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Go or no go? Ardelyx and Chemocentryx among those waiting FDA decisions

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Big regulatory events for July include a panel for Fibrogen's roxadustat and decision time for Albireo; elsewhere, Jak inhibitor delays could persist.

A number of small biotechs are awaiting news on FDA approval in July, including Albireo and Chemocentryx, in a month that looks quiet on the regulatory front for larger developers. Fibrogen's anaemia pill will go under the spotlight at a panel meeting in mid July, a project that has been dogged by safety concerns.

Big pharma has an interest in the ongoing regulatory delays for the Jak inhibitor class, however, where decisions on four projects are pegged for early in the third quarter. FDA opinions for Rinvoq, Olumiant, abrocitinib and Xeljanz are all due, from Abbvie, Eli Lilly and Pfizer, but with a safety review ongoing timings are hard to know.

Jak delay

Last week the Pdufas for Abbvie's Jak inhibitor Rinvoq in psoriatic arthritis and ankylosing spondylitis were missed with no new date disclosed. Abbvie said that FDA is still reviewing Pfizer's post-marketing study, Oral Surveillance, that raised concerns about Xeljanz in rheumatoid arthritis and the class more broadly.

Xeljanz already has a black-box warning for thrombosis and malignancies and data from Oral Surveillance, released in January, failed to show that the Pfizer drug was non-inferior to a TNF inhibitor on rates of major adverse cardiovascular events and cancers.

It is not known when the FDA's review will conclude. Abbvie has much riding on Rinvoq's label expansion, and plans to file in ulcerative colitis before the end of the year. Maintenance data released this week raised no new safety issues.

Stay of play: upcoming regulatory decisions for Jak inhibitors				
Product	**Company**	**US decisions**	**EU decisions**	**2026 WW sales ($m, all indications)**
Rinvoq (Jak 1)	Abbvie	Atopic dermatitis: decision delayed from April to early Q3. June Pdufas in psoriatic arthritis and ankylosing spondylitis missed.	June: CHMP positive opinion in atopic dermatitis (adults at 15mg or 30mg and adolescents 15mg).	8,868
Xeljanz (Jak 1, 2 & 3)	Pfizer	Ankylosing spondylitis: decision delayed from Q2 to early Q3.	-	1,226
Olumiant (Jak 1 & 2)	Lilly	Atopic dermatitis: decision delayed from Q2 to early Q3.	-	1,103
Abrocitinib/ PF-04965842 (Jak 1)	Pfizer	Atopic dermatitis: decision delayed from April to early Q3.	EMA decision in atopic dermatitis expected H2 2021.	971
Jyseleca (Jak1)	Galapagos/ Gilead	Received CRL August 2020 in rheumatoid arthritis.	EMA decision in ulcerative colitis due H2 2021.	634
Sources: company releases, Evaluate Pharma.				

Reputation and rare diseases

Roxadustat's US advisory panel hearing is set for July 15, and a recent positive opinion in Europe could be considered encouraging. However, a previous admission of a major error in published data and the NDA filing means the FDA will be closely scrutinising the submission.

Fibrogen needs roxadustat to be approved with a broad label without a black box warning of potential cardiotoxicity. That is far from guaranteed, however *(Fibrogen stretches the bounds of credibility, April 7, 2021).*

Albireo, meanwhile, could have the first bile acid transporter inhibitor on the market in the US; approval of odevixibat is being sought in progressive familial intrahepatic cholestasis (PFIC), a rare paediatric liver disorder.

PFIC is characterised by the build-up of bile in the liver and is usually treated surgically by partial external biliary diversion or liver transplant. There are a number of different types of disease, each characterised by specific gene mutations. Type 2 makes up around half of cases.

Albireo's odevixibat aims to improve patients' quality of life, in phase 3 odevixibat met both co-primary endpoints; the change in pruritus, and bile acid reduction in type 1 and 2 patients *(Albireo sets the standard for Mirum to hit, September 8, 2020).*

The ultimate goal is to prevent liver transplants, but it is too soon to know whether odevixibat can contribute to that outcome.

The table below lists first-time US approvals and advisory meetings due next month, with consensus forecasts from *Evaluate Pharma.*

Notable first-time US approval decisions due in July					
Project	**Company**	**PDUFA date**	**Indication(s)**	**2026e sales by indication ($m)**	**Note**

Notable first-time US approval decisions due in July				($m)	
Finerenone	Bayer	Est July	CKD and type 2 diabetes.	899	Filed in US on basis of ph3 Fidelio-DKD study, but could struggle commercially *(Bayer faces an uphill fight with finerenone).*
Teplizumab	Provention Bio	July 2	Delay or prevention of type 1 diabetes in at-risk individuals.	-	Adcom voted in favour of approving teplizumab, however the FDA had concerns about pharmacokinetic inconsistencies *(Provention's diabetes project takes a tentative step forward).*
Vynpenta	Chemocentryx	July 7	ANCA-associated vasculitis.	639	FDA adcom split 9-9 on whether efficacy data support approval *(Chemocentryx's future in doubt as avacopan foundation crumbles).*
V114	Merck/Ligand	July 18	Pneumococcal infection vaccine (adults).	786	Pfizer gained US approval of Prevnar 20 in adults in June. Readout and filing of V114 (15-valent) in paediatric populations expected by YE, competitor to Prevnar 13.
Bylvay (odevixibat)	Albireo	July 20	Progressive familial intrahepatic cholestasis.	297	See text.
Leukotac (inolimomab)	Gruppo Mediolanum farmaceutici	Est July 23	Acute steroid-resistant graft-vs.-host disease (SR-aGVHD).	-	Anti-IL-2 MAb.
Sulopenem etzadroxil/probenecid (oral sulopenem)	Iterum	July 25	uUTIs.	132	Adcom not needed, had been scheduled for June.
Retifanlimab	Incyte	July 25	Squamous cell carcinoma of the anal canal.	53	Adcom voted 13-4 for confirmatory study (No fast way to eighth place for Incyte).
Ibsrela (tenapanor)	Ardelyx	July 29	Control of serum phosphorus in adult patients with chronic kidney disease.	701	Extended from April, FDA asked for additional analyses to understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies.
Anifrolumab	Astrazeneca	H2	SLE	488	Mixed clinical data (Astrazeneca looks to power lupus effort over the finish line)
Source: Evaluate Pharma & company releases.					

Advisory committee meeting in July					
Project	**Company**	**Adcom date**	**Indication**	**2026e sales by indication ($m)**	**Note**
Evrenzo (roxadustat)	Astrazeneca/ Fibrogen/Astellas	July 15	Anaemia due to chronic kidney disease in adult patients not on dialysis and on dialysis.	2,551*	Recent positive opinion by European CHMP, in the US the company recently admitted presenting the wrong data, raising further doubts about roxadustat's safety *(EU thumbs up for roxadustat, but US panel approaches).*
**Total sales across all regions and partners. Source: Evaluate Pharma & FDA adcom calendar.*					

This article has been updated to include anifrolumab's Pdufa.