Evaluate Vantage

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The biggest launches of 2022: a reboot

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New Alzheimer's launches are all but ruled out, so projects from Lilly, Alynlam and Roche top 2022's biggest hopes.

Before the fallout from Biogen's ongoing travails quashed the prospect of a fast-growing market for novel Alzheimer's therapies, anti-amyloid-beta MAbs from Lilly and Roche sat among 2022's biggest potential launches. Not any more.

Evaluate Vantage's latest look at the projects approaching the market this year that are considered by the sellside to have the largest commercial potential still finds Lilly way out in front with tirzepatide. But the diabetes asset is now flanked by a wider range of prospects, with Alnylam's amyloidosis hope vutrisiran and Roche's macular degeneration bispecific standing out.

That last drug is Vabysmo, containing the active ingredient faricimab, which has already secured a green light from the FDA. Grabbing a share of what is a highly competitive market might be harder than these punchy numbers suggest, however. As Bernstein analysts noted recently, the product is not yet available in a pre-filled syringe, while its benefits versus Eylea are far from clear.

It is also worth noting that there were several big approvals in the closing days of 2021 that could arguably be considered 2022 launches. This includes Argenx's Vyvgart, which became the first FcRn antagonist to win US approval, and Amgen and Astrazeneca's Tezspire, an antibody for severe asthma. Both are forecast to be in blockbuster territory by 2026.

Elsewhere, Pfizer's contender in the Jak inhibitor class, Cibinqo, received approval in the all-important US market in January, a couple of months after getting the nod in Europe. *Evaluate Vantage* has restricted the below analysis to first-time 2022 approvals, however.

Blockbusters in waiting? Big arrivals on the horizon for 2022				
Product	**Company**	**Description**	**Status**	**2026e sales**
Tirzepatide	Lilly	GLP-1/GIP dual agonist for type 2 diabetes & obesity	Approvals expected around mid-year in US, EU & Japan	$5.4bn
Vutrisiran	Alnylam	RNAi therapy for ATTR amyloidosis	Pdufa Apr 14, 2022; EU approval expected Q4 2022	$1.8bn
Vabysmo	Roche	Anti-VEGF-A & ANG 2 bispecific for wet age-related macular degeneration & diabetic macular oedema	Approved in US in Jan, decisions expected in EU & Japan later this year	$1.8bn
Carvykti	Johnson & Johnson	Anti-BCMA Car-T for multiple myeloma	Pdufa Feb 28, 2022 (extended by 3mth); EU approval expected Q1 2022	$1.7bn
Adagrasib	Mirati	KRAS G12C inhibitor for NSCLC	Acceptance of FDA filing pending; Aug Pdufa date possible	$1.7bn
Mavacamten	Bristol Myers Squibb	Cardiac myosin inhibitor for cardiomyopathy	Pdufa Apr 28, 2022 (extended by 3mth); EU approval expected H2 2022	$1.7bn
Deucravacitinib	Bristol Myers Squibb	Tyk2 inhibitor for psoriasis & other autoimmune conditions	Pdufa Sep 10, 2022; EU approval expected Q4 2022	$1.7bn
Ublituximab	TG Therapeutics	Anti-CD20 MAb for multiple sclerosis	Pdufa Sep 28, 2022	$1.6bn
Lenacapavir	Gilead	Long-acting HIV-1 capsid inhibitor, initially targeting heavily pretreated patients	Pdufa Feb 28, 2022, EU approval expected early 2022	$877m
177Lu-PSMA-617	Novartis	PSMA-directed, Lu-labelled radioligand, for prostate cancer	FDA decision expected H1, EU decision H2	$851m
Source: Evaluate Pharma.				

This analysis was previously conducted for our 2022 Preview, which is available as a free download. Back then, Lilly and Roche Alzheimer's projects donanemab and ganterenumab featured as this year's biggest launches. But with Roche effectively putting speculation of an accelerated approval submission to bed, and Lilly saying its application would be delayed, the prospect of these agents becoming available imminently is very low.

Another project that no longer features is Reata's bardoxolone, which received a savaging from an FDA advisory committee in December, prompting panel members to vote unanimously against its approval.

On the other hand, there are other potential blockbusters that might yet make it to market this year, though the timing is tight. One is Apellis's geographic atrophy project APL-2, or pegcetacoplan, which the group has promised to file in the second quarter; a speedy and hitch-free FDA review remains the bull case, of course.

Elsewhere, some analysts reckon Nektar's bempegaldesleukin, partnered with Bristol Myers Squibb, might have a chance of approval this year. This depends on success in the crucial Pivot trial, and not many have faith in that happening.

At least Bristol has two other projects to fall back on – three if relatlimab is counted, since forecasts for the Lag3 inhibitor sit at $437m, according to *Evaluate Pharma* consensus. It is worth noting that consensus for deucravacitinib has come down substantially in the past few months, amid concerns that the FDA's caution around the safety of the Jak inhibitors might extend to the Tyk2 class.

It remains true, however, that projects owned by smaller developers should be treated with the most caution. Take Mirati, which has fumbled adagrasib's programme at a time when doubts are growing about the potential

for the Kras inhibitor class.

Consensus around TG Therapeutics' ublituximab is also highly debateable. If approved, this anti-CD20 MAb will compete in a crowded market, while missteps by the company elsewhere could be interpreted as lowering the chances of getting there in the first place. Bulls argue that TG's issues with its cancer ambitions are separate from its work in MS, but the risk of complete disaster can never be ruled out.

(Since this article was published Lilly has trademarked tirzepatide as Mounjaro.)