Eskata™ (hydrogen peroxide) – New drug approval

- On December 15, 2017, Aclaris Therapeutics announced the FDA approval of Eskata (hydrogen peroxide) for the treatment of seborrheic keratoses (SK) that are raised.

- SKs are non-cancerous skin growths affecting more than 83 million Americans. SKs are often elevated, waxy, or scaly in appearance and vary in color and size, from a millimeter to a few centimeters in width.

- The approval of Eskata was based on two vehicle-controlled trials involving 937 patients with 4 clinically typical SK lesions. In these trials, patients received up to 2 treatments with Eskata. The primary endpoint was the proportion of subjects that became clear of their lesions by day 106.

    — Across both trials, more patients treated with Eskata became clear of all 4 lesions vs. vehicle (4% – 8% vs. 0%).
    — In addition, more Eskata-treated patients were clear in at least 3 out of 4 lesions vs. vehicle (13% – 23% vs. 0%).

- Warnings and precautions of Eskata include eye disorders and local skin reactions.
- Common adverse reactions with Eskata use were erythema (99%), stinging (97%), edema (91%), scaling (90%), crusting (81%), and pruritus (58%).

- During a single in-office treatment session, Eskata should be applied to SK lesions four times, approximately 1 minute apart. After one use, the unit dose applicator should be discarded.

    — If the treated lesions have not completely cleared approximately 3 weeks after treatment, another treatment may be administered following the same procedure.
    — Eskata is to be administered by a health care provider and for topical use only. It is not for oral, ophthalmic, or intravaginal use.
    — Eskata should not be applied to open or infected SK.

- Aclaris Therapeutics plans to launch Eskata in the spring of 2018. Eskata will be available as a 40% (w/w) topical solution in a unit dose package.