Absci Announces First Participants Dosed in Phase 1/2a HEADLINE™ Trial of AI-Designed Antibody ABS-201™ for Androgenetic Alopecia

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Study to evaluate safety and efficacy of novel anti-PRLR antibody; interim data anticipated in the second half of 2026

Trial design leverages operational synergies to enable accelerated registrational trials for androgenetic alopecia (AGA) and Phase 2 for endometriosis

KOL seminar scheduled for December 11 to discuss new human ex vivo *data, clinical trial design, and market opportunity in AGA*

VANCOUVER, Wash. and NEW YORK, Dec. 04, 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 the Phase 1/2a HEADLINE study evaluating ABS-201, an investigational anti-prolactin receptor (PRLR) antibody engineered with Absci's generative AI platform.

The Phase 1/2a clinical trial will assess the safety, tolerability, immunogenicity, pharmacokinetics (PK), pharmacodynamics (PD), and efficacy of ABS-201. Interim data are expected in the second half of 2026.

"This milestone represents a truly exciting and transformative leap forward for regenerative biology. By advancing ABS-201 into the clinic, we are executing on our strategy to deliver a pipeline of differentiated assets," said Sean McClain, Founder & CEO. "We believe this program highlights the massive leverage in our business model: using our AI engine to unlock high-value biological targets like PRLR, and then efficiently navigating clinical development to address significant unmet needs in both dermatology and women's health."

"Current treatments for androgenetic alopecia and endometriosis are often characterized by limited efficacy and significant side effects. As prolactin has been demonstrated to be a key driver for both hair loss and endometriosis, this offers us a novel pathway for treatment for these patients," said Andreas Busch, PhD, Chief Innovation Officer at Absci. "ABS-201 represents a potential best-in-class approach, targeting the prolactin receptor with a highly specific antibody designed for superior durability and potency. We are eager to evaluate how this novel mechanism translates in the clinic, with the goal of providing a safe, effective, long-lasting solution for millions of patients who have been underserved by the standard of care for decades."

The Phase 1/2a HEADLINE trial in AGA is a randomized, double-blind, placebo-controlled first-in-human study, enrolling up to 227 healthy volunteers with or without AGA. The primary endpoints are safety and tolerability. Secondary endpoints include PK, PD, immunogenicity, and efficacy readouts measuring target area hair count (TAHC), target area hair width (TAHW), target area darkening/pigmentation (TAHD), and patient/investigator reported outcome measures.

The single ascending dose (SAD) portion of the trial will test approximately 4-6 IV dose groups for safety, tolerability, PK and PD. Following the SAD portion of the trial, a multiple ascending dose (MAD) portion will test approximately 3-4 subcutaneous dose groups in healthy volunteers with androgenetic alopecia.

The MAD portion of this clinical trial is powered to demonstrate human proof-of-concept for the use of ABS-201 to treat androgenetic alopecia by stimulating significant hair regrowth. The company believes that this trial, if successful, will position the program for accelerated registrational trials.

"Human hair growth is tightly regulated by specific molecular signals, but our ability to intervene has been limited," said Rodney Sinclair, MD, Professor of Dermatology at the University of Melbourne and principal investigator. "The scientific premise behind ABS-201 is compelling. It directly targets the prolactin receptor, a known driver of catagen, the regression phase of the hair cycle. Blocking prolactin signaling effectively removes the 'hand-brake' on hair growth. This approach works upstream of testosterone and DHT. It acts earlier in the balding process and before miniaturization. I believe this represents one of the most scientifically sound approaches to hair restoration I have seen."

Absci will be hosting a virtual KOL seminar on Thursday December 11 to discuss the anticipated clinical development path, market opportunity, and differentiated profile of the ABS-201 program. The company will also disclose additional, new human *ex vivo* data that further supports the PRLR mechanism of action underlying this program.

In November 2025, Absci announced that the company will also be pursuing endometriosis as an additional indication for its ABS-201 anti-PRLR antibody. The Phase 1/2a clinical trial in AGA will provide safety, tolerability, and PK assessments that the company believes would enable Phase 2 clinical development in endometriosis. The company plans to initiate Phase 2 clinical development of ABS-201 in endometriosis in the fourth quarter of 2026, leveraging the insights, including safety and tolerability data, generated from the SAD portion of this Phase 1/2a AGA study. Given this synergistic development plan, Absci expects to achieve an interim readout from the Phase 2 trial in endometriosis in the second half of 2027.

About ABS-201 and Androgenetic Alopecia
Androgenetic alopecia, commonly known as male-pattern or female-pattern hair loss, affects approximately 80 million Americans. The condition causes crown balding and receding hairlines in men, and progressive hair thinning in women. Currently, the only FDA-approved treatments – minoxidil and finasteride – show limited efficacy and notable side effects, leaving patients with limited therapeutic options.

ABS-201 represents a novel therapeutic approach targeting prolactin receptors to stimulate hair follicle regeneration and promote durable hair regrowth as demonstrated in *in vivo* studies. In preclinical studies, the antibody demonstrated statistically significant superior hair regrowth compared to minoxidil in a preclinical mouse model. Absci anticipates an interim efficacy readout from its Phase 1/2a HEADLINE study in the second half of 2026.

About ABS-201 and Endometriosis
Endometriosis is an inflammatory disease defined by endometrial-like lesions found outside the uterine lining. Symptoms include pelvic pain, heavy bleeding, infertility, and ovarian cysts. It is a chronic, painful condition that significantly impacts the quality of life of these patients. There is currently no medical or surgical cure for this disease, which is prevalent in an estimated 5-10% of women of reproductive age worldwide, including an estimated 9

million women in the US.

ABS-201 has potential to become an efficacious and safe therapeutic treatment for endometriosis. This program is well-positioned to be best-in-class with respect to the anti-prolactin receptor mechanism based on its affinity, superior half life and bioavailability in NHPs, and high concentration formulation. Absci anticipates initiation of a Phase 2 study in endometriosis in the fourth quarter of 2026, with an interim data readout in the second half of 2027.

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 including 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 hair-loss. ABS-201 is also being investigated as a potential "best-in-class" therapeutic for endometriosis, a condition with significant unmet medical need and market potential. 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 or follow us on LinkedIn (@absci), X (@Abscibio) and YouTube.

Absci Forward Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding any or all of the following: (i) Absci's preclinical studies, clinical trials, as well as partnered and internally developed programs, including, without limitation, manufacturing capabilities, status of such studies and trials and expectations regarding data, safety and efficacy generally; (ii) data included in the above-described oral presentation, as well as the ability to use data from ongoing and planned clinical trials for the design and initiation of further clinical trials; (iii) Absci's strategy, goals, anticipated financial performance and the sufficiency of its cash resources; (iv) regulatory submissions and authorizations, including timelines for and expectations regarding any anticipated regulatory agency decisions; (v) the expected benefits of its collaborations with partners; and (vi) the therapeutic value, development, and commercial potential of antibody therapies, as well as other technologies. Risks that contribute to the uncertain nature of the forward-looking statements include, without limitation, the risks and uncertainties discussed under the heading "Risk Factors" in Absci Corporation's most recent annual report on Form 10-K and in any other subsequent filings made by Absci Corporation with the U.S. Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. We disclaim any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

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