Cibinqo® (abrocitinib) – Expanded indication

- On February 10, 2023, Pfizer announced the FDA approval of Cibinqo (abrocitinib), for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
    - Cibinqo was previously approved for this indication in adults only.
    - Cibinqo is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressants.
- The approval of Cibinqo for the expanded indication was based on Trial-AD-4, a randomized, double-blind, placebo-controlled study in 284 patients who were 12 to less than 18 years of age with moderate-to-severe atopic dermatitis. Patients received background topical corticosteroids and once daily Cibinqo 100 mg, Cibinqo 200 mg, or placebo. The co-primary endpoints were Investigator's Global Assessment (IGA) and Eczema Area and Severity Index (EASI)-75 responses at week 12.
    - The IGA response rates were 39% with Cibinqo 100 mg, 46% with Cibinqo 200 mg, and 24% with placebo.
    - The EASI-75 response rates were 64% with Cibinqo 100 mg, 71% with Cibinqo 200 mg, and 41% with placebo.
- Cibinqo carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The recommended dosage of Cibinqo is 100 mg orally once daily. If an adequate response is not achieved with Cibinqo 100 mg orally daily after 12 weeks, increasing dosage to 200 mg orally once daily can be considered. If inadequate response is seen after dosage increase to 200 mg once daily, therapy should be discontinued.