Rinvoq® (upadacitinib) – New indication

- On January 14, 2022, AbbVie announced the FDA approval of Rinvoq (upadacitinib), for the treatment of adults and pediatric patients 12 years of age and older 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 are inadvisable.
    - Rinvoq is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressants.
- Rinvoq is also approved for the:
    - Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
    - Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- In addition to the new indication, the FDA approved an additional extended-release (ER) tablet strength of Rinvoq (30 mg). Previously, Rinvoq was available as a 15 mg ER tablet.
- The approval of Rinvoq for the new indication was based on three randomized, double-blind studies in a total of 2,584 patients (12 years of age and older) with moderate to severe AD not adequately controlled by topical medication(s). In all three studies, patients received Rinvoq once daily oral doses of 15 mg, 30 mg, or placebo for 16 weeks. In study AD-3, patients also received Rinvoq or placebo with concomitant topical corticosteroids (TCS). All three studies assessed the co-primary endpoints of the proportion of patients with a validated Investigator's Global Assessment (vIGA)-AD 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 16.
    - Across the three studies, Rinvoq (15 mg and 30 mg) monotherapy and with TCS met all primary endpoints at week 16. Results are provided in the tables below.
    - Additional pediatric data is further outlined in the drug label.

Monotherapy studies:

	Study AD-1			Study AD-2		
	Placebo	**Rinvoq 15 mg**	**Rinvoq 30 mg**	**Placebo**	**Rinvoq 15 mg**	**Rinvoq 30 mg**
vIGA-AD response	8%	48%	62%	5%	39%	52%
Difference from placebo (95% CI)		40 (33, 46)	54 (47, 60)		34 (28, 40)	47 (41, 54)
EASI-75	16%	70%	80%	13%	60%	73%
Difference from placebo (95% CI)		53 (46, 60)	63 (57, 70)		47 (40, 54)	60 (53, 66)

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Concomitant TCS study

	Study AD-3		
	Placebo + TCS	**Rinvoq 15 mg + TCS**	**Rinvoq 30 mg + TCS**
vIGA-AD response	11%	40%	59%
Difference from placebo (95% CI)		29 (22, 35)	48 (41, 54)
EASI-75	26%	65%	77%
Difference from placebo (95% CI)		38 (31, 45)	51 (44, 57)

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

- The most common adverse reactions (≥ 1%) with Rinvoq use for atopic dermatitis were upper respiratory tract infections, acne, herpes simplex, headache, increased blood creatine phosphokinase, cough, hypersensitivity, folliculitis, nausea, abdominal pain, pyrexia, increased weight, herpes zoster, influenza, fatigue, neutropenia, myalgia, and influenza like illness.

- In pediatric patients 12 years of age and older weighing at least 40 kg and adults less than 65 years of age, the recommended initial dose of Rinvoq for the treatment of atopic dermatitis is 15 mg orally once daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily.

    — Rinvoq should be discontinued if an adequate response is not achieved with the 30 mg dose. The lowest effective dose needed to maintain response should be used.

- For adults 65 years of age and older, the recommended dose of Rinvoq is 15 mg orally once daily.

- Refer to the Rinvoq drug label for dosing for its other indications.