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Go or no go? Biogen and Astellas head towards key Pdufas



[Joanne Fagg](#)

Two of this year's [biggest FDA approval decisions](#) are due next month, that of Astellas's Zimura and Biogen/Sage's zuranolone. The latter is filed in major depressive disorder and postpartum depression and is expected to be approved. Zuranolone is forecast to be Biogen's biggest growth driver but questions remain on its commercial prospects given its short two-week course of therapy. Biogen needs to reinvigorate investor sentiment after announcing job cuts [on its recent second quarter call](#), today it disclosed a [hefty buyout of Reata](#). For Astellas, Zimura was gained through its \$5.9bn acquisition of Iveric Bio, and is intended to treat geographic atrophy. On a cross-trial basis Zimura, a complement factor C5 inhibitor, looks fairly similar to Apellis's approved Syfovre that targets C3. Syfovre got off to a strong launch in March but confidence in the therapy was knocked recently after six cases of retinal vasculitis were reported. The safety issue was not evident in clinical studies and could be related to manufacturing or delivery, noted TD Cowen analysts, leaving room for Zimura to pile on the pressure. More safety details are expected at this [weekend's American society of retina specialists meeting](#).

Notable first-time US approval decisions due in August 2023

Project	Company	Pdufa date	Indication(s)	2028e SBI (\$m)	Note
Ryoncil (remestemcel-L)	Mesoblast/ JCR Pharmaceuticals	2 Aug (resubmission)	Children with steroid-refractory acute graft versus host disease	223	Mesoblast can't catch a break
PDP-716 (0.35% brimonidine tartrate)	Visiox	4 Aug	Glaucoma	-	-
Zuranolone	Biogen/Sage	5 Aug	Major depressive disorder and postpartum depression	1,177	See text
Talvey (talquetamab)	J&J	Estimated 9 Aug	Relapsed or refractory multiple myeloma	300	Bispecific T-cell engager antibody targeting both GPRC5D and CD3
Avasopasem	Galera	9 Aug	Radiotherapy-induced severe oral mucositis	-	Selective dismutase mimetic
Hepzato kit	Delcath	14 Aug (resubmission)	Unresectable hepatic-dominant metastatic ocular melanoma	-	Previous CRL in 2013, after a negative adcom, needed another trial
Sohonos (palovarotene capsules)	Ipsen	16 Aug (resubmission)	Fibrodysplasia ossificans progressiva	-	After an earlier CRL received a positive adcom
Zimura	Astellas (Iveric Bio)	19 Aug	Geographic atrophy	1,179	See text
Pozelimab	Regeneron	20 Aug	Adults and children as young as 1 year of age with Chape disease	-	Subcutaneous anti-complement C5 antibody
Elranatamab	Pfizer	Estimated 22 Aug	Relapsed or refractory multiple myeloma	829	BCMA T-cell engager
Lytenava (ONS-5010)	Outlook	29 Aug	Wet AMD	590	Ophthalmic Avastin
VLA1553	Valneva	End of Aug	Single-shot chikungunya vaccine	333	Bavarian falls short of Valneva in Chikungunya
Tuoyi (toripalimab)	Coherus	Q3	Nasopharyngeal carcinoma	-	Previous inspection delays
Pombiliti + Opfolda	Amicus	Q3	Adults with late-onset Pompe disease	443	Previous inspection delays
Bimzelx	UCB	Q3 (resubmission)	Plaque psoriasis	937	Delayed from Q2 to Q3, previous CRL due to failed pre-approval inspections
Etrasimod	Pfizer	H2	Ulcerative colitis	825	S1P inhibitor, competitor to Bristol's Zeposia (Pfizer seeks to put etrasimod first)

SBI: sales by indication. Sources: Evaluate Pharma & company releases.

Supplementary and other notable approval decisions due in August 2023

Product	Company	Indication (clinical trial)	Date
Abrysvo	Pfizer	Prevention of (severe) lower respiratory tract disease caused by RSV in infants from birth through 6 months by active immunisation of pregnant individuals	Aug
Lonsurf	Taiho/Otsuka	Monotherapy or in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (Sunlight)	13 Aug
Daxxify	Revance	Cervical dystonia (Aspen-1 , Aspen OLS)	19 Aug
Ingrezza	Neurocrine	Chorea associated with Huntington disease (Kinect-HD , Kinect-HD2)	20 Aug
Reblozyl	Bristol	First-line treatment of anaemia in lower risk myelodysplastic syndromes	28 Aug
Jardiance	Lilly/Boehringer	Reduce the risk of kidney disease progression and cardiovascular death in adults with chronic kidney disease (Empa-Kidney)	Estimated Q3
AVT04 (Stelara biosimilar)	Alvotech/Teva	Inflammatory conditions	H2
Cosentyx	Novartis	Hidradenitis suppurativa (Sunshine , Sunrise)	H2
Intravenous Cosentyx	Novartis	Adult patients with psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis (Invigorate 1 , Invigorate 2)	H2

Sources: Evaluate Pharma & company releases.

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