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Bubs Announces US-Based Infant Formula Clinical Trial, Reinforcing Its Commitment to the North American Market

7 September, 2023, Melbourne: Bubs Australia Limited (ASX: BUB) (“**Bubs**” or “**the Company**”) today announced it had commenced nationwide enrolment for its Growth Monitoring Study (GMS) clinical trial in the United States, as part of its ongoing commitment to serve North American families. The first infant was enrolled in the study in late August, and Bubs plans to actively enrol infants online and through thirteen highly regarded healthcare clinics across the United States. The study is designed to evaluate the growth, tolerance, and safety of new infant formulas as a standard part of the U.S regulatory process.

Bubs began importing its infant formulas into the United States in May 2022 as a response to the infant formula shortage. Bubs was the first company to offer assistance from abroad and was pleased to participate in the US government’s Operation Fly Formula program to bring formula to retail shelves as quickly as possible. Since then, Bubs has been building its brand with caregivers and pediatricians and has cemented its position as the number one goat milk formula brand in the United States.

Following the guidelines set by the U.S Food and Drug Administration (FDA), Bubs is actively taking steps to transition from temporary ‘enforcement discretion’ to a permanent market position. Planning for Bubs’ clinical trial has been underway since the beginning of the year, in partnership with the FDA. The successful completion of the Protein Efficiency Ratio (PER) study in June 2023, a key U.S regulatory milestone that validates protein quality, paved the way to proceed with the clinical trial.

In line with the regulatory timeline, Bubs plans to submit results from the GMS to the FDA by September 2024 with a full infant formula submission by October 2024. The ongoing partnership with the FDA and formal processes associated with regulatory approval continue to be an operational and strategic priority for Bubs’ management team.

“Bubs answered the call when we were needed by American families, and in so doing established a trusted relationship with many US healthcare professionals, parents and caregivers. We are excited to build upon that relationship by providing the FDA with the data necessary for Bubs to take up its permanent place in the American market,” said Richard Paine, COO.

Bubs’ clinical trial involves a nationwide Growth, Tolerance, and Safety study of healthy term infants consuming Bubs’ infant formulas monitored by healthcare professionals. The study evaluates all three Stage 1 formulas in the market including Goat Milk, two Cow Milk products as well as a commercially available formula as the control. Additionally, the study contains a breast-feeding cohort for reference. Infant growth during the study is measured by healthcare professionals at designated clinical sites, with additional input from parents and caregivers.



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The study is being conducted by Validcare, an innovative Contract Research Organization (CRO) that is a pioneer in electronic data capture to streamline patient enrolment, participation, and analysis of results. The study is overseen by Principal Investigator Dr. Keith Aqua, who is the Co-Founder of the HCA Florida Institute for Women's Health and Body and the Co-Founder of Visions Clinical Research. He is Board-certified in obstetrics and gynecology. As a Certified Physician Investigator, he has been a Principal Investigator on over 350 clinical trials.

“As this study’s principal investigator and practicing clinician, I am pleased to lead this important study and potentially provide moms and babies with ongoing, expanded choices for quality infant formula – especially in light of recent shortages.” said Dr. Keith Aqua, MD.

The study is approved by the Institutional Review Board (IRB) and registered on clinicaltrials.gov. For more information on eligibility for the Bubs Growth Monitoring Study, please visit <https://validcare.com/bubs-gms/>

About Bubs Australia

Bubs Australia is on a mission to nourish new generations of happy Bubs, with clean label nutritional products that provide the foundation for setting up a lifetime of good eating habits. Founded in 2005 and long trusted by families throughout APAC, Bubs entered the U.S. market first with its toddler formulas in 2021 and then with its infant formulas in 2022 at the height of the U.S. formula crisis. Today, Bubs is the #1 Goat Milk Infant and Toddler Formula in the U.S. Other products include Bubs 365 Day Organic Grass Fed Cow Milk Formula and Bubs Supreme Infant Formula. Bubs can be purchased at aussiebubs.com and major retailers including Target, Amazon and Walmart. Visit aussiebubs.com for more information.

About Validcare

Validcare is a high-performance CRO (Contract Research Organization) for pharma, biotech and supplement companies. Validcare uniquely applies a combination of 1st principles engineering and 21 CFR Part 11 compliant automation to de-risk and optimize study performance from protocol design through database lock. Founded by experts with more than 20 years of industry experience, Validcare offers the leading solution for best practices in streamlining research for regulatory compliant, life-improving products. For more information, visit validcare.com or call 844-825-4322.

This release is approved by the Board of Directors.

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