FDA Adverse Event Reporting System (FAERS)
FOIA Batch Printing Report for Cases

Date - Time: 09-May-2023 19:30:42 EDT

Run by: KIA.BAZEMORE@FDA.HHS.GOV

Case ID(s) Printed:

22134131

Total Cases: 1

Total number of Inactive cases: *0

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22134131

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** 15-Mar-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 27-Apr-2023 **Mfr Rcvd Date:** 17-Apr-2023 **Mfr Control #:** US-APELLIS PHARMACEUTICALS-APL-2023-002150 **Application #:** 217171

Patient Information:

Age: 87 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Syfovre		/		UNK	Product used for unknown indication	15-Mar-2023	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Syfovre	1 Day	Unknown	NA				APELLIS PHARMACEUTICALS	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Endophthalmitis	
Visual impairment	

Event/Problem Narrative:

This spontaneous case, manufacturer control number, APL-2023-002150, received from a HCP in the United States, is a serious case report of Medically significant for ENDOPHTHALMITIS (suspected endophthalmitis) and non-serious event of VISUAL IMPAIRMENT (reduced vision) (previously reported as BLINDNESS, Vision loss (right eye)) that occurred in an 86-year-old female patient. No relevant medical history was provided. No relevant concomitant medications were provided. The patient received Syfovre (pegcetacoplan) intravitreally for unknown dose, frequency, and indication beginning on 15-Mar-2023 and the last dose prior to event onset was 15-Mar-2023. On 15-Mar-2023 (a couple hours after the appointment), the patient experienced suspected endophthalmitis and reduced vision (where treatment was administered). She had count fingers vision at that point. The treatment was unknown antibiotics prescribed and further

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testing to confirm endophthalmitis or not. Patient was improving from bacterial culture positive endophthalmitis presenting within a day of injection. At the time of report, the outcome of VISUAL IMPAIRMENT was unknown and ENDOPHTHALMITIS was recovering/resolving. The action taken with Syfovre was unknown. All follow-up information is blended into the initial case narrative above. Case correction performed on 29-Mar-2023 included update of the type of case in the narrative (from PSP to spontaneous). Follow-up information was received on 17-Apr-2023 from the physician, included outcome of the event Endophthalmitis and reporter causality of both events was updated, event Vision loss (right eye) was updated to reduced vision, VISUAL IMPAIRMENT from BLINDNESS. The case APL-2023-002151 was identified as a duplicate and the information was merged. The present case will be retained as case of record. Company comment The reporter (HCP) assessed the causal relationship between VISUAL IMPAIRMENT, ENDOPTHALMITIS as not related with Syfovre but due to injection procedure. There is no detail regarding the patient demographics, concomitant medications, and the results of further testing is sought. However, Apellis assessed the relationship between VISUAL IMPAIRMENT, ENDOPTHALMITIS and Syfovre as related, as the events were reported to occur after administration of Syfovre.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** APELLIS PHARMACEUTICALS **503B Compounding Outsourcing Facility?:**

Literature Text: