

Incyte Presents Phase 1/2 Multidose Data for VGA039 (Latacibart) at ISTH 2026, Showing Substantial Bleed Reductions in Patients with all Von Willebrand Disease Types

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- Treatment with latacibart led to an 81% median reduction in annualized bleeding rate (ABR) across all bleeding categories and patient types with von Willebrand disease (VWD)
- Latacibart, administered via a once monthly subcutaneous dosing regimen, was shown to be safe and well tolerated over multiple doses in this study
- Pivotal Phase 3 VIVID-6 trial evaluating latacibart's potential to be the first targeted therapy for VWD is currently enrolling

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 13, 2026-- Incyte (Nasdaq: INCY) today announced complete safety and efficacy data from all patients (n=16) enrolled in the Phase 1/2 multidose study of VGA039 (latacibart), a novel, Protein S-targeting, investigational monoclonal antibody for patients with von Willebrand disease (VWD). The data are being shared in an oral presentation today at the 34th Congress of the International Society on Thrombosis and Haemostasis (ISTH 2026 Congress) in Paris.

Latacibart modulates Protein S to improve hemostasis, potentially enhancing the body's ability to prevent or reduce the frequency of bleeding episodes. Latacibart is in pivotal Phase 3 development for patients with VWD, the most common inherited bleeding disorder. If approved, latacibart has the potential to be the first, once monthly subcutaneous prophylactic therapy for patients with VWD, offering an important alternative to the frequent intravenous infusions of replacement factor concentrates commonly used in the prophylactic setting today. Given its novel mechanism, latacibart may also have potential in other bleeding disorders.

"These results continue to build a highly consistent body of evidence supporting latacibart as a significant potential treatment advancement for patients with VWD," said Pablo J. Cagnoni, M.D., President, Incyte and Global Head of Research and Development. "This multidose dataset underscores the potential of latacibart to address the longstanding need for a prophylactic therapy that provides meaningful protection for patients with all types of VWD. We are continuing to enroll the Phase 3 VIVID-6 study as we work toward redefining the standard of routine prophylactic care for patients with VWD."

As of May 5, 2026, data from all 16 patients enrolled in the Phase 1/2 multidose study were available, and all participants had completed the multidose regimen of six doses of latacibart, with maintenance doses administered subcutaneously every four weeks. Key data highlights include:

- Substantial reductions in ABR (annualized bleeding rate) were seen across study patients, including all VWD types and bleed types, such as serious GI and hemophilia-like joint and muscle bleeds.
 - The median ABR reduction across all VWD types and bleed categories was 81%.
 - In patients switching from prior von Willebrand factor (VWF)-containing prophylaxis (IV infusions multiple times per week), bleed reductions were 75-100%, indicating potential improvement over current standard of care.
 - Among patients not previously receiving IV prophylaxis, 7 had historical ABRs >12, a key eligibility criterion for the Phase 3 VIVID-6 study. In this group, ABR reductions ranged from 46-100%, with nearly all patients (6/7) achieving reductions >73%.
 - Latacibart treatment resulted in ~86% reduction in VWF-treated breakthrough bleeds, with 70% of patients with prior VWF-treated bleeds not experiencing a VWF-treated breakthrough bleed while on treatment.
- All participants who entered the study with a substantial bleed burden transitioned to continue receiving latacibart in the ongoing open-label extension study.
- Latacibart once monthly subcutaneous prophylaxis was safe and well tolerated over multiple doses.
 - Three treatment-emergent adverse events (TEAEs) related to latacibart were reported: two Grade 2 headaches in one patient and one report of Grade 1 injection site reactions. There was also one unrelated serious adverse event of severe gastrointestinal (GI) bleeding in a patient with a history of frequent and severe GI bleeding.

