S. annual sales in 2019.
- **Banzel® (rufinamide oral susp):** Hikma launched their generic version of Eisai's Banzel for the treatment of seizures associated with Lennox-Gastaut syndrome. Hikma forfeited its eligibility for 180-day marketing exclusivity. Banzel oral suspension generated \$112 million in U.S. annual sales in 2019.
- **Timoptic® Ocudose ophth soln (timolol pf ophth soln 0.5%):** Akorn has launched their generic version of Bausch Health's Timoptic Ocudose for treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Timoptic Ocudose U.S. annual sales in 2019 are unknown.
- **Taytulla® (norethindrone/ethinyl estradiol/fe cap, 1mg-20mcg):** Xiromed has launched their generic version of Allergan's Taytulla, as an oral contraceptive for pregnancy prevention. There are no longer any regulatory exclusivities for Taytulla. Taytulla generated \$178 million in U.S. annual sales in 2019.

*Specialty medication

REFERENCES

1. <https://www.biospace.com/article/releases/kala-pharmaceuticals-announces-fda-approval-of-eyusvis-for-the-short-term-treatment-of-the-signs-and-symptoms-of-dry-eye-disease/>
2. <https://www.biospace.com/article/releases/sedor-pharmaceuticals-receives-fda-approval-for-sesquient-fosphenytoin-sodium-for-the-treatment-of-status-epilepticus-in-adult-and-pediatric-patients/>
3. <https://www.neurologylive.com/view/sesquient-approved-for-treatment-of-adult-and-pediatric-status-epilepticus>
4. <https://www.pharmacytimes.com/news/fda-approves-sutab-tablets-for-colonoscopy-preparation#:~:text=Sebela%20Pharmaceuticals%20has%20received%20FDA,preparation%20for%20colonoscopy%20in%20adults.>

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