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Physician Views: Anti-CGRP mAbs Looking to Shake Up Migraine Prevention – How and Where Will They Fit in?

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Abstracts

Drugmakers may finally have cracked the code to developing safe and effective inhibitors of the calcitonin gene-related peptide (CGRP), a neuropeptide long believed to be associated with migraine headaches but which had proven exceedingly difficult to target with pharmaceuticals.

As it turns out, the key was moving on from small molecules, where companies like Boehringer Ingelheim and Merck & Co. ran into problems with off-target liver toxicities, and taking advantage of the highly specific nature of monoclonal antibodies. Four companies – Alder, Amgen, Eli Lilly and Teva – have recently reported Phase II results for mAbs candidates that are so far living up to the hype. (See ViewPoints: New data suggest the anti-CGRP race is closer than once thought.)

Cross-study comparisons of the products are fraught with difficulties given the highly variable and important differences in baseline characteristics, but Morgan Stanley analyst Matthew Harrison said that “in general, the placebo-adjusted responses are comparable across agents with an one-day reduction in mean migraine days and a roughly 10-percent to 25-percent increase in 50-percent responder rate.”

The most obvious differentiator among the four programmes is their target as Alder, Eli Lilly and Teva are developing mAbs that hit the CGRP ligand while Amgen’s AMG 334 binds directly to the CGRP receptor. Bernstein analyst Geoff Porges notes Amgen has floated the possibility that its approach may offer certain efficacy and/or dosing advantages over ligand-directed products, however, these have yet to emerge.

In fact, the opposite may turn out to be true when it comes to dosing as AMG 334’s

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short half-life (potentially a result of targeting of the CGRP receptor directly) may put it at a disadvantage to other products on dosing, particularly Alder's ALD403, which has a half-life of 26 days and is expected to be dosed quarterly. AMG 334's half-life is estimated at only 11 days, meaning it is likely to require monthly dosing. Eli Lilly's LY2951742 and Teva's TEV-48125 are testing monthly dosing schedules as well at the moment. Dosing is not a clear victory for Alder, however, as its ALD403 is only available – for the time being anyway – for intravenous delivery, whereas the other three agents can be self-administered subcutaneously.

Unlike its three competitors, which have only reported data in patients with episodic migraines, Teva's TEV-48125 is the only agent that has generated data in the all-important chronic migraine setting, a distinction that Porges said could give the Israeli drugmaker a potential leg up. (See ViewPoints: Handicapping the four-horse race among anti-CGRP mAbs for migraine.)

Patients, physicians, payers and investors will be watching the progress being made with anti-CGRP mAbs closely as there is a clear unmet need for safe and effective prophylactic therapies for high-frequency episodic and chronic migraines, which is a market that Cowen analyst Eric Schmidt believes could represent a multi-billion dollar opportunity for products that pass regulatory muster. And no wonder given estimate from the US Centers for Disease Control that more than 14 percent of adults have experienced a migraine or severe headache in the past three months.

Preventative therapy for patients with episodic migraines involves some combination of antihypertensives, antiepileptics and antidepressants, often supplemented by acute rescue medications like triptans. Recently, Botox (botulinum toxin A) from Actavis became the first FDA-approved prophylactic product for chronic migraines and, while it is not indicated for episodic migraines, it has become the go-to agent in this setting for many doctors, according to UBS analyst Marc Goodman. Also in the mix is STX-Med's Cefaly, a transcutaneous electrical nerve stimulation (TENS) device that last year became the first device to be approved in the US for migraines.

Given the complex treatment environment into which the anti-CGRP mAbs are heading towards, characterised by the large unmet need and highly variable nature of the management and responses from patients with episodic or chronic migraines, FirstWord PLUS commissioned a poll of neurologists and primary care physicians in the US and EU5. To gain a better understanding of how they see the new class of migraine prophylactic fitting in, as well as what factors might help set individual products apart from the rest, the questions they are being asked include…

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What drug(s) do you tend to prescribe for the prevention of high-frequency episodic migraines (defined as fewer than 15 migraine days per month)?

In patients with (high-frequency) episodic migraines, preliminary Phase II data for several anti-CGRP mAbs showed roughly a 1-day reduction in mean migraine days per month and 10% to 25% improvement in 50%-responder rates. If anti-CGRP mAbs are eventually approved based on similar data, which would you be more likely to prescribe first to prevent episodic migraines?

In patients with chronic migraines (defined as more than 15 migraine days per month), preliminary Phase II data for one anti-CGRP mAb showed 50%-responder rates of greater than 50%, rapid onset and lower consumption of acute migraine medications. If this product and/or others from the CGRP class are approved based on similar data, which would you be more likely to prescribe first to prevent chronic migraines?

If multiple anti-CGRP mAbs are approved at roughly the same time based on comparable safety and efficacy data, what other factors will be most important when you decide which drug to prescribe?

For patients with moderate to severe migraines, would you be more likely to prescribe a subcutaneous drug that is dosed monthly or an intravenous drug that is dosed quarterly?

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