

## Another blockbuster year looms for approvals



[Amy Brown](#)



### **Biogen's Alzheimer's candidate and Fibrogen's new anaemia pill top the list of the biggest commercial hopes that could reach the market in 2020.**

Swift and sometimes surprising decisions from the US FDA kept biopharma on its toes last year, and it looks like 2020 will deliver its fair share of regulatory drama. *Vantage's* annual analysis of the biggest approvals on the horizon reveals several projects that have potential for delay and controversy, with lofty expectations already building in some quarters.

The table below is based on *EvaluatePharma's* sellside consensus, and lists the 10 top products up for approval this year, ranked on projected 2024 sales. Seven are forecast to breach the \$1bn threshold by this time, though of course this depends on whether they first pass regulatory muster.

Biogen and Eisai's [controversial Alzheimer's disease project](#) aducanumab tops the list, with global sales of just over \$2bn pencilled in for 2024. This figure is little more than a dart throw in the dark, however; aside from substantial uncertainty around whether regulators will permit the antibody on the market, the price at which it might be sold is another important unknown.

The second project, roxadustat, also [has questions hanging over it](#), largely relating to safety; the pivotal programme supporting the novel anaemia pill was hugely complex, and the developers have been criticised for the ways the results were presented. As such, the FDA's verdict remains hard to call, though approvals in Japan and China contribute some confidence.

An advisory committee is certain to be called, though none has been announced yet, and chances of delays that might push a roxadustat decision into 2021 cannot be ruled out. Immunomedics, meanwhile, will hope that the setbacks are behind it: this will be the second verdict the FDA delivers on its antibody-drug conjugate sacituzumab govitecan, [after last year's complete response letter](#).

## Going for gold - 2020's biggest pending arrivals

Product	Company	2024e sales (\$m)	Note
Aducanumab	Biogen/Eisai	2,012	US filing expected early 2020.
Roxadustat (Evrenzo)	Astrazeneca/Astellas/Fibrogen	1,459	US decision due late 2020 (filed in late December 2019).
Sacituzumab Govitecan	Immunomedics	1,402	2 June PDUFA.
Filgotinib	Gilead/Galapagos	1,281	17 July PDUFA; EU decision due mid-year.
Palforzia	Aimmune	1,263	January PDUFA.
Valoctocogene Roxaparvovec	BioMarin	1,262	20 Aug PDUFA; EU decision due mid-year.
Ozanimod	Bristol-Myers Squibb	1,068	25 March PDUFA; EU decision H1'20.
Rimegepant (Zydis ODT)	Biohaven	885	Q1 PDUFA date for oral tablet formulation.
Selpercatinib	Lilly	820	US filing due by YE'19, currently unconfirmed.
Risdiplam	Roche	801	22 May PDUFA.

*Source: EvaluatePharma.*

The considerable consensus that sacituzumab boasts is boosted by numbers emanating from the more bullish investment banks. Even if Immunomedics gets a green light the company's work will be far from over.

Other projects that invite divided opinions includes Aimmune's peanut allergy therapy Palforzia, and Biohaven's rimegepant, for migraine. Approval of the former seems fairly certain after a positive advisory committee, so again [the commercial potential is the big question here](#); similar concerns exist for Biohaven, [which is gearing up to enter a highly competitive space](#).

Biomarin, meanwhile, will hope to get the first gene therapy for haemophilia to market in valoctocogene roxaparvovec (valrox). Lingering questions about the durability of the project means that this will be a very closely scrutinised application, and again the potential for delays cannot be dismissed.

Hidden stumbling blocks can never be ruled out, of course, though the reviews of Gilead/Galapagos's rheumatoid arthritis project filgotinib, Bristol's multiple sclerosis therapy ozanimod, Lilly's targeted cancer treatment selpercatinib, and Roche's new option for spinal muscular atrophy are widely expected to progress smoothly.

