

ReST Committee Update on Intraocular Inflammation (IOI)

ASRS ReST Committee

Research and Safety in Therapeutics Committee:

- The ASRS Research and Safety in Therapeutics (ReST) Committee is dedicated to apprising members of adverse events (AEs) associated with all retina drugs and devices
- Monitors and reviews member-initiated reports to the ASRS ReST adverse event reporting system
- Serves as a post-market data and safety monitor to help protect patients, and works closely with the US CDC, the US FDA, and pharmaceutical companies to identify and investigate AEs.
- Has investigated numerous AEs and has alerted ASRS members about events ranging from cases of ocular inflammation/noninfectious endophthalmitis following intravitreal injections to cases of suspected fungal endophthalmitis following adjuvant-assisted vitrectomy procedures.
- Generates member alerts, conducts literature reviews, and drafts white papers and articles to provide members with timely information about emerging events that may impact patient safety.

ASRS ReST Committee Relevant COI

- Peter K. Kaiser, MD, FASRS (**Chair**) Apellis (G), Genentech (C,G), IvericBio (C)
- Andre J. Witkin, MD, FASRS (**Chair-elect**) Apellis (G), Genentech (G)
- Ferhina S. Ali, MD, MPH Apellis (C), Genentech (C)
- Fernando Arevalo, MD, PhD, FACS, FASRS Genentech (C), IvericBio (C)
- Netan Choudhry, MD, FACS(C), FASRS Apellis (C)
- Nieraj Jain, MD, FASRS None relevant
- Henry A. Leder, MD Apellis (C)
- Eric W. Schneider, MD, FASRS None relevant
- Lejla Vajzovic, MD, FASRS Apellis (C), Genentech (C,G), IvericBio (C)
- Robin A. Vora, MD IvericBio (C)
- Yoshihiro Yonekawa, MD, FASRS Genentech (G)

C=consultant, G=Research Grant support, S=Stock ownership

Full COI available at <https://www.asrs.org/>


ASRS Exec Committee Relevant COI

- Judy Kim, MD, FASRS – **President** Apellis (C), Genentech (C)
- Philip J. Ferrone, MD, FASRS – **Past President** Apellis (C, G), Genentech (C, G)
- Reginald J. Sanders, MD – **President Elect** None
- Geoffrey G. Emmerson, MD, PhD, FASRS IvericBio (S)
- Jeffrey S. Heier, MD, FASRS Apellis (C,G), Genentech (C,G), IvericBio (C,G)
- J. Michael Jumper, MD, FASRS Genentech (G)
- Gaurav K. Shah, MD, FASRS None relevant
- Audina M. Berrocal, MD, FASRS None relevant

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Timeline of Pegcetacoplan Member Communication

- **ReST AE Reporting System received FIRST case of panuveitis with ROV (July 3, 2023)**
 - **Apellis contacted ReST to discuss safety concerns (July 5, 2023)**
 - Over the next week, ReST committee received 6 additional cases (on file)
 - Apellis and ReST met to discuss severe intraocular inflammation and vasculitis cases from post-marketing surveillance and clinical trials (July 12, 2023)
 - ReST committee **unanimously** agreed to prepare a Member Communication
 - Draft of Member Communication discussed between ReST and Apellis over next 2 days
 - After agreement, draft sent to ASRS Executive Committee (July 14, 2023)
 - ASRS Executive Committee **unanimously** approved member communication (July 15, 2023)
 - Mock-up of **FINAL Member Communication reviewed and agreed to by Apellis (July 15, 2023)**
 - **Member Communication released to membership (July 15, 2023)**
 - **Apellis, ASRS Exec Committee, and ReST reviewed and agreed to this talk (July 22, 2023)**
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Intraocular inflammation[§] reported to ReST (4/18/23-7/21/23)

| pegcetacoplan | ReST | APL |
|---|------|-----|
| All Cases of intraocular inflammation (IOI), n | 21 | 26 |
| Anterior uveitis | 3 | - |
| Posterior uveitis | 1 | - |
| Panuveitis | 17 | - |
| Retinal Vasculitis | 1* | 2** |
| Retinal Occlusive Vasculitis | 7* | 4** |
| Infectious endophthalmitis | 3 | 2 |

Apellis Pharmaceuticals estimates 65,000 vials distributed to date

* Reviewed by ReST Committee, ASRS Executive Committee, and an Independent uveitis/retina specialist panel with no conflict of interest in subject matter; ASRS is aware of 2 suspected cases of retinal vasculitis (awaiting FA to confirm) and 1 suspected case of retinal occlusive vasculitis;

** Apellis cases reviewed by an independent panel of uveitis and retina specialists and Apellis Medical Governance Committee; all Apellis cases (6 confirmed, 2 suspected) are included in the ASRS ReST count. Apellis and ASRS have agreed on the data presented on this slide

Include data from Apellis, ReST Committee call on July 12 and July 22, 2023

[§] Classified by the SUN Classification: THE STANDARDIZATION OF UVEITIS NOMENCLATURE (SUN) WORKING GROUP, Standardization of Uveitis Nomenclature for Reporting Clinical Data. Results of the First International Workshop, Amer J Ophthalmol. 2005 Sep; 140(3) 509-516.

ReST Committee Update on IOI

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