



## Absci Announces First Participants Dosed in Phase 1 Clinical Trial of ABS-101, a Potential Best-In-Class anti-TL1A Antibody for the Treatment of Inflammatory Bowel Disease

05/13/2025

*Absci becomes clinical stage company with ABS-101, first AI-designed biologic for IBD, beginning Phase 1 trial*

*Preclinical data for ABS-101 demonstrates high potency and potential for quarterly dosing, an improvement in efficacy and convenience over first-generation anti-TL1As*

*Interim data anticipated in the second half of 2025*

VANCOUVER, Wash., May 13, 2025 (GLOBE NEWSWIRE) -- [Absci Corporation](#) (NASDAQ: ABSI) a clinical-stage biopharmaceutical company advancing breakthrough therapeutics with generative AI, today announced that the first healthy volunteers have been dosed in a randomized, placebo-controlled Phase 1 study evaluating ABS-101, an investigational anti-TL1A antibody engineered with Absci's generative AI platform. ABS-101 is formulated for quarterly subcutaneous dosing, superior potency against monomeric and trimeric TL1A, and reduced immunogenicity risk enabling improved efficacy, patient convenience, and adherence. Interim safety, PK/PD, and immunogenicity data are expected in the second half of 2025.

"We are excited to advance ABS-101 into Phase 1 clinical trials," said Andreas Busch, PhD, Absci Chief Innovation Officer. "Designed and optimized using our generative AI platform, ABS-101 exhibits high affinity and potency, expected low immunogenicity, and an extended dosing interval—all of which are intentional attributes achieved through AI."

The Phase 1 ([ACTRN12625000212459p](#)) randomized, double-blind, placebo-controlled, first-in-human study of single ascending doses of ABS-101 will evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) in healthy volunteers. The study is expected to enroll approximately 40 healthy adult participants. The primary endpoint is safety and tolerability, with PK, PD, and immunogenicity serving as secondary endpoints. The Phase 1 interim data readout is expected in the second half of 2025.

"The initiation of our first clinical trial marks Absci's transition to a clinical-stage biotech, with a pipeline wholly designed and optimized using AI," said Sean McClain, Founder and CEO of Absci. "ABS-101 is the first proof point of our generative AI platform—a therapeutic engineered with speed and precision using AI. With a growing pipeline of AI-designed biologics, we're accelerating a new chapter to bring better biologics to patients, faster."

In addition to ABS-101, Absci is rapidly advancing a pipeline of AI-designed biologics targeting high-value indications, including ABS-201—an anti-prolactin receptor antibody for androgenetic alopecia, commonly known as male and female pattern hair loss. ABS-201 is an important innovation in an indication with significant unmet medical need and large patient population. Preclinical data for ABS-201 shows improved hair regrowth versus existing standard of care, high potency, and a favorable safety profile, with Phase 1 trials expected to begin in early 2026.

### **About ABS-101**

ABS-101 is a potential best-in-class anti-TL1A antibody that demonstrates high affinity and potency, ability to bind the monomer and trimer of TL1A, anticipated low immunogenicity, high bioavailability in non-human primates (NHP), and potential to be administered subcutaneously with an anticipated dosing interval of 8-12 weeks, or even less frequently. Absci has also shared data illustrating that ABS-101 shows reduced internalization of TL1A immune-complexes in *in vitro* THP-1 immunogenicity tests compared to a competitor molecule with a high clinical anti-drug antibody (ADA) rate, suggesting a lower chance of ABS-101 developing ADAs in clinical settings. Additionally, Absci has shown data from ABS-101's NHP PK/PD study, demonstrating confirmatory prolonged target engagement, dose dependency of target engagement (including a ceiling effect), and significantly improved target engagement as compared to competitor molecules at a comparative dosing regimen. ABS-101 was well-tolerated at all doses in a 13-week GLP study in cynomolgus monkeys. Absci anticipates reporting interim Phase 1 data for this study in the second half of 2025.

### **About Absci**

Absci is advancing the future of drug discovery with generative design to create better biologics for patients, faster. Our Integrated Drug Creation™ platform combines cutting-edge AI models with a synthetic biology data engine, enabling the rapid design of innovative therapeutics that address challenging therapeutic targets. Absci's approach leverages a continuous feedback loop between advanced AI algorithms and wet lab validation. Each cycle refines our data and strengthens our models, facilitating rapid innovation and enhancing the precision of our therapeutic designs. Alongside collaborations with top pharmaceutical, biotech, tech, and academic leaders, Absci is advancing its own pipeline of AI designed therapeutics. These include ABS-101, a potentially best-in-class antibody to treat inflammatory bowel disease (IBD), as well as other indications, and ABS-201, a groundbreaking innovation in hair regrowth with the potential to redefine treatment possibilities for androgenetic alopecia, commonly known as male and female pattern baldness. Absci is headquartered in Vancouver, WA, with an AI Research Lab in New York City, and Innovation Center in Switzerland. Learn more at [www.absci.com](http://www.absci.com) or follow us on LinkedIn ([@absci](#)), X ([@Abscibio](#)) and [YouTube](#).

### **Absci Forward-Looking Statements**

Certain statements in this press release that are not historical facts are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements containing the words "will," "may," "pursues," "anticipates," "plans," "believes," "aims," "potential," "forecast," "estimates," "extends," "expects," and "intends," or similar expressions. We intend these forward-looking statements, including statements regarding the capabilities of our Integrated Drug Creation platform, our technology development efforts and the application of those efforts, the potential benefits of our partnership with Twist, the plans and success of our current and future partnerships and the ability to generate advancements towards treating disease using generative AI drug creation to accelerate the development of novel candidate therapies, the anticipated value to us under our partnerships, and our internal therapeutic asset programs, to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, and we make this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies, and prospects, which are based on the information currently available to us and on assumptions we have made. We can give no assurance that the plans,

intentions, expectations, or strategies will be attained or achieved, and furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control, including, without limitation, risks and uncertainties relating to our ability to effectively collaborate on research, drug discovery and development activities with our partners or potential partners, our dependence on third parties to support our internal development programs, including for the manufacture and supply of preclinical and clinical supplies of our product candidates or components thereof, our existing and potential partners' ability and willingness to pursue the development and commercialization of programs or product candidates under the terms of our partnership agreements, and overall market conditions and regulatory developments that may affect our and our partners' activities under these agreements, along with those risks set forth in our most recent periodic report filed with the U.S. Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the U.S. Securities and Exchange Commission. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

**Absci Investor Contact**

Alex Khan

VP, Finance & Investor Relations

[investors@absci.com](mailto:investors@absci.com)

**Absci Media Contact**

[press@absci.com](mailto:press@absci.com)