Ycanth™ (cantharidin) – New drug approval

- On July 21, 2023, Verrica Pharmaceuticals announced the FDA approval of Ycanth (cantharidin), for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

- Molluscum is a highly contagious viral skin disease that affects approximately six million people, primarily children, in the U.S. Molluscum is caused by a pox virus that produces distinctive raised, skin-toned-to-pink-colored lesions that can cause pain, inflammation, itching and bacterial infection.

    — Without treatment, molluscum can last for an average of 13 months, and in some cases, up to several years.

- Ycanth is a proprietary drug-device combination product that contains a formulation of cantharidin delivered via a single-use applicator. The mechanism of action of cantharidin in the treatment of molluscum contagiosum is unknown.

    — Ycanth is the first and only FDA-approved treatment for molluscum contagiosum.

- The efficacy of Ycanth was established in two double-blind, randomized, placebo-controlled trials in 528 patients ages 2 years and older with molluscum contagiosum. Patients' lesions were treated with either Ycanth or vehicle at intervals of approximately 21 days until complete clearance of the lesion or for a maximum of 4 applications (on days 1, 21, 42, and 63). The primary endpoint was the proportion of patients achieving complete clearance of all treated molluscum contagiosum lesions by day 84.

    — In study 1, complete clearance at day 84 was achieved in 46% and 18% of patients with Ycanth and vehicle, respectively (treatment difference 29, 95% CI: 19, 38).
    — In study 2, complete clearance at day 84 was achieved in 54% and 13% of patients with Ycanth and vehicle, respectively (treatment difference 40, 95% CI: 30, 51).

- Warnings and precautions for Ycanth include toxicities associated with inappropriate administration, local skin reactions, and flammability.

- The most common adverse reactions (≥ 1%) with Ycanth use were local skin reactions at the application site: vesiculation, pain, pruritus, scabbing, erythema, discoloration, application site dryness, edema, and erosion.

- Ycanth is applied as a single application directly to each lesion every 3 weeks as needed. More than two applicators should not be used during a single treatment session.

    — All healthcare professionals should receive instruction and training prior to preparation and administration of Ycanth.

- Verrica Pharmaceuticals plans to launch Ycanth by September 2023. Ycanth will be available as a 0.7% topical solution.