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Go or no go? UCB bids to make a mark in psoriasis

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Chemocentryx and Avadel will also see important FDA regulatory action this month, while Omeros gets another delay.

UCB's number-one growth driver, Bimzelx, will get its US regulatory decision this month in psoriasis, but even if it gets the nod it will be a late entrant. Meanwhile, Avadel's narcolepsy project FT218 will have to contend with a legal challenge from Jazz if it gets a green light.

Also, Chemocentryx will find out whether its filing amendment for avacopan is enough for approval, and Jaks from Pfizer, Lilly and Abbvie might finally get closure after numerous regulatory delays caused by a safety review of the class.

One company that will not get closure just yet is Omeros, which today said it had received a deficiency letter from the FDA, meaning that the October 17 Pdufa date for narsoplimab will be missed. Narsoplimab is intended to treat haematopoietic stem cell transplant-associated thrombotic microangiopathy. The review had already been extended once before, and today's setback has sent Omeros shares down 36% in early trading.

Fashionably late

Expected by October 15 is a decision for UCB's bimekizumab in psorasis, an incredibly crowded space. The anti-IL-17A and IL-17F MAb is already approved in Europe under the brand name Bimzelx.

It impressed in clinical studies, beating Novartis's Cosentyx and Abbvie's Humira in the Be Radiant and Be Sure studies respectively. The trade-off was an increase in oral candidiasis with Bimzelx.

On a cross-trial basis Bimzelx also looks better than a potential future rival, Bristol's oral Tyk2 inhibitor deucravacitinib, on Pasi-75.

Despite forecast psoriasis sales for Bimzelx nearing $1bn in 2026, the asset is not expected to make a huge dent in the market. Abbvie's anti-IL-23 MAb Skyrizi stands out as the sector leader with a huge $7.8bn expected in sales the same year, according to *Evaluate Pharma* consensus.

Data on Bimzelx in ankylosing spondylitis and psoriatic arthritis are due in the fourth quarter, and these uses could add another $837m revenues in 2026, consensus suggests.

Chemocentryx's time

October should see Chemocentryx finally getting a decision on avacopan in ANCA-associated vasculitis, a condition that leads to inflammation and destruction of small blood vessels.

The Pdufa had been set for July, but the company submitted a filing amendment in response to issues raised at a panel meeting. The delay, rather than an outright knockback, came as a lifeline for Chemocentryx.

The adcom featured questions over the design of the pivotal Advocate study and its multiple variables including steroid tapering, which panellists felt made the clinical data difficult to interpret. Heading into the new Pdufa, investors will cling to some recent good news: just this week avacopan received approval in Japan, where it is branded Tavneos.

Avadel versus Jazz

Avadel hopes to take on Jazz Pharmaceuticals with FT218, a project aimed at treating excessive daytime sleepiness in narcolepsy sufferers that could be more convenient than the incumbent's offering.

FT218 contains sodium oxybate, the same ingredient used in Jazz's Xyrem and the low-sodium follow-on Xywav; however, Avadel's asset is given once-nightly, versus Jazz's twice-nightly products. In terms of efficacy FT218 looks on a par with Xyrem, with slightly better safety.

In Avadel's Rest-On study there were statistically significant improvements over placebo at all doses on three co-primary endpoints: maintenance of wakefulness test; clinical global impression scale improvement; and mean weekly cataplexy attacks. Common adverse events included nausea, vomiting, headache, dizziness and enuresis.

Both Xyrem and Xywav come with a black box warning of respiratory depression, and their potential for misuse means that both have a restricted REMS programme. This is also a likely scenario for FT218.

Despite the restrictions, Xyrem and Xywav combined are forecast to bring in just over $1bn in narcolepsy sales by 2026, according to *Evaluate Pharma* consensus. Unsurprisingly, Jazz has started a lawsuit against Avadel that claims a number of patent infringements, with a tentative preliminary injunction hearing scheduled for November should Jazz file a motion.

Notable first-time US approval decisions due in October					
Project	**Company**	**PDUFA date**	**Indication(s)**	**2026e sales by indication ($m)**	**Note**
Vynpenta (avacopan)	Chemocentryx	Oct 7	ANCA-associated vasculitis	610	See text
Bimzelx (bimekizumab)	UCB	Oct 15	Plaque psoriasis	994	See text
FT218	Avadel	Oct 15	Narcolepsy	332	See text
OC-01	Oyster Point	Oct 17	Dry eye disease	-	Inhaled Chantix, 505(b)2 submission
Mydcombi	Eyenovia	Oct 28	Pupil dilation agent	28	To be used in eye exams
Xipere	Bausch Health/ Clearside	Oct 30	Macular oedema associated with uveitis	-	CRL in 2019 requesting stability data and for reinspection of the medicine's manufacturer
Kyzatrex	Marius	Oct 31	Primary and secondary male hypogonadism	-	Oral testosterone replacement
Cibinqo (abrocitinib)	Pfizer	Q4?	Atopic dermatitis	1,035	Timings to be confirmed; with the FDA's recent safety review of the class any approval may come with suboptimal dosing and black box warnings (*Jaks capped in arthritis – but the FDA might not be finished*)
Source: Evaluate Pharma & company releases.					

Advisory committee meetings in October					
Project	**Company**	**Adcom date**	**Indication**	**2026e sales by indication ($m)**	**Note**
Maribavir	Takeda	Oct 7	Adults with post-transplant cytomegalovirus infection/disease	354	Pdufa in November
Pepaxto	Oncopeptides	Oct 28	In combination with dexamethasone for the treatment of adults with r/r multiple myeloma who have received at least four prior lines of therapy	552	Has accelerated approval already but with controversies over confirmatory study (*End in sight for Oncopeptides' stormy Ocean voyage*)
Source: FDA & Evaluate Pharma.					

Supplementary and other notable approval decisions in October			
Product	**Company**	**Indication (clinical trial)**	**Date**
Tyvaso DPI	Mannkind/United Therapeutics	PAH and pulmonary hypertension associated with interstitial lung disease (Breeze)	Oct
Andexxa	Astrazeneca	Addition of edoxaban and enoxaparin (FXa inhibitors) to the label	Est Oct
Tecartus	Gilead	Adults with r/r ALL (Zuma-3)	Oct 1
Dextenza	Ocular Therapeutix	Ocular itching associated with allergic conjunctivitis	Oct 18
Dupixent	Sanofi/ Regeneron	Asthma in ages 6-11 (Voyage)	Oct 21
Lucentis port delivery system	Roche	Wet AMD (Archway)	Oct 23
Cortrophin Gel	ANI	Multiple sclerosis, rheumatoid arthritis and nephrotic syndrome	Oct 29
Xeljanz	Pfizer	Ankylosing spondylitis (A3921120)	Q4?
Olumiant	Lilly	Atopic dermatitis (Breeze-AD programme)	Q4?
Rinvoq	Abbvie	Atopic dermatitis, psoriatic arthritis and ankylosing spondylitis	Q4?
Source: Evaluate Pharma & company releases.			