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New label warnings raise hopes for Jak safety closure

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The full fallout from the FDA's safety review of the Jak inhibitors remains unknown, amid concerns about moves to curb these drugs' use drastically. But two label updates that emerged late Friday are raising hopes that draconian measures are off the table. Abbvie and Pfizer announced new boxed warnings for their respective products, Rinvoq and Xeljanz. These black boxes now highlight the higher rate of major adverse cardiac events seen versus anti-TNF agents in the Oral Surveillance trial of Xeljanz. As expected, both have also had rheumatoid arthritis indications scaled back, with patients required to have failed at least one TNF blocker. Analysts believe that Abbvie has come off as well as could be expected, with the label wording making it clear that the Mace signal was seen with "another Jak inhibitor", and no restrictions on duration of use; some were expecting harsher action from the regulator. Still, several approvals are pending for Rinvoq and others, and a tougher line in less life-limiting settings, like atopic dermatitis, cannot be ruled out. Whatever the outcome, the potential of these agents has surely already been curtailed, which was the probably the FDA's goal in the first place.

Safety fallout: decisions on the horizon that could be impacted

Product	Company	US and EU decisions due
Rinvoq	Abbvie	Atopic dermatitis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis remain under review in the US; EU approved in atopic dermatitis in Aug 2021
Abrocitinib/PF-04965842	Pfizer	Atopic dermatitis approval pending in the US (H1 2022); CHMP recommended EU approval in Oct 2021
Xeljanz (Jak 1, 2 & 3)	Pfizer	Ankylosing spondylitis approval pending in the US
Olumiant (Jak 1 & 2)	Lilly	Atopic dermatitis approval pending in the US
Deucravacitinib (Tyk2)	Bristol Myers Squibb	Mechanistically related to Jaks; US approval in psoriasis due by 10 Sep 2022

Source: Evaluate Omnium.

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