

## Go or no go? Aducanumab's day of reckoning



[Joanne Fagg](#)



### Next month the FDA will determine Biogen's fate in Alzheimer's, while Ascendis and Novo Nordisk also await Pdufa decisions.

The biggest regulatory event of the year happens next month, when Biogen's Alzheimer's candidate aducanumab receives a final verdict from the FDA. While the US regulator has been enthusiastic about aducanumab the project's advisory committee meeting was overwhelmingly negative, making a green light far from certain.

One June approval that jumped the gun was that of Myovant's relugolix combination Myfembree, for uterine fibroids. This had been due on June 1 but came yesterday. The FDA still has a busy month ahead: Ascendis could gain its first approval with the growth hormone asset Transcon hGH, and Novo Nordisk has obesity in its sights with semaglutide.

But June really is all about aducanumab, and for the MAb to be approved the FDA would have to rule against its own adcom, [an outcome that is rare but not unknown](#). The most damning vote at the meeting was [10-0 against](#) on the question of whether the Emerge trial could be considered primary evidence of the project's effectiveness.

Emerge, along with adu's other pivotal trial, Engage, failed at interim analyses, but Biogen later said longer-term data showed a hit in the former ([Shock revelation sees Biogen erase its aducanumab losses](#), October 22, 2019). The FDA has [been supportive](#), and given the lack of Alzheimer's treatment options there is pressure to approve.

The outcome will be relevant for other companies with beta-amyloid MAbs in development; Roche and Lilly both have [several in clinical trials](#), while Biogen itself also has a second MAb, BAN2401, in phase 3.

### Convenience

Meanwhile, Ascendis could see its first US approval next month with Transcon hGh, a long-acting once-weekly human growth hormone for paediatric growth hormone deficiency.

Transcon hGh has a shot at being market leader in the space by 2026, overtaking Novo's once-daily growth hormone norditropin - if it can get a superiority claim on its label. Phase 3 data showed greater efficacy than daily injections ([Ascendis shoots higher on pivotal win](#), March 4, 2019). Consensus forecasts, as compiled by *Evaluate Pharma*, see Transcon hGh sales of \$1.4bn by 2026.

Other once-weekly projects to watch include Pfizer/Opko's somatrogon, which has a Pdufa in October, although

it has so far only shown non-inferiority to daily injections ([Pfizer's growth hormone falls short](#), October 22, 2019). Novo's once-weekly candidate somapacitan is further behind, with data from a paediatric phase 3 study expected in the second half.

### **Big opportunity**

Pegged for the second quarter, approval of Novo's semaglutide in obesity looks to be in the bag after impressive data from the Step programme. Novo had been targeting non-placebo-adjusted weight loss of at least 12%, while clinical trials found 17-18% ([Novo adds weight to its obesity goals](#), September 10, 2020).

Sellside consensus forecasts from *EvaluatePharma* see \$2.4bn for sema in obesity by 2026, outdoing Novo's own existing obesity drug Saxenda, which has only shown around 5-7% weight loss. Semaglutide is already marketed for diabetes as Ozempic, an injectable, and Rybelsus, a pill.

Novo is also testing semaglutide in the [Essence](#) study in Nash and a [phase 3 trial in HFpEF](#). Two studies in Alzheimer's, [Evoke](#) and [Evoke Plus](#), also recently started.

The tables below list first-time and supplementary US approvals and advisory meetings due next month, with consensus forecasts from *Evaluate Pharma*.