### Elsewhere

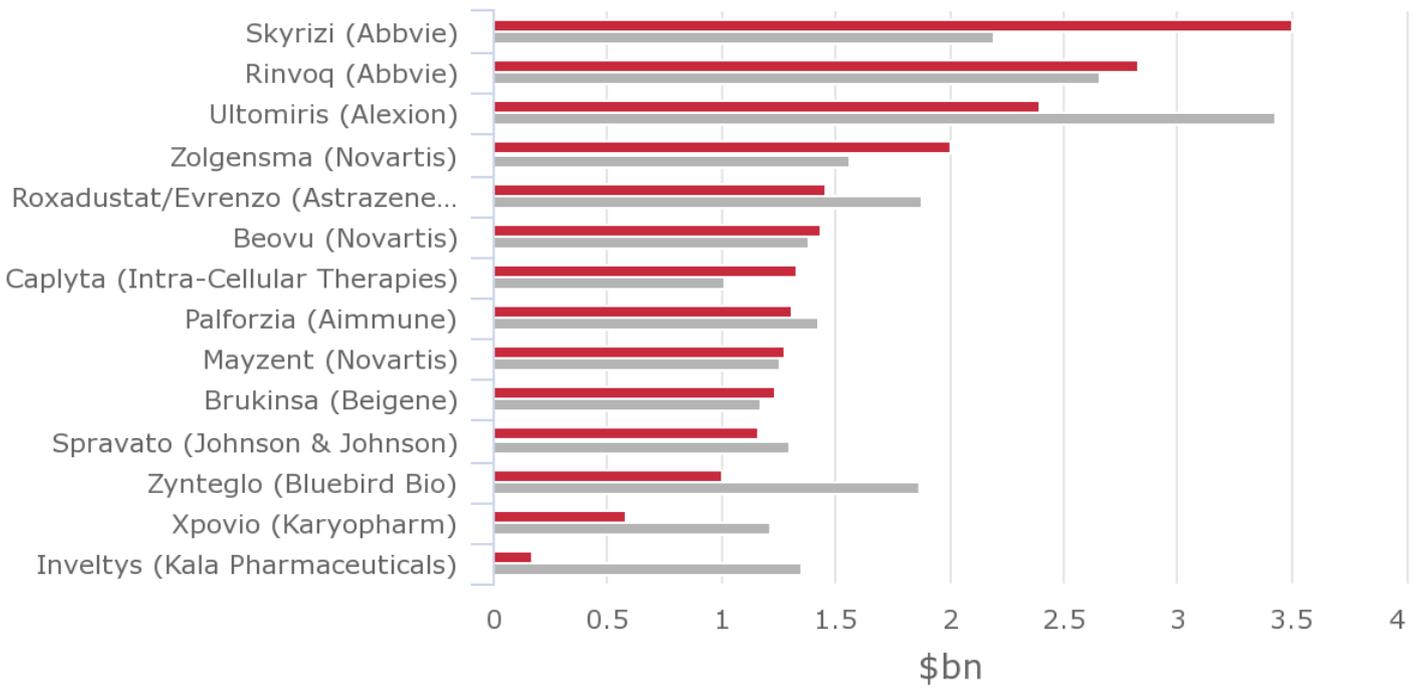
This list is far from the complete overview of next year's regulatory action, of course. Another high-profile decision will involve Esperion's bempedoic acid in February - with projected sales of \$716m the cardiovascular project falls just outside the top 10.

And there will be other closely watched launches: thanks to earlier than expected approvals, Daiichi Sankyo and Astrazeneca's breast cancer therapy Enhertu and Global Blood Therapeutics' sickle cell treatment Oxbryta reached the market late last year.

A look at how the biggest expected 2019 arrivals actually fared serves as a reminder of how unpredictable the regulatory and launch phases can be. There were no substantial setbacks last year, for the top 10 at least, though roxadustat and Palforzia failed to reach the market as soon as some had hoped.

Consensus has come down considerably for a couple of projects, however, and it is no coincidence that this was seen most markedly with products launched by small developers. The reality of the market will defeat enthusiasm, eventually.

# How 2019's biggest projected launches fared



● 2024 sales forecast - Jan 2020 (\$bn)  
 ● 2024 sales forecast - Jan 2019 (\$bn)

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