

## Upcoming events - first anti-CGRP comes before the FDA, and Darzalex's combination data



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Welcome to your weekly digest of approaching regulatory and clinical readouts. Aimovig is likely to become the first anti-CGRP MAB approved for migraine by its May 17 US action date, though competitors are not far behind, and Amgen will need to make the most of its first-mover advantage.

Also by the summer data are due from the Maia trial testing Darzalex in first-line multiple myeloma in combination with Revlimid. Earlier this week the drug gained US approval in the indication but in combination with Velcade, and as Revlimid is dominant in the US the upcoming phase III data are key for it to gain traction (see tables below).

### A migraine first

In two phase III trials Aimovig, an injectable anti-CGRP MAB for the prevention of migraine, showed placebo-adjusted 1.1 and 1.4-1.9 reductions in monthly episodic migraine days. In a third trial, a phase II in chronic patients, the injectable showed a placebo-adjusted reduction of 2.4 days.

Other anti-CGRP MABs are hot on Aimovig's heels, the closest of which, Lilly's galcanezumab, is due US approval in the third quarter. Teva's fremanezumab is not far behind, though a warning letter regarding the plant where this drug is to be manufactured means that its time in front of the regulator likely will not come until next year. Alder's eptinezumab is to be filed later this year.

Once Aimovig is approved its biggest issue will be pricing. In a market where triptans are largely generic and the other go-to treatment, Botox, is still going strong, the marginal benefit shown by MABs heralds some difficult payer negotiations.

The US Institute for Clinical and Economic Review (Icer) has suggested an \$8,500-per-year price for the injectables, and Amgen's head of commercial operations, Tony Hooper, said this price was "reasonable". He also said Amgen would look "very carefully" at value-based pricing ([Snippet roundup: Nuplazid reviewed by FDA and Nucala reviewed by Icer, April 27, 2018](#)).

A lower price would put pressure on competitors; consensus forecasts from *EvaluatePharma* show Aimovig as the biggest-selling anti-CGRP MAB by 2024. With little to distinguish between the different MABs in terms of efficacy, Amgen will need to make its first-mover advantage count.

**Top selling anti-CGRP migraine MABs by 2024**

Project	Company	Global sales (\$m)		Status	PDUFA dates
		2018e	2024e		
Aimovig (erenumab)	Amgen/Novartis	126	1,882	Filed	May 17, 2018
Fremanezumab	Teva/Otsuka	7	983	Filed	Teva claim it can get approval before YE 2018, analysts expect mid-2019
Galcanezumab	Eli Lilly	39	927	Filed	Q3 2018, likely Oct
Eptinezumab	Alder	-	788	Phase III	Filing expected H2 2018

Source: *EvaluatePharma*.

### Darzalex's US target

Earlier this week Johnson and Johnson's Darzalex, an anti CD-38 MAb, got US approval for first-line multiple myeloma in transplant-ineligible patients in combination with Velcade, melphalan and prednisone, a backbone used often in Europe.

Arguably its bigger test will be results due in the summer from the Maia trial. This studies Darzalex in combination with Celgene's US-dominant backbone of Revlimid and dexamethasone, also first line.

Progression-free survival is the primary efficacy measure in this 745-patient study. Genmab's chief executive earlier told *EP Vantage* that a PFS benefit in Maia would surpass that seen in the phase III Pollux trial, which tested Darzalex plus Revlimid in second-line patients, and in which a median had not been reached at 33 months (*Interview – Genmab aims at multiple new markets for Darzalex, February 19, 2018*).

Worldwide Darzalex sales are forecast to exceed \$6bn by 2024, according to *EvaluatePharma* consensus, \$3.8bn of which is expected to come from the US. Genmab receives worldwide royalties.

Revlimid's entrenched position in the US could make the first-line market hard to penetrate. Revlimid is therefore still expected to be the market leader in multiple myeloma by 2024, but Darzalex sits in second place, and success in Maia will go some way to helping it at least stay there.

#### Top-selling multiple myeloma treatments by 2024

Product	Company	Global indication sales (\$bn)		Status
		2017	2024e	
Revlimid	Celgene	7.8	11.3	Marketed
Darzalex	Johnson & Johnson/Genmab	1.2	6.0	Marketed Maia: NCT02252172 Pollux: NCT02076009
Ninlaro	Takeda	0.5	2.4	Marketed
Pomalyst	Celgene	1.6	2.2	Marketed
Kyprolis	Amgen/Ono Pharmaceutical	0.9	1.9	Marketed

Source: *EvaluatePharma*.

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