Drug Databases (http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Postmarket Requirements and Commitments

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You searched for: Both CBER and CDER; Tavneos; Delayed; Neither

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Applicant:	CHEMOCENTRYX INC A WHOLLY OWNED SUB OF AMGEN INC
Product:	Tavneos (Avacopan)
NDA/BLA Number:	214487
NDA/BLA Approval Date:	10/07/2021
Annual Report Due Date: (must be submitted within 60 days of this date)	10/07/2026
Annual Report Received:	11/25/2025

Requirement/Commitment Number: 1

Required Under:	FDAAA Section 505(o)(3)
Original Projected Completion Date:	09/30/2031
Description:	PMR 4155-1: Conduct a randomized controlled clinical trial of at least five years duration in patients with anti-neutrophil cytoplasmic autoantibody (ANCA)associated vasculitis to evaluate safety outcomes, including hepatotoxicity and drug-induced liver injury, and serious hypersensitivity reactions, including angioedema and anaphylaxis.
Current Status:	Delayed
Explanation of Status:	The final protocol milestone date was missed because of continued discussions with the Agency. Per the applicant's annual status report, as of 9/30/2025, 21 participants have been randomized into the study.

Requirement/Commitment Number: 3

Required Under:	N/A

Original Projected Completion Date:	09/30/2031
Description:	PMC 4155-3: Conduct a randomized controlled clinical trial of at least five years duration in patients with anti-neutrophil cytoplasmic autoantibody (ANCA)associated vasculitis to evaluate efficacy outcomes with long-term avacopan treatment.
Current Status:	Delayed
Explanation of Status:	The final protocol milestone date was missed because of continued discussions with the Agency. Per the applicant's annual status report, as of 9/30/2025, 21 participants have been randomized into the study.

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Page Last Updated: 08/09/2013