

US FDA approval tracker: January 2021



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The first month of 2021 saw the approval of Aurinia's Lupkynis, one of the most [valuable launches of the year](#), according to sellside sales forecasts. The drug, indicated for use in lupus nephritis, is Aurinia's sole product, and with approval in the bag some believe that the [prospect of a takeover has increased](#). Other approvals of note include an early decision on Exelixis/Ipsen's Cabometyx in combination with Bristol Myers Squibb's Opdivo in first-line renal cell carcinoma, which could help [cement Opdivo as leader in the space by 2026](#). Elsewhere, Darzalex Faspro, the subcutaneous version of J&J/Genmab's anti-CD38 MAb, gained approval in patients with newly diagnosed light-chain (AL) amyloidosis. Jefferies analysts forecast \$2bn worldwide peak sales for Darzalex outside multiple myeloma, predominantly in amyloidosis. The other big regulatory news last month was a three-month delay to the FDA's decision on Biogen's Alzheimer's project aducanumab, a move that many interpreted positively and caused Biogen's shares to rise 5.5%.

Notable first-time US approval decisions in January

Project	Company	2026e sales by indication (\$m)	Outcome
Lupkynis (voclosporin)	Aurinia	1,092	Approved
Cabenuva (cabotegravir + rilpivirine)	GSK/J&J	681	Approved
Tepmetko (tepotinib)	Merck KGaA	492	No decision yet
Verquvo (vericiguat)	Merck/Bayer	389	Approved
Ansofaxine hydrochloride	Luye Pharma	-	No decision yet
Vocabria (oral cabotegravir)	Glaxosmithkline	-	Approved

Sources: EvaluatePharma & company releases.

Supplementary and other notable approval decisions in January

Product	Company	Indication (clinical trial)	Outcome
Xalkori	Pfizer	Paediatric patients with r/r systemic Alk-positive anaplastic large cell lymphoma (study ADVL0912 and A8081013)	Approved
Nplate	Amgen	Hematopoietic syndrome of acute radiation syndrome	Approved
Enhertu	Astrazeneca	Her2 +ve gastric or gastroesophageal junction (GEJ) adenocarcinoma (Destiny-Gastric01)	Approved
Xolair	Roche	Self-administration option across all approved US indications	No decision yet
Botox	Abbvie	Detrusor (bladder muscle) overactivity, paediatric patients	No decision yet
Estelle	Mithra	Prevent pregnancy	No decision yet
Darzalex Faspro	J&J/Genmab	AL amyloidosis (Andromeda , for use in combination with bortezomib, cyclophosphamide and dexamethasone)	Approved
Opdivo plus Cabometyx	Bristol/Exelixis	1L renal cell carcinoma (Checkmate-9ER)	Approved (~1 month early)

Sources: EvaluatePharma & company releases.

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