Dexycu™ (dexamethasone intraocular suspension) – New drug approval

- On February 9, 2018, the FDA approved Icon Bioscience's Dexycu (dexamethasone intraocular suspension), for the treatment of postoperative inflammation.

- In the U.S., over 4 million cataract surgeries are performed per year.

- Dexycu is the first long-acting intraocular product approved to treat inflammation after cataract surgery.

- The efficacy of Dexycu was demonstrated in a placebo-controlled study enrolling 394 patients. Patients received an intraocular dose of 517 mcg, 342 mcg, or placebo administered by a physician at the end of surgery. The primary endpoint was the proportion of patients with anterior chamber cell clearing on postoperative day 8.

    — The percentage of patients meeting the primary endpoint was 20% in the placebo group, and 57% (difference: 37% [97.5% CI: 24%, 50%]) and 60% (difference: 40% [97.5% CI: 27%, 54%]) in the 342 and 517 mcg treatment groups, respectively.
    — In addition, the percentage of patients receiving rescue medication of ocular steroid or a nonsteroidal antiinflammatory drug was significantly lower at day 3, 8, 15 and 30 in the 342 and 517 mcg treatment groups vs. placebo.

- Warnings and precautions of Dexycu include increase in intraocular pressure, delayed healing, exacerbation of infection, and cataract progression.

- The most common adverse reactions (5 - 15%) reported with Dexycu use were increased intraocular pressure, corneal edema and iritis.

- The recommended dosage of Dexycu is 0.005 mL of dexamethasone 9% (equivalent to 517 mcg) administered as a single dose, intraocularly in the posterior chamber at the end of surgery.

- Icon Bioscience's launch plans for Dexycu are pending. Dexycu will be available as a 9% intraocular suspension equivalent to dexamethasone 103.4 mg/mL in a single-dose vial provided in a kit.