Doctors and Patients Petition FDA to Approve Amarin's Vascepa for High Triglycerides

Amarin is Appealing to The Office of Drug Evaluation II – Dr. Curtis Rosebraugh

NEW YORK, NY, USA, February 10, 2014 /EINPresswire.com/ -- Below is a selection of the many comments that we have received from health care workers and patients in relation to the controversial decisions taken by the FDA and the compelling need for the approval of Vascepa.

MEDICAL DOCTOR* 'Doctors' need this drug to help treat patients with hypertriglyceridemia!

GERONTOLOGY SPECIALIST* With the recent ruling on the drug Vascepa for the treatment of triglyceride levels of 200 to 500 mg dl range, the FDA sends an unwelcome message to millions of Americans at risk of disability or death due to heart disease.

MEDICAL DOCTOR* The FDA has failed to consider that the vast majority of Lovaza use is OFF LABEL, to treat this exact type of problem, mixed dyslipidemia in the setting of trig in the range 200-500. Vascepa is safe, effective and is the preferred choice for this patient type, given the ADVERSE EFFECTS OF LOVAZA on the lipid panel. LOVAZA could NEVER get this indication with the adverse lipid panel effects on LDL. They failed with the FDA for this exact reason. Vascepa approval for this type of treatment would give us the ability to now use an "indicated" therapy for patients AND also have positive effects on other lipid parameters and inflammatory markers. Many medications, including for lipids, are approved and used for cholesterol and LDL lowering per treatment guidelines, even in the absence of a study that can actually prove a positive CV outcome. Approving VASCEPA for this indication of mixed dyslipidemia with a statin is simply the right thing.

DIETITIAN* I am a registered dietitian who is very disappointed that Vascepa has not been approved for mixed dyslipidemia. Studies show that a lower serum EPA/AA ratio is significantly associated with an increased risk of coronary heart disease. No association was observed for DHA/AA ratio. Vascepa is an omega-3 agent containing 96% EPA. The current American diet is high in simple, highly-processed carbohydrates and omega-6 oils; consumption of omega-3 fatty acids is poor and represents only approximately 200mg per day of both EPA and DHA combined. Completed studies of Vascepa at 2 and 4 gram doses showed significant reductions in triglycerides, non-HDL-C, LDL-C, ApoB, LDL particle concentration, Lp-PLA2, hsCRP, ApoC, and cholesterol....all of which are considered risk factors in cardiac disease. The study JELIS, which observed 18,645 Japanese men and women, showed a major coronary event reduction of 19% when a drug similar to Vascepa was administered, 53% reduction in a sub-group of those with the highest risk. The mixed dyslipidemia market is estimated at approximately 36 million Americans. Failure to approve Vascepa for this group would unnecessarily put many lives at risk. I humbly ask the FDA to approve Vascepa for this

indication to help the fight against heart disease.

PATIENT* I quote, from the FDA website: "Triglycerides are another form of fat in your blood that can raise your risk for heart disease. You may need treatment if your triglycerides are: Borderline High (150-199 mg/dL) High (200 mg/dL or more)" Vascepa is proven to reduce triglyceride levels and with a high safety profile compared to other drugs that have been approved such as Fenofibrates! Give people a choice and a safer but still effective option.

OMEGA-3 EXPERT* As an experienced researcher in the field of omega-3 fatty acids, I found the reported results of the FDA's advisory panel on Vascepa absolutely shocking, and in no way defensible on scientific grounds. The FDA would have absolutely no legitimate scientific or medical grounds for refusing approval of Vascepa for mixed dyslipidemia, and I would urge them to make this approval if they are to retain any credibility whatsoever. To do otherwise would be scandalous in the face of the evidence, and would be doing a massive disservice to healthcare professionals and their many patients with high triglycerides who could benefit from this treatment, as demonstrated by the results of the Anchor trial in accordance with the SPA that Amarin agreed with the FDA before conducting this trial in the first place. It would also sabotage the completion of the ongoing REDUCE-IT trial, which is an extremely important study - and for which the company has again done everything that was asked of it by the FDA.

NURSE* We need to do the right thing and approve Vascepa. As a practicing RN, I have been taught to lower triglycerides in the mixed dyslipidemia population and yet FDA says we don't need to lower the level for 200 to 500 mg/dL. FDA's role is not to limit medicine but give choices to doctors who in turn will make the choices that best suits their own patients. Please approve Vascepa.

PATIENT* I am very worried about the new AHA guidelines. By their standards, I should be on statins. I have been on Vascepa (2 gram) for four months now and feeling good. New blood test results should be available next week and I am very confident the numbers will show improvement. I hope the FDA recognizes my right in deciding my treatment plan along with my doctor’s guidance, not some Big Pharma interest. Currently, feeling great with no side effects and new guidelines wants me on statins where I have to worry about on-set diabetes (already have a family history), foggy memory, muscle aches etc. does not make any sense.

MEDICAL DOCTOR* I personally take Vascepa off label because of its anti-inflammatory effects as proven by the significant reduction in hs-CRP in clinical trials. The correlation between inflammation and CVD is well established the medical literature. In my opinion, it would be a travesty to not allow Vascepa to be marketed for the ANCHOR indication of TG's >200 until after the results of the REDUCE-IT trial. Real people's lives and health are at stake here, not just numbers. Many people will benefit from this drug. Please do the right thing and approve.

About The EPA Drug Initiative:

The EPA Drug Initiative is a group of physicians, patients and concerned citizens, who are bound by a common objective to encourage the Food and Drug Administration to approve Vascepa for the expanded label indication of treating high triglycerides. Members of EPADI share a common view that the highly purified form of EPA, as only found in Vascepa, offers significant therapeutic value in treating cardiovascular disease. http://epadruginitiative.com

We currently have sponsored two important petitions:

• The Citizen’s Petitions from many members of EPADI, relative to the FDA’s Vascepa SPA rescission decision (Docket number FDA-2013-P-1612), can be found at: http://www.regulations.gov/#!docketDetail;D=FDA-2013-P-1612

• An online petition urging the FDA to approve Vascepa for high triglycerides/mixed dyslipidemia can be found here: http://www.thepetitionsite.com/176/817/515/urge-the-fda-to-approve-vascepa-for-mixed-dyslipidemia

Help us by providing your support, comments and testimonials and by continuing to make your views known to Congress and the FDA.

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The EPA Drug Initiative
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