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Intrommune Reports Positive Update from Ongoing Phase 1 Study in Peanut Allergy

INT301 Met Safety Goals Across Four Dose Levels in Cohort 1

Patient Treatment Now Ongoing in Fully Enrolled Cohort 2

Intrommune Launches Series B Financing

NEW YORK, Feb. 08, 2022 (GLOBE NEWSWIRE) -- Intrommune Therapeutics, Inc., a New York-based, clinical stage biotechnology company developing a patient-friendly treatment platform for peanut and other food allergies, today announced an initial update from its ongoing Phase 1 OMEGA Trial of INT301 in patients with peanut allergy. INT301 is a novel peanut desensitization immunotherapy formulated as a fully-functioning toothpaste and conveniently administered during a patient's daily toothbrushing routine.

"After acceptance of our IND for INT301, we launched and completed Cohort 1 of our Phase 1 OMEGA Clinical Study last year in adults with peanut allergy. While the study remains blinded, there were no significant adverse events in any patient," said Michael Nelson, CEO, Intrommune Therapeutics. "We believe that these results support the potential for oral mucosal immunotherapy (OMIT) to be a safe and convenient option for people with food allergies."

Intrommune Therapeutic's Phase 1 OMEGA Clinical Study is a randomized, double-blind, placebo-controlled study that enrolled adults with peanut allergy in a 3:1 ratio to receive either an escalating dose of INT301 or placebo. Cohort 1 patients started at the lowest dose and were titrated through four increasing doses of INT301. The study groups are blinded to the investigator, participants, and the Intrommune study team.

Based on pre-specified criteria, including the safety profile of patients enrolled in Cohort 1, the internal Safety Monitoring Committee approved the opening of Cohort 2. Cohort 2 is designed to help ascertain the next highest safe starting dose, which may shorten the period required to reach INT301 maintenance dosing. Cohort 2 has been fully enrolled at this time.

"Today there is a high unmet need for other medical options in patients suffering from peanut allergy. The successful progress of this study of INT301 through its first safety hurdle is a very promising signal," said Dr. Michael Blaiss, Clinical Professor of Pediatrics, Medical College of Georgia at Augusta University.

"The momentum demonstrated in the clinic has enabled the initiation of the company's Series B fundraising process. The proceeds of this financing will accelerate the growth of Intrommune by expanding our operations, clinical research, and regulatory efforts, while moving INT301 aggressively towards registration," said Mr. Nelson.

About Peanut and Other Food Allergies
Food allergies affect more than 220 million people, including approximately 32 million people in the U.S.

Management of food allergies currently focuses on avoidance of exposure to triggering foods, though often such foods, including peanuts, are common ingredients in food products and therefore difficult to avoid. Many people with peanut allergy are accidentally exposed and experience potentially life-threatening reactions, including anaphylaxis, each year. Unfortunately, food allergy remains an area of tremendous unmet medical need.

About Oral Mucosal Immunotherapy™
Oral mucosal immunotherapy (OMIT) uses a specially formulated toothpaste to stabilize and deliver allergenic proteins to immunologically active areas of the oral cavity with the greatest potential for allergy desensitization. Success with allergy immunotherapy hinges on consistent exposure of a patient's immune system to gradually "desensitize" the patient to the specific allergy trigger over time. OMIT presents advantages over other approaches to allergy immunotherapy due to its targeted delivery and simplified administration, which supports the potential for improved adherence.

About Intrommune Therapeutics
Intrommune, dedicated to improving and protecting the lives of people with food allergy, is developing the revolutionary oral mucosal immunotherapy (OMIT) treatment platform for food allergies. OMIT is a patient-friendly solution for over 220 million people, including 32 million people in the U.S., who suffer from life-altering food allergies. Intrommune Therapeutic's lead product, INT301, has entered phase 1 clinical trials. All of phase 1 results along with future studies are intended to support the premise of OMIT being a safe, effective and convenient therapy for patients who suffer from peanut allergy.

For more information on Intrommune Therapeutics, please visit http://www.intrommune.com

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