Consumer Group Challenges FDA to Abide by Its Own Guidelines

Urges Reinstatement of SPA for Heart Drug Vascepa

NEW YORK, NY, USA, February 4, 2014 /EINPresswire.com/ -- The EPA Drug Initiative (EPADI) asserts that the FDA did not live up to its own scientific integrity standards in rescinding the Special Protocol Assessment (SPA) related to the "ANCHOR" sNDA for the triglyceride (TG) lowering drug, Vascepa, and urges that the Agency adhere to its own policies in the appeal of the SPA rescission decision.

Specifically, EPADI believes that in drawing conclusions from three other failed triglyceride-lowering studies (ACCORD-Lipid, AIM HIGH and HPS2 THRIVE) – each of which involved drugs, objectives/endpoints and patient characteristics different from those in the ANCHOR study – the Agency's integrity has been compromised severely.

Consistent with the Agency's own Staff Manual Guide issued on February 3, 2012 (SMG 9001.1), EPADI urges the FDA to strictly adhere to its own stated policy of placing scientific integrity at the forefront of its mission.

The first key principle of scientific integrity listed in this guide states "Maintaining a firm commitment to science-based, data-driven decision-making." Maintaining scientific integrity is especially important given the very high legal threshold required to rescind a SPA. EPADI believes the Agency has not lived up to this policy commitment, in that:

• As most of the patients in ACCORD-Lipid, AIM HIGH and HPS2 THRIVE had normal or borderline elevated TG levels, these trials could not answer the question of whether TG lowering would be beneficial in patients with high TG levels. Thus, the Agency's reviewing division erred in extrapolating that these three outcome trials proved that TG lowering therapy would not be beneficial in patients with high TG level (~ 200 and < 500 mg/dl), the population covered by the ANCHOR SPA.

• The FDA completely ignored subgroup analyses from these trials, which showed that patients with high TG and low HDL had a reduction in CVD risk of 28% and 37% in ACCORD-Lipid and AIM HIGH, respectively.

• Ironically, analyses of the data from these subgroups support Vascepa's approval for high TGs

based on the effectiveness of these other TG lowering agents in achieving robust CVD risk reduction outcomes for patients already on background statin therapy. This is exactly the ANCHOR population.

The Agency has the opportunity to re-evaluate the data from these studies under the appeal currently underway.

A second key principle of SMG9001.1, “Shielding the Agency’s science and its scientific staff from political influence”, should be taken into account relative to the competitive landscape for Vascepa’s parent company, Amarin Corp. Amarin is a much smaller company than the large pharmaceutical companies whose drugs would compete with Vascepa. Large pharmaceutical companies are constantly accused of attempting to influence FDA decision-making. EPADI hopes this has not occurred during the FDA’s review of Vascepa and urges senior Agency officials to be sure this policy has indeed been vigorously enforced.

We contend that denying patients on background statin therapy the proven and safe TG and LDL-C lowering effects of Vascepa makes absolutely no sense given the epidemic nature of heart disease, the associated costs and toll in terms of human suffering, and the undesirable side effect profile associated with statin therapy. Furthermore, while statins have been shown to reduce CV risk, patients on such therapies continue to have significant residual risk of a repeat event, such as a heart attack.

- Heart disease is the number one cause of death for both men and women in the United States, claiming approximately 1 million lives annually.

- Every 33 seconds someone in the United States dies from cardiovascular disease, which is roughly the equivalent of a September 11th-like tragedy repeating itself every 24 hours, 365 days a year.

- More Americans die of heart disease than of AIDS and all cancers combined.

- In 2013, more than 920,000 Americans will have experienced a heart attack, nearly half of them occurring without prior symptoms or warning signs.

- 250,000 Americans (680 every day of the year) die annually of Sudden Cardiac Death.

- One-half of the victims of Sudden Cardiac Death are under the age of 65.

- An estimated 80 million Americans have one or more types of heart disease.

- Each year, about 8.9 million Americans have chest pain (angina) caused by reduced blood flow to the heart muscle, which occurs when the coronary arteries become blocked with a build-up of plaque.

• While the cost in terms of human suffering is incalculable, in 2008, the total financial cost of cardiovascular disease (coronary heart disease, hypertensive disease, heart failure and stroke) in the U.S. was estimated at $448.5 billion (this includes direct costs such as costs of doctors, hospital services, medications, etc., and indirect costs such as lost productivity). In comparison, the estimated economic cost of cancer in 2007 was $219 billion.

The American Heart Association acknowledges that the amount of triglycerides (or blood fats) in the blood is an important indicator of metabolic health; high TG levels are associated with coronary heart disease, diabetes and fatty liver disease.

Vascepa has demonstrated a remarkable efficacy in lowering TG levels. In ANCHOR, the largest trial ever conducted of an Omega-3 therapy in patients with high TGs on background statin therapy, a 4-gram dose of Vascepa was shown to reduce TG levels by over 21% ($p < .0001$). Significant LDL-C reduction of > 6% was also achieved. No other Omega-3 therapy has been shown to reduce TGs without raising LDL-C. ANCHOR also statistically demonstrated significant decreases in all predefined secondary endpoints, including: Non-HDL-C, Apo B, Lp-PLA2 and VLDL-cholesterol. Of the 702 patients enrolled in ANCHOR, 73% were diabetic. The side effect profile for Vascepa was similar to placebo, making it the safest of all TG lowering agents.

The full FDA Staff Manual Guide on scientific integrity (SMG 9001.1) can be found at: http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm289975.htm

In closing, the EPADI urges Drs. Margaret Hamburg, FDA Commissioner; Stephen Ostroff, FDA Chief Scientific Officer; Janet Woodcock, FDA Director of the Center for Drug Evaluation and Research; and Dr. Curtis Rosebraugh, FDA Director for Drug Evaluation II, to carefully review the Agency's SPA rescission argument to determine whether it fully and conscientiously adheres to all policies issued in SMG 9001.1 on scientific integrity.

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

Please help us by providing your support, comments and testimonials and “spreading the word”.

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