Sernivo™ (betamethasone dipropionate) – New Drug Approval

- On February 8, 2016, Promius Pharma announced the FDA approval of Sernivo (betamethasone dipropionate) spray, for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older.

- Betamethasone dipropionate is generically available as a topical cream, lotion, ointment, and gel, for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Betamethasone dipropionate is also available in combination with calcipotriene, for the topical treatment of psoriasis vulgaris in adults 18 years of age and older for up to 4 weeks.

- The efficacy and safety of Sernivo were based on two randomized, double-blind, vehicle-controlled studies in adults with moderate plaque psoriasis. The primary endpoint was treatment success, defined as clear or almost clear of symptoms based on the Investigator Global Assessment score and at least a 2-grade reduction from baseline.
  - After 28 days of treatment, more patients achieved treatment success with Sernivo compared to those in the vehicle group (study 1: 42.7% vs. 11.7%, p < 0.001; study 2: 34.5% vs. 13.6%, p < 0.001).
  - Greater treatment success with Sernivo vs. vehicle was also evident at day 15 (study 1: 21.5% vs. 7.4%; study 2: 19% vs. 2.3%).

- Warnings and precautions of Sernivo include hypothalamic-pituitary-adrenal axis suppression and other unwanted systemic glucocorticoid effects, and allergic contact dermatitis.

- The most common adverse events (≥ 1%) with Sernivo use were application site reactions, including pruritus, burning and/or stinging, pain, and atrophy.

- Sernivo is recommended as a twice daily topical application to the affected skin areas.
  - Use Sernivo for up to 4 weeks, but no longer than 4 weeks.
  - Avoid Sernivo use on the face, scalp, axilla, groin, or other intertriginous areas.

- Promius Pharma plans to launch Sernivo in the coming quarter. Sernivo will be available as a 0.05% (equivalent to 0.5 mg of betamethasone per gram) topical spray in 60 mL and 120 mL bottles.