

Lilly's cluster buster puts Amgen in a fluster



[Jonathan Gardner](#)

Ahead of Amgen's day of destiny this week for its migraine agent Aimovig, Lilly gave a glimpse of how its rival galcanezumab might be able to gain an edge. Its hopes lie in success yesterday in one of two studies in cluster headache, a migraine-related condition that for now has no specific treatment.

Thanks to its first-mover position in migraine, Aimovig has earned the sellside's biggest forecasts in what, efficacy-wise, looks like a fairly evenly matched contest between the two agents plus Teva's fremanezumab (see tables below). Having positive data in cluster headaches might result in a raised outlook for galcanezumab. But of course the headway of this entire class still relies on pharma getting the pricing right.

Three-way race

The three agents are the first anti-CGRP antibodies to be reviewed by drug regulators, with a decision due on Aimovig on May 17 ([Upcoming events - first anti-CGRP comes before the FDA, and Darzalex's combination data, May 11, 2015](#)). Galcanezumab is close behind, with a US FDA decision deadline sometime in late summer.

Aimovig's head start could account for its richer forecast, with the sellside expecting blockbuster sales by 2022. At present fremanezumab is forecast to edge ahead of galcanezumab, but with concerns that the Teva injection will be delayed from its scheduled June approval date this might not hold.

Teva's chief executive, Kåre Schultz, said during the group's first-quarter earnings call that he was hoping for approval and launch before the end of 2018, a timeline that many consider ambitious.

Not much in it: the outlook for anti-CGRP antibodies

Project	Company	Global sales (\$m)				Status
		2018e	2020e	2022e	2024e	
Aimovig (erenumab)	Amgen/Novartis	125	801	1,432	1,883	Filed
Fremanezumab	Teva	7	285	630	983	Filed
Galcanezumab	Lilly	39	335	664	927	Filed
Eptinezumab	Alder Biopharmaceuticals	-	105	416	709	Phase III

Source: EvaluatePharma.

Lilly will be hoping that yesterday's data in cluster headache could give it a chance to differentiate galcanezumab. While it can claim success in episodic cluster headache, a study in chronic disease, which represents 10-15% of the cluster headache population, failed to meet its primary endpoint.

Cluster headaches differ from migraines in that they are shorter-lived but can repeat in the course of a day; tears and runny noses often accompany them. In the episodic form the cluster lasts for several weeks and then goes into remission. Subcutaneous Imitrex is the only drug labelled for treatment of cluster headaches.

Lilly will no doubt point to the fact that the study in the bigger episodic indication met its primary endpoint, with galcanezumab treatment resulting in a statistically significant reduction in the number of weekly cluster headache attacks versus placebo across weeks one to three of the two-month, double-blind treatment period (-8.7 for galcanezumab versus -5.2 for placebo, $p=0.036$).

But a win in only one of two trials could raise doubts about galcanezumab's utility in cluster headache in general. Teva is also running phase III studies in these conditions, and data due later this year will help confirm the anti-CGRP's efficacy here.

Given that the topline data have only just come in, it seems unlikely for the cluster headache indication to

make it onto the initial label should galcanezumab win approval in a couple of months, though off-label use is possible. But the lack of specific treatments for cluster headaches gives the drug a good shot of winning a label expansion and a market all to itself, at least for a while.

\$8,500 or bust

The anti-CGRP agents have probably done enough to get approval in migraine, but their commercial success will also depend on how aggressive pharma companies and payers are in price negotiations. With triptans available generically, and Botox having penetrated deeply into migraine treatment, payers have a fair amount of leverage.

The US third-party assessor the Institute for Clinical and Economic Review (Icer) has suggested that an \$8,500 annual price would meet cost-effectiveness guidelines, a level that Amgen sees as reasonable. That same Icer [draft review](#) did not include a cost-effectiveness estimate for galcanezumab because the group said it lacked data.

Nevertheless, payers could soon be reviewing data from three fairly similar new migraine agents, and will have the ability to threaten exclusions if satisfactory price concessions are not achieved. Having a cluster headache indication on the label could help Lilly argue for a place on formularies. But given Amgen's recent woes with another expensive new antibody class, the PCSK9s, this is a fight it will not want to lose.

Project	Study details	Trial ID	Data due
Galcanezumab	Episodic cluster headache	NCT02397473	Reported
Galcanezumab	Chronic cluster headache	NCT02438826	Reported
Fremanezumab	Episodic cluster headache	NCT02945046	Primary completion May 2018
Fremanezumab	Chronic cluster headache	NCT02964338	Primary completion Oct 2018

This article was corrected to state that subcutaneous Imitrex is used to treat cluster headaches.

To contact the writer of this story email Jonathan Gardner in Virginia at jonathang-us@epvantage.com or follow [@ByJonGardner](https://twitter.com/ByJonGardner) on Twitter

[More from Evaluate Vantage](#)

Evaluate HQ
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

© Copyright 2023 Evaluate Ltd.