"Many people with VWD struggle with bleeding and need more effective and convenient prophylactic treatments. The study results showed treatment with latacibart delivered consistent and clinically meaningful reductions in bleeding across a diverse group of VWD patients, including patients with all major types of the disease and individuals transitioning from intensive IV prophylaxis," said Allison Wheeler, M.D., MSCI, Associate Professor of Pediatrics at the University of Washington. "Equally important, the favorable safety profile and once monthly subcutaneous dosing regimen have the potential to substantially reduce treatment burden while providing consistent bleed protection. Together, these findings provide a strong foundation for the Phase 3 study and support latacibart's potential as an important new treatment option for patients with VWD."

More information regarding the ISTH 2026 Congress can be found on the ISTH website: <https://www.isthcongress.org/> (Session details: Novel Therapies for Bleeding Disorders, Including VWD and Rare Bleeding Disorders – 2; Publication Number: OC 32.3).

About VGA039 (latacibart)

VGA039 (latacibart) is an investigational monoclonal antibody therapy with a novel mechanism of action that targets Protein S, with dual actions promoting platelet attachment and enhancing fibrin deposition to restore hemostasis. Latacibart has the potential to be a universal prophylactic therapy for numerous bleeding disorders, starting with all types of von Willebrand disease (VWD) and bleeding sites. As a subcutaneously self-administered investigational antibody therapy with a once monthly dosing regimen, latacibart has the potential to improve bleeding outcomes,

convenience, and quality of life for patients.

Latacibart has received Breakthrough Therapy, Fast Track, orphan drug and rare pediatric disease designations from the U.S. Food and Drug Administration (FDA). Latacibart has advanced into the Phase 3 VIVID-6 study ([NCT07115004](#)), a global single arm cross-over study to investigate safety and efficacy of the subcutaneous administration of latacibart as prophylaxis for bleeding in patients with every type of VWD, including those with a high disease burden.

Incyte acquired VGA039 (latacibart) in July 2026 as part of its acquisition of Vega Therapeutics, Inc., a wholly owned subsidiary of Star Therapeutics LLC.

About the VIVID Clinical Program

The VIVID multinational clinical program consists of multiple clinical trials, from Phase 1 to 3, in both a platform multi-phase protocol (VIVID-1-5) and a standalone Phase 3 protocol (VIVID-6) evaluating the safety and efficacy of VGA039 in VWD. The VIVID clinical program is active across 6 continents and designed to support future registrational filings globally.

About von Willebrand Disease

Von Willebrand disease (VWD) is the most common inherited bleeding disorder in which the blood does not clot properly, caused by low or defective von Willebrand factor (VWF). People with VWD may experience excessive bleeding with varying severity and frequency, negatively impacting their daily lives. Current therapies for VWD prophylaxis include factor replacement therapies requiring multiple intravenous (IV) infusions every week. Approximately 135,000 people in the United States have been diagnosed with von Willebrand disease.¹

About Incyte®

Incyte is redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive portfolio of next-generation medicines across our key franchises: Hematology, Oncology and Inflammation & Autoimmunity.

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Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the data to be presented by Incyte at the ISTH 2026 Congress; Incyte's expectations regarding VGA039's (latacibart's) clinical development and regulatory approvals; the potential and promise latacibart offers patients with bleeding disorders, including the potential to be the first once monthly subcutaneous prophylactic therapy for patients with VWD, its potential improvement over current standards of care for patients with VWD and other bleeding disorders, and its potential ability to address significant unmet need, reduce treatment burden and improve quality of life; and Incyte's aspirations and goals as set forth under the heading "About Incyte."

Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including results from clinical trials of and the sufficiency of clinical trial data for latacibart, as well as Incyte's other products and product candidates, to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Incyte's ability to achieve commercial success for latacibart, if approved; Incyte's ability to obtain and maintain protection of intellectual property for its products and technology; Incyte's reliance on third parties and partners; the acceptance of Incyte's products in the marketplace; market competition, sales, marketing, manufacturing and distribution requirements; and those risks and uncertainties discussed in greater detail in Incyte's reports filed with the U.S. Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2025 and its quarterly report on Form 10-Q for the quarter ended March 31, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

¹ Data on File.

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