

Gelteq Announces Commencement of Preclinical Trial for Novel Gel-Based Antihistamine Formulation Targeting Allergy Market

Study to Support Potential FDA Approval via 505(b)(2) Pathway

MELBOURNE, Australia, Sept. 05, 2025 (GLOBE NEWSWIRE) -- Gelteq Limited ("Gelteq" or the "Company"), a clinical and science-based company specialising in gel-based oral delivery solutions, today announced plans to commence a preclinical bioequivalence study in September 2025 to evaluate its novel gel-based formulation of a widely used antihistamine for allergy treatment. The study will be conducted by Adgyl Lifesciences (a partner of Eurofins Advinus), a leader in preclinical contract research services.

If preclinical results are successful, Gelteq anticipates advancing to human clinical trials targeting U.S. Food and Drug Administration (FDA) approval via the 505(b)(2) regulatory pathway.

"Our gel-based delivery platform is expected to transform traditional pharmaceutical products currently available on the market, especially where patient compliance and dosage control are critical," said Nathan Givoni, CEO of Gelteq. "By applying our technology to a well-established antihistamine, we see a significant opportunity to capture value in the allergy market, where patient-friendly formats and flexible dosing remain unmet needs."

Allergic conditions affect over 50 million people annually in the United States alone (1). The global antihistamine market was valued at approximately USD \$9 billion in 2023 growing at a 6% CAGR, projected to reach over USD \$12 billion by 2028 (2). Demand spans paediatric, adult, and increasingly, animal health (3), reflecting the diverse applications for antihistamine therapies.

Gelteq's proprietary gel formulations aim to address key limitations of traditional tablets and syrups, including palatability challenges for children, swallowing difficulties for elderly patients, and precise dosing needs in veterinary medicine (3).

"Our innovative gel technology offers potential advantages in taste masking, ease of administration, and flexible dosing," added Mr. Givoni. "These attributes are particularly relevant in paediatrics and veterinary care where delivering effective allergy treatments can be challenging."

About Gelteq Ltd.

Headquartered in Melbourne, Australia, Gelteq (NASDAQ: GELS) is a clinical and science-based company dedicated to developing and commercialising gel-based oral delivery

solutions for prescription drugs, nutraceuticals, pet care, sports nutrition, and other applications. Gelteq's proprietary formulation technology aims to address challenges associated with conventional drug delivery, including taste masking, swallowing difficulties, and precision dosing. For more information, visit www.gelteq.com.

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Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, contained herein are forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those expressed or implied in such statements. For a discussion of these risks and uncertainties, refer to Gelteq's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 20-F filed on November 15, 2024. Gelteq undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date hereof.

References

1. American College of Allergy, Asthma & Immunology. (2023). *Allergy facts*. American College of Allergy, Asthma & Immunology. <https://acaai.org/allergies/>
2. Grand View Research. (2024, March). *Antihistamine market size, share & trends analysis report*. Grand View Research. <https://www.grandviewresearch.com/industry-analysis/antihistamine-market>
3. MarketsandMarkets. (2023, November). *Veterinary dermatology drugs market by product, animal type, route of administration, end user – Global forecast to 2028*. MarketsandMarkets. <https://www.marketsandmarkets.com/Market-Reports/veterinary-dermatology-drugs-market-177021512.html>



Source: Gelteq Limited