Cibinqo® (abrocitinib) – New drug approval

- On January 14, 2022, Pfizer announced the FDA approval of Cibinqo (abrocitinib), for the treatment of adults with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

    — Cibinqo is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressants.

- Cibinqo is a JAK inhibitor. Inhibition of JAK1 is thought to modulate multiple cytokines involved in pathophysiology of AD.

- Cibinqo and AbbVie's Rinvoq® (upadacitinib) are the only oral JAK inhibitors approved for AD. However, the FDA is also reviewing Eli Lilly's Olumiant® (baricitinib) for this use.

- The efficacy of Cibinqo was established in three randomized, double-blind studies in 1,615 patients 12 years of age and older (Cibinqo is not approved for use in pediatric patients) with moderate-to-severe AD. Patients had inadequate response to previous topical therapy, or were patients for whom topical treatments were medically inadvisable, or who had received systemic therapies including Dupixent® (dupilumab). Studies AD-1 and AD-2 were monotherapy studies and in Study AD-3 patients received concomitant topical corticosteroids (TCS). The studies evaluated the co-primary endpoints of the proportion of patients with an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point improvement and the proportion of patients with Eczema Area and Severity Index (EASI)-75 (improvement of at least 75% in EASI score from baseline) at week 12.

    — Across the three studies, Cibinqo (100 mg and 200 mg) monotherapy and with TCS met all primary endpoints at week 12. Results are provided in the tables below.

Monotherapy studies:

	Study AD-1			Study AD-2		
	Placebo	**Cibinqo 100 mg**	**Cibinqo 200 mg**	**Placebo**	**Cibinqo 100 mg**	**Cibinqo 200 mg**
IGA response	8%	24%	44%	9%	28%	38%
Difference from placebo (95% CI)		16 (7, 25)	36 (26, 46)		19 (9, 29)	29 (19, 39)
EASI-75	12%	40%	62%	10%	44%	61%
Difference from placebo (95% CI)		28 (18, 39)	51 (40, 61)		33 (23, 44)	50 (40, 61)

Concomitant TCS study

	Study AD-3		
	Placebo + TCS	**Cibinqo 100 mg + TCS**	**Cibinqo 200 mg + TCS**
IGA response	14%	36%	47%

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Difference from placebo (95% CI)		23 (15, 31)	34 (25, 42)
EASI-75 Difference from placebo (95% CI)	27%	58% 32 (22, 41)	68% 41 (32, 51)

- Cibinqo carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.

- Cibinqo is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤ 81 mg daily), during the first 3 months of treatment.

- Additional warnings and precautions for Cibinqo include laboratory abnormalities and immunizations.

- The most common adverse reactions (≥ 1%) with Cibinqo 100 mg and 200 mg use were nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, and gastroenteritis. The most common adverse reactions (≥ 1%) in patients receiving either 100 mg or 200 mg also include impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

- The recommended dose 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 once daily can be considered. Therapy should be discontinued if inadequate response is seen after dosage increase to 200 mg once daily.

- Pfizer plans to launch Cibinqo in the coming weeks. Cibinqo will be available as 50 mg, 100 mg, and 200 mg tablets.
- uivalent to 7.5 mg of hydrocodone)/325 mg tablet.