Zelsuvmi™ (berdazimer) – New drug approval

- On January 5, 2024, Ligand Pharmaceuticals announced the FDA approval of Zelsuvmi (berdazimer), for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients one year of age and older.

- MC is a highly contagious viral skin infection characterized by skin-colored to red lesions. Approximately 6 million Americans, primarily children, are infected each year.

    — Treating the lesions is critical to preventing the viral infection from spreading to other people or to other areas of the body.

- Zelsuvmi is a nitric oxide releasing agent. Although the mechanism of action of Zelsuvmi is unknown, nitric oxide has been shown to have antiviral properties.

- The efficacy of Zelsuvmi was established in three randomized, double-blind, vehicle-controlled studies in 1,598 patients with MC. Patients received Zelsuvmi or placebo applied to the lesions once daily for up to 12 weeks. The primary endpoint for all studies was the proportion of patients achieving complete clearance at week 12.

    — Efficacy was demonstrated in studies 1 and 2. See chart below.
    — In study 3, the complete clearance rates at week 12 were 26% vs. 22% for Zelsuvmi and vehicle, respectively, with 95% CI: -5, 14.