## Eucrisa™ (crisaborole) – New Drug Approval

- On December 14, 2016, the FDA announced the approval of Pfizer's Eucrisa (crisaborole) ointment, for topical treatment of mild to moderate atopic dermatitis (AD) in patients 2 years of age and older.

- AD is a chronic, inflammatory skin condition. It is the most common form of eczema and affects an estimated 18 million children and adults in the U.S. Approximately 90% of people living with AD have the mild to moderate form of the disease.

    - In AD, the skin develops red, scaly and crusted bumps, which are extremely itchy. Scratching leads to swelling, cracking, "weeping" clear fluid, and eventual coarsening and thickening of the skin.
    - The onset of AD typically begins in childhood and can last through adulthood.
    - The cause of AD is a combination of genetic, immune, and environmental factors.

- Eucrisa contains crisaborole, a non-steroidal, topical agent that inhibits the phosphodiesterase-4 (PDE-4) enzyme. Overactive PDE-4 has been shown to contribute to the signs and symptoms of AD.

- The safety and efficacy of Eucrisa were based on two vehicle-controlled trials involving 1,522 patients with mild to moderate AD. The primary endpoint was the proportion of subjects at day 29 who were clear or almost clear with ≥ 2-grade improvement from baseline.

    - Overall, more patients receiving Eucrisa achieved the primary endpoint compared to vehicle (31.4% - 32.8% vs. 18.0% - 25.4%)

- Warnings and precautions of Eucrisa include hypersensitivity reactions.

- The most common adverse event (≥ 1%) with Eucrisa use was application site pain.

- The recommended dose of Eucrisa is a thin layer to affected areas twice daily.

    - Eucrisa is for topical use only and not for ophthalmic, oral, or intravaginal use.

- Pfizer plans to launch Eucrisa in late January 2017. Eucrisa will be available as a 2% topical ointment.