Xelpros™ (latanoprost ophthalmic emulsion) – New formulation approval

- On September 14, 2018, Sun Pharma announced the FDA approval of Xelpros (latanoprost ophthalmic emulsion), for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension.

- Xelpros is the first benzalkonium chloride (BAK)-free formulation of latanoprost. BAK is a preservative commonly used in topical ocular preparations.

    - Xelpros was developed using proprietary Swollen Micelle Microemulsion (SMM) technology.
    - A BAK-containing ophthalmic solution formulation of latanoprost is available generically.

- Latanoprost is a prostaglandin analogue that is used as first-line treatment for OAG or ocular hypertension. Latanoprost is believed to reduce IOP by increasing the outflow of aqueous humor.

- In randomized, controlled clinical trials of patients with OAG or ocular hypertension with mean baseline IOP of 23 to 26 mmHg, the mean IOP-lowering effect of Xelpros administered once daily in the evening was up to 6 to 8 mmHg.

- Xelpros is contraindicated in patients with known hypersensitivity to latanoprost, or any other ingredients in the product.

- Warnings and precautions of Xelpros include pigmentation; eyelash changes; intraocular inflammation; macular edema; herpetic keratitis; bacterial keratitis; and use with contact lenses.

- The most common ocular adverse reactions (≥ 5%) with Xelpros use were eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening.

- The recommended dose of Xelpros is one drop in the affected eye(s) once daily in the evening.

- Sun Pharma's launch plans for Xelpros are pending. Xelpros will be available as an ophthalmic emulsion containing latanoprost 50 mcg/mL (0.005%).