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A Phase 1 Randomized Study: Garadacimab Pharmacokinetics, Safety, and Tolerability After Administration via Autoinjector/Pre-Filled Pen Versus Pre-Filled Syringe in Healthy Participants

January 2026 – *The Journal of Clinical Pharmacology* (JCP)

Why is this article important to you?

Learners that complete this activity will have increased knowledge of the pharmacokinetics and safety of garadacimab between pre-filled syringe (PFS) and autoinjector pre-filled pen (AI/PFP) modes of administration. Additionally, learners will acquire deeper insights into the patho-physiology of hereditary angioedema (HAE) and mechanism of action of garadacimab. This activity is designed to increase knowledge of the pharmacokinetics (PK), safety and tolerability of garadacimab following administration by PFS and AI/PFP, as well as across different injection sites.



ACPE Accreditation Statement

The American College of Clinical Pharmacology® is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

UAN: 0665-0000-26-001-H01-P – ACPE 1 Contact Hours

Activity Type: Knowledge-based **Format:** Home-study **Target Audience:** 'P'



ACCME Accreditation Statement

The American College of Clinical Pharmacology® is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

ACCME Designation Statement

The Accreditation Council for Continuing Medical Education designates this journal CE activity for 1 *AMA PRA Category 1™* credit. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Target Audience

Interprofessional team of Physicians, Pharmacists, PhDs and other healthcare professionals interested in expanding their knowledge on the pharmacokinetics and safety of garadacimab between PFS and AI/PFP modes of administration.

Learning Objectives

After completing this activity, the learner will be able to:

1. Describe the study design required to bridge understanding of pharmacokinetics and tolerability of garadacimab between pre-filled syringe and autoinjector/pre-filled pen;
2. Identify the pharmacokinetics of garadacimab administered via pre-filled syringe and autoinjector/pre-filled pen;
3. Explain the pathophysiology of hereditary angioedema;
4. Identify the most common adverse events of garadacimab administered via pre-filled syringe and autoinjector/pre-filled pen.

Requirements to Receive Credit

In order to receive continuing medical education (CME) or continuing pharmacy education (CPE) credit, the learner must register for the educational activity, study the provided journal article, complete the online learning Self-assessment Post-test as well as the online course Evaluation and CME/CPE

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Certificate. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the article, Post-test and Evaluation. Contact CE@ACCP1.org with any questions.

Disclosures:

Article Selection: John N. van den Anker, MD, PhD, Editor-in-Chief, JCP, selected the article for this course and has nothing to disclose.

Planner: Ahmed Abulfathi, PhD, Associate Director, Certara USA, Inc, salary paid through GSK plc, planned the continuing education documentation for this course and all of the relevant financial relationships have been mitigated.

CE Reviewer: Steven Crosby, MA, BSP, RPh, FASCP, FCP, Associate Dean, Associate Professor of Pharmacy Practice, Massachusetts Coll of Pharmacy & Health Sciences, served as the CE Reviewer and has nothing to disclose.

Schedule & Fees

JCP monthly Journal CE articles are generally released on the 1st or 2nd Tuesday of each month. They are priced in packages of January to December for each year. Packages are available at no cost to ACCP Members and \$75/calendar year to Non-members. Once you register, you have access to all of the Journal CE articles for the calendar year.

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Home Study Initial Release and Expiration Dates

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Expiration Date: 1/1/2029

Online Location:

https://accp1.org/Members/ACCP1/4Continuing_Education/Journal_CE.aspx?hkey=adecf2ad-e111-4e26-92b5-bbd8ce8fda14