Impoz™ (clobetasol propionate) – New drug approval

- On November 28, 2017, the FDA approved Promius Pharma’s Impoz (clobetasol propionate) 0.025% cream, for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

- Clobetasol propionate is also available generically as a 0.05% cream, 0.05% emollient cream, 0.05% foam, 0.05% gel, 0.05% liquid spray, 0.05% lotion, 0.05% ointment, 0.05% shampoo, and 0.05% solution.
  - Refer to individual drug labels for indication information.

- The approval of Impoz was based on two vehicle-controlled studies evaluating 532 patients ≥ 18 years with moderate to severe plaque psoriasis. The primary endpoint was the proportion of subjects who achieved treatment success at day 15.
  - In study 1, 30.2% of Impoz-treated patients achieved the primary endpoint vs. 9.0% of vehicle-treated patients.
  - In study 2, 30.1% of Impoz-treated patients achieved the primary endpoint vs. 9.7% of vehicle-treated patients.

- Warnings and precautions of Impoz include effects on the endocrine system, local adverse reactions, concomitant skin infections, and allergic contact dermatitis.

- The most common adverse reaction (≥ 1%) with Impoz use was application site discoloration.

- Impoz should be applied as a thin layer to the affected skin areas twice daily and rubbed in gently and completely.
  - Impoz may be used for up to two consecutive weeks.
  - The total dosage should not exceed 50 grams/week.
  - Do not use on the face, scalp, axilla, groin, or other intertriginous areas.

- Promius Pharma’s launch plans for Impoz are pending. Impoz will be available as a 0.025% cream in 60 g and 112 g tubes.