Intrommune Receives IND Clearance From U.S. Food and Drug Administration for INT301

Milestone Marks Advance for Oral Mucosal Immunotherapy for Peanut Allergies

NEW YORK, Feb. 04, 2021 (GLOBE NEWSWIRE) -- Intrommune Therapeutics, a New York-based biotechnology company developing a patient-friendly treatment platform for peanut and other food allergies, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug application (IND) for its lead product, INT301. INT301 is an oral mucosal immunotherapy (OMIT) in development for the treatment of peanut allergies. