

Molecular Partners/Allergan's abicipar will go 'head-to-head' with Novartis' brolucizumab in wet AMD

BERLIN, 18 June (APM) - Molecular Partners/Allergan's wet age-related macular degeneration drug abicipar will challenge Novartis' new anti-VEGF brolucizumab once it is launched in 2020, Molecular Partners' chief executive officer Patrick Amstutz told APM.

Abicipar will play "in the same league" as brolucizumab, which is expected to hit the market earlier - in 2019, Amstutz said in a telephone interview last week.

Abicipar, a first-in-kind designed ankyrin repeating protein (DARPin) initially developed by the Swiss biotech, was out-licensed to Allergan in 2011 (APMHE 23375). Allergan plans to announce Phase III data in the second half of this year, Amstutz said.

Dosing has shown that around 70% of patients can go on to a three-month dosing regime with abicipar, which is better than Novartis' compound, Amstutz said.

The HAWK and HARRIER studies, presented in May, showed that 50% of brolucizumab-treated AMD patients can maintain a rate of one injection every three months (APMHE 58035).

As rival current standard therapies including Bayer/Regeneron's Eylea (aflibercept) have a higher injection frequency, which is a burden for patients and caregivers, brolucizumab is seen as becoming "best-in-class," Amstutz said.

Weighing on abicipar's dosing regime is mild-to-moderate inflammation seen in 10% of patients in the trial, Amstutz said. However, he is confident that Allergan's new formulation, which is a purified version not yet being used, can address the issue.

"We did not have the final material, meaning there are still some bacterial contaminants leading to residual inflammation," Amstutz said. Allergan has a new trial ongoing with the new purified formulation. "We are likely to see safety later and, together [with dosing], that will give us a full picture of how strong the product will be."

Allergan will have "a solid understanding" of the open trial in the second half of 2018, Amstutz added. Allergan has said it will then file for licensing of the new formulation when appropriate.

Allergan is set to launch Phase III abicipar trials in diabetic macular oedema (DME) later in 2018. It has forecast peak sales of \$1.5 billion to \$3.0 billion for wet-AMD and DME indications combined.

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Molecular Partners' focus is now on its lead cancer compound MP0250, Amstutz said. Phase II dosing trials in combination with Johnson & Johnson's cancer drug Velcade (bortezomib) and dexamethasone to treat multiple myeloma are ongoing, and safety and initial efficacy read-outs are expected in the second half of 2018.

Amstutz hinted that the company would consider new combinations to treat multiple myeloma if readouts are satisfactory. New trials for MP0250 would go beyond the company's budget. "If we have good data and we have a clear plan then we might need to refinance," he said.

In the event of new cash requirements, Molecular Partners might access capital markets, out-license earlier molecules or look at regional deals, he said.

The Swiss company is also exploring MP0250 in EGFR-mutated non-small cell lung cancer (NSCLC) and clinched a collaboration agreement with AstraZeneca in April to study a combination with Tagrisso (osimertinib).

The agreement has saved Molecular Partners "millions", Amstutz said. First safety data for this trial is expected by the end of 2018.

Molecular Partners will not look at any fully out-licensed Allergan/abicipar-style deal for the time being. It seeks to build a company on the DARPin platform and market its own drugs, Amstutz said.

"It's important that we stick with it longer than we did with abicipar," he said.

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