

US FDA approval tracker February



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Backed by a [positive panel meeting](#) Johnson & Johnson's JNJ-78436735 became the third Covid-19 vaccine granted US emergency use authorisation (EUA), but it is the first that requires only one dose. The company plans to deliver 100 million doses to the US during the first half of the year. An EUA was also granted to Lilly's bamlanivimab plus etesevimab after the antibody combo [significantly cut Covid-19-related hospitalisations and deaths](#) in studies. February saw Bristol Myers Squibb's Breyanzi become the third anti-CD19 Car-T therapy approved, and the [project's efficacy looks on a par with Gilead's Yescarta](#), with less toxicity. However, Breyanzi is even more expensive to manufacture than existing Car-T products. Novartis's Entresto gained approval in a broad heart failure population, but the group [will need to make the most of this before generic competition hits](#). And Athenex had a knockback for Oraxol, a combination of oral paclitaxel and encequidar, in metastatic breast cancer. The FDA cited toxicity concerns and requested another clinical study. The Pdufa was scheduled for the last day of February and the news, released today, knocked half a billion dollars off the company's market cap.

Notable first-time US approval decisions in February

| Project | Company | 2026e sales by indication (\$m) | Outcome |
|---|----------------------|---------------------------------|-------------------------------------|
| Breyanzi (liso-cel) | Bristol Myers Squibb | 1,096 | Approved |
| Oraxol (oral paclitaxel + encequidar) | Athenex | 781 | CRL |
| Cosela (trilaciclib) | G1 Therapeutics | 583 | Approved |
| Tepmetko (tepotinib) | Merck KGaA | 505 | Approved |
| Pepaxto (melphalan flufenamide/melflufen) | Oncopeptides | 490 | Approved |
| Ukoniq (umbralisib) | TG Therapeutics | 296 | Approved* |
| Defencath/Neutrolin | Cormedix | 230 | CRL |
| Amondys 45 (casimersen) | Sarepta | 202 | Approved |
| Posimir | Direct | 195 | Approved |
| StrataGraft | Mallinckrodt | 59 | Deferred (manufacturing inspection) |
| Nulibry (fosdenopterin) | Bridgebio | 29 | Approved |
| Evkeeza (evinacumab) | Sanofi/Regeneron | - | Approved |

*Gained approval in marginal zone lymphoma and follicular lymphoma. Sources: EvaluatePharma & company releases.

Advisory committee meetings in February

| Project | Company | 2026e sales by indication (\$m) | Outcome |
|----------|------------|---------------------------------|--|
| Keytruda | Merck & Co | 3,943* | Negative, 10-0 (neoadjuvant/adjuvant use in triple-negative breast cancer) |

*SBI includes the approved use in triple-negative breast cancer in combination with chemotherapy. Sources: EvaluatePharma & company releases.

FDA issued EUAs to treat Covid-19

| Project | Company | 2026e sales by indication (\$m) | Setting |
|----------------------------|-------------------|---------------------------------|---|
| Bamlanivimab + etesevimab | Lilly | 303 | Treatment of mild to moderate Covid-19 in adults and paediatric patients aged 12 and over |
| Ad26.COV2.S (JNJ-78436735) | Johnson & Johnson | _* | Prevention of Covid-19 (after positive adcom also in February) |

*Consensus not yet available. Sources: FDA.gov & EvaluatePharma

Supplementary and other notable approval decisions in February

| Product | Company | Indication (clinical trial) | Outcome |
|--------------------------|------------------|---|-----------------|
| Gocovri | Adamas | Off episodes in Parkinson's disease patients receiving levodopa-based therapy | Approved |
| Plegridy (intramuscular) | Biogen | Relapsing-remitting MS | Approved |
| Libtayo | Sanofi/Regeneron | NSCLC with $\geq 50\%$ PD-L1 expression (Empower-Lung-1) | Approved |
| Vazalore | Plx Pharma | Liquid-filled aspirin capsule (325mg and 81mg doses) | No decision yet |
| Entresto | Novartis | Heart failure with preserved ejection fraction (Paragon HF) | Approved |
| Rapivab | Biocryst | Acute uncomplicated influenza to include patients six months and older | Approved |
| Libtayo | Sanofi/Regeneron | Full approval in locally advanced basal cell carcinoma and accelerated approval in metastatic BCC (NCT03132636) | Approved |
| Panzyga | Pfizer | Chronic inflammatory demyelinating polyneuropathy (NCT02638207) | Approved |
| Humira | Abbvie | Paediatric patients with moderate to severe ulcerative colitis (Envision I) | Approved |

Sources: EvaluatePharma & company releases.

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