## Notable first-time US approval decisions due in June

Project	Company	PDUFA date	Indication(s)	2026e sales by indication (\$m)	Note
PF-06482077	Pfizer	June	Pneumonia	1,037	20-valent pneumococcal conjugate vaccine
Lybalvi (ALKS 3831)	Alkermes	June 1 (resubmission)	Schizophrenia and bipolar I disorder	380	CRL last year over CMC issues
Brexafemme	Scynexis	June 1	Vulvovaginal candidiasis	302	-
Infigratinib	Bridgebio	Est June 1	2L cholangiocarcinoma	253	FGFR inhibitor
Ryplazim	Liminal	June 5 (resubmission)	Congenital plasminogen deficiency	65	CRL in 2017 over CMC issues
Aducanumab	Biogen/Eisai	June 7	Alzheimer's disease	2,396	See text
Miplyffa (arimoclomol)	Orphazyme	June 17	Niemann Pick disease type C	293	Extended from March
Ephedrine injection (ET-203)	Eton/Sintetica	June 18	Hypotension	37	-
VP-102	Verrica	June 23 (resubmission)	Molluscum contagiosum	271	CRL in 2020 over CMC issues
Transcon hGH	Ascendis	June 25	Paediatric growth hormone deficiency	1,388	See text
Verkazia	Santen	June 26	Keratoconjunctivitis (patients aged 4-18)	-	Topical ophthalmic cyclosporine
Nexobrid	Mediwound/Vericel	June 29	Severe thermal burns	50	<a href="#"><i>Mediwound could feel the burn with Nexobrid launch</i></a>
Eohilia/TAK-721	Takeda	June?	Eosinophilic oesophagitis	341	Pdufa was in Apr but no decision has been made
IV Tramadol	Avenue	June?	Acute pain	263	Pdufa was in Apr but no decision has been made
StrataGraft	Mallinckrodt	June?	Adults with deep partial-thickness thermal burns	59	Action was deferred in Feb owing to travel restrictions, no new date given
Tanezumab	Pfizer/Lilly	June?	Moderate-severe osteoarthritis pain	63	Negative adcom in Mar, no new Pdufa date set

Source: Evaluate Pharma & company releases.

### Advisory committee meetings in June

Project	Company	Adcom date	Indication	2026e sales by indication (\$m)	Note
Covid-19 vaccines	-	June 10	Prevention of Covid-19	-	To discuss data needed to support the use of Covid-19 vaccines in children less than 12 years of age. The committee will not discuss any specific products.
Retifanlimab (INCMGA0012)	Incyte/Macrogenics	June 24	Adults with locally advanced or met squamous carcinoma of the anal canal who have progressed on or who are intolerant of platinum chemo	53	Anti-PD-1 MAb

Source: Evaluate Pharma & FDA adcom calendar.

## Supplementary and other notable approval decisions in June

Product	Company	Indication (clinical trial)	Date
Cosentyx	Novartis	Moderate-severe plaque psoriasis in children and adolescents ( <a href="#">NCT03668613</a> , <a href="#">NCT02471144</a> )	Est June
Rinvoq	Abbvie	Psoriatic arthritis ( <a href="#">Select-PsA 1</a> , <a href="#">Select-PsA 2</a> )	June
		Ankylosing spondylitis ( <a href="#">Select-Axis 1</a> )	
Ultomiris	Alexion/ Astrazeneca	Children and adolescents with PNH	June 7
Trikafta	Vertex	Children aged 6 to 11 who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive ( <a href="#">NCT03691779</a> )	June 8
Ayvakit	Blueprint	Advanced systemic mastocytosis ( <a href="#">Pathfinder</a> , <a href="#">Explorer</a> )	June 16
Ruxolitinib cream	Incyte	Atopic dermatitis ( <a href="#">TruE-AD1</a> , <a href="#">TruE-AD2</a> )	June 21
Jakafi	Incyte/Novartis	Paediatric patients with steroid-refractory GvHD ( <a href="#">Reach3</a> )	June 22
Solosec	Lupin	Treatment of trichomoniasis in adults and adolescents	June 30
Nurtec ODT	Biohaven	Migraine prevention (Study <a href="#">305</a> , <a href="#">201</a> )	Q2
Alecensa	Roche	1st-line Alk-positive NSCLC ( <a href="#">Bfast</a> )	Q2
Semaglutide 2.4mg (Ozempic)	Novo Nordisk	Obesity (Step <a href="#">1</a> , <a href="#">2</a> , <a href="#">3</a> and <a href="#">4</a> )	Q2

Source: Evaluate Pharma & company releases.

This article has been updated to include the June panel meeting to discuss paediatric use of Covid-19 vaccines.