An Open Letter to Dr. Margaret A. Hamburg, FDA Commissioner

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December 12, 2013

The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Hamburg:

We are writing to request that you personally intervene in the FDA's recent decision to rescind the ANCHOR SPA agreement with Amarin Corp and we ask you overturn this unjust decision.

Background:

On October 29th, 2013, in a highly controversial move, the FDA reviewing division rescinded the special protocol assessment (SPA) with the Amarin Corporation in relation to the application for the use of Vascepa for lowering triglyceride (TG) in patients with high TG level (200-500 mg/dl) with mixed dyslipidemia. (Vascepa had already been approved for lowering TG in patients with very high TG level ≥ 500 mg/dl.) The reviewing division stated that the decision to rescind the ANCHOR SPA was based on the 3 recently completed outcome trials (ACCORD-Lipid, AIM-HIGH, HPS2-THRIVE) and erroneously concluded TG lowering in patients with high TG levels (200-500 mg/dl) would not be clinically beneficial.

As the ANCHOR trial fulfilled all aspects of ANCHOR SPA, including a safety profile equal to placebo, the only mechanism available for the FDA to deny approval was to use the "substantial new scientific issue" argument. In taking such an unprecedented action, the reviewing division completely ignored the basic tenets of sound scientific review and made an extreme, leap-of-faith extrapolation to conclude that TG lowering in patients with high TG (200-500 mg/dl) would not have clinical benefit. The conclusion of the reviewing division is not supported by the clinical

data and the actions taken to rescind the SPA are then baseless and without any scientific merit.

Discussion:

The FDA reviewing division's use of the 3 outcome trials to somehow demonstrate that TG lowering therapy does not benefit patients with high TG levels (200-500 mg/dl) is fundamentally flawed and contradicted by the study results. The three major reasons are as follows:

1) The drugs used in each of the referenced trials were very different compounds (fenofibrates and niacin) from Vascepa and had distinct mechanisms of action and effects on lipid levels (e.g. fenofibrates lower TG but raise LDL-cholesterol while Vascepa lowers both TG and LDL-cholesterol).

2) None of the three trials were designed or statistically-powered to study the TG lowering effects in high TG population, and most of the patients in the trials had either normal or borderline TG levels; thus the trials simply could not inform whether TG lowering effects would be clinically beneficial in patients with high TG levels.

3) The sub-group analysis of the trials based on TG levels indicated that patients with high TG (≥ 200 mg/dl) and low HDL-cholesterol, (the patient sub-population covered by the ANCHOR SPA), had an impressive reduction in cardiovascular disease (CVD) risks of 28 and 37%, prompting the investigators to conclude that these "patients likely benefited from TG lowering therapy."

There is no scientific evidence to support the FDA reviewing division's conclusion that these trials somehow indicate that TG lowering will not improve clinical outcome in patients with high TG levels. Therefore, the decision to rescind the ANCHOR SPA has no valid scientific justification. In fact, the outcomes results suggests the contrary; that TG lowering therapy may be highly beneficial in the ANCHOR sub-population.

Approximately 800,000 Americans die of heart disease each year with roughly 715,000 Americans experiencing a heart attack, or one every 44 seconds. Besides the personal impact and burden CVD puts on American families, this health epidemic carries an economic burden of enormous proportions. It is estimated that over $300 billion will be spent in the U.S. this year treating CVD, and that number is projected to grow to around $830 billion by 2030. The financial cost of CVD is a tremendous economic strain to the continually rising health care expenses. Although the new AHA/ACC guidelines focus mainly on the role of statins in lowering LDL-cholesterol, it is well established that the statins only lower CVD risk by 30 % and significant residual CVD risk persists. Many patients, despite being on statin therapy, continue to have high TG levels. Recent meta-analysis studies demonstrated that each 10 mg/dl rise in TG level predicts a 1.4 % increase in CVD risk. Thus, treating high TG level (≥ 200 mg/dl) is potentially important adjunctive therapy to statins to further lower the CVD risk.

Vascepa is an ultra-pure eicosapentaenoic acid (EPA) (an omega-3 fatty acid) that has been shown to be highly efficacious in lowering TG when added to statin therapy. In the only large outcomes trial of ultra-pure EPA, when given in combination with statins, there was an overall 19 % reduction in CVD events. Patients with high TG and low HDL (ANCHOR sub-population) had a remarkable 53 % reduction in CVD events, confirming that pure EPA reduces CVD risks and saves lives in patients with high TG levels. While a clinical outcome trial with Vascepa called REDUCE-IT is currently underway, it won't be completed until 2017, or later. Waiting 4 years is far too much to ask of millions of Americans who will pay not only with deteriorated health, but many are likely to die needlessly.

The FDA routinely makes difficult decisions pertaining to drugs in terms of weighing therapeutic benefit against the risk of serious side effects. Given its excellent safety profile and efficacy, the risk-to-benefit considerations clearly favor Vascepa approval.

Conclusions:

The FDA decision to rescind the ANCHOR SPA is simply not supported by the evidence cited by the reviewing division. The reviewing division made a serious error in extrapolating that the lack of clinical benefit by fenofibrates and niacin therapy in patients with mostly normal and borderline TG levels somehow demonstrates that Vascepa would not have clinical benefit in patients with high TG levels, the ANCHOR population. In direct contradiction to the FDA reviewing division’s assertion, the sub-group analyses from these trials indicated that patients with high TG and low HDL had a remarkable reduction in CVD events of 28 % (ACCORD-Lipid), 37 % (AIM-HIGH), and 53 % (JELIS), clearly supporting a therapeutic benefit in ANCHOR sub-population.

We urge you to intervene in this important matter and take actions to overturn the reviewing division’s decision to rescind the ANCHOR SPA. For unclear reasons, the FDA reviewing division is going to great lengths to deny Vascepa for lowering TG in patients with high TG levels and mixed dyslipidemia, even if it means that they have to rely on flawed analysis. We respectfully request that the FDA make this important drug available without undue delay. We admire your integrity and your outstanding track record of compassion and dedication to improving medical care to the underserved, we remain very hopeful that you will investigate this matter fully and fairly, and conclude that the reviewing division erred in its review and that the decision to rescind the ANCOR SPA was unjust.

Kind regards and on behalf of many,

The EPA Drug Initiative

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