Release Details

Apellis Provides Updates on Injection Kits and Rare Safety Events with SYFOVRE® (pegcetacoplan injection)

August 22, 2023

- *Internal structural variations were identified in the 19-gauge filter needle included in certain injection kits; Apellis recommends use of kits with the 18-gauge filter needle, which are already in distribution*
- *More than 100,000 vials have been distributed/administered between real world and clinical trials; since last update, confirmed one additional event of retinal vasculitis that occurred in May*

WALTHAM, Mass., Aug. 22, 2023 (GLOBE NEWSWIRE) -- Apellis Pharmaceuticals, Inc. (Nasdaq: APLS) ("the Company") today provided an update on injection kits supplied by Apellis and an update on the rare events of retinal vasculitis reported in real-world treatment with SYFOVRE® (pegcetacoplan injection) for geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Recommended use of filter needles included in certain injection kits

As part of the comprehensive investigation into the real-world safety events, internal structural variations were identified in the specific 19-gauge x 1½ inch filter needle included in certain injection kits. Filter needles are used to withdraw treatment from the vial when preparing for an injection procedure. A causal relationship has not been established between the structural variations in this 19-gauge filter needle and the rare events of retinal vasculitis in the real world.

The Company recommends that practitioners immediately discontinue use of any injection kits that contain the 19-gauge filter needle and use injection kits with the 18-gauge filter needle, which are already in distribution. While injection kits previously contained one of two types of filter needles (either 18- or 19-gauge), Apellis is now exclusively distributing injection kits with the 18-gauge filter needle.

"Based on the findings from our investigation, we believe it is prudent that practitioners only use the kits with the 18-gauge filter needle, which are already in distribution. This recommendation is out of an abundance of caution as patient safety is our top priority," said Caroline Baumal, M.D., chief medical officer of Apellis.

Update on rare events of retinal vasculitis reported to date

"To date, more than 100,000 vials have been distributed for commercial use and for administration in clinical trials, and the events of retinal vasculitis continue to be very rare at an estimated real-world rate of 0.01% per injection. We believe SYFOVRE is an important medicine for patients living with this chronic disease and are committed to providing patients with a meaningful and safe treatment," Dr. Baumal continued.

- Over 100,000 SYFOVRE vials have been distributed in the real world and for administration in clinical trials. This includes:
    - Over 78,000 vials distributed since launch, including commercial vials shipped and sample vials distributed to physician practices. Over 26,000 vials distributed in the third quarter to date.
    - Approximately 24,000 SYFOVRE injections administered in clinical trials to date.

- In total, eight events of retinal vasculitis (five occlusive, three non-occlusive) have been confirmed. The last confirmed event of retinal vasculitis occurred on June 20, based on a review of adverse events reported to the Company.
    - This includes one additional event of occlusive retinal vasculitis, which occurred in May, and was reported after our last communication on July 29.
    - Two of the patients had their SYFOVRE injection in April, three in May, and three in June.
    - All events of retinal vasculitis were observed after the first injection of SYFOVRE.
    - One patient remained stable at baseline vision, two patients have recovered vision nearly back to baseline, two patients have severe vision impairment which is unlikely to be resolved, and three patients' outcomes are still pending.
- There are two events of suspected retinal vasculitis. As previously disclosed, there was one event that occurred in May and the patient's vision has returned to baseline. The other event occurred in August and the patient's outcome is pending. Neither event has been confirmed.

All post-marketing adverse events reported to the company, including events of retinal vasculitis, are reviewed by Apellis' Medical and Safety Committee. Any suspected events of vasculitis are also evaluated by external retina/uveitis specialists for adjudication.

About Geographic Atrophy (GA)

Geographic atrophy (GA) is an advanced form of age-related macular degeneration and a leading cause of blindness worldwide, impacting more than one million Americans and five million people worldwide.[1,2] It is a progressive and irreversible disease caused by the growth of lesions, which destroy the retinal cells responsible for vision. The vision loss caused by GA severely impairs independence and quality of life by making it difficult to participate in daily activities. On average, it takes only 2.5 years for GA lesions to start impacting the fovea, which is responsible for central vision.[3]

About SYFOVRE® (pegcetacoplan injection)

SYFOVRE® (pegcetacoplan injection) is the first and only approved therapy for geographic atrophy (GA). By targeting C3, SYFOVRE is designed to provide comprehensive control of the complement cascade, part of the body's immune system. SYFOVRE is approved in the United States for the treatment of GA secondary to age-related macular degeneration.

Marketing applications are currently under review with five regulatory agencies worldwide. A decision in the EU is expected in early 2024, and decisions in Canada, Australia, Switzerland, and the United Kingdom are expected in the first half of 2024.

U.S. Important Safety Information for SYFOVRE® (pegcetacoplan injection)

CONTRAINDICATIONS

- SYFOVRE is contraindicated in patients with ocular or periocular infections, and in patients with active intraocular inflammation

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments
    - Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
- Neovascular AMD
    - In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the

control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.

- Intraocular Inflammation
  - In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.
- Increased Intraocular Pressure
  - Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.
- To report suspected adverse reactions, contact Apellis Pharmaceuticals, Inc. at 1-833-866-3346 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for more information.

About Apellis

Apellis Pharmaceuticals, Inc. is a global biopharmaceutical company that combines courageous science and compassion to develop life-changing therapies for some of the most challenging diseases patients face. We ushered in the first new class of complement medicine in 15 years and now have two approved medicines targeting C3. These include the first and only therapy for geographic atrophy, a leading cause of blindness around the world. With nearly a dozen clinical and pre-clinical programs underway, we believe we have only begun to unlock the potential of targeting C3 across many serious diseases. For more information, please visit http://apellis.com or follow us on Twitter and LinkedIn.

Apellis Forward-Looking Statement

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the safety profile of SYFOVRE. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether the benefit/risk profile of SYFOVRE following these reported events will impact our commercialization efforts; whether SYFOVRE will receive approval from foreign regulatory agencies for GA when expected or at all, including the impact on the likelihood and timing of such approvals of the reported events of retinal vasculitis; and other factors discussed in the "Risk Factors" section of Apellis' Annual Report on Form 10-K with the Securities and Exchange Commission on February 21, 2023 and the Risk Factors section of Apellis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 31, 2023 and in other filings that Apellis may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Apellis specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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[3] Lindblad AS, et al, and AREDS Research Group. Arch Ophthalmol. 2009;127(9):1168-1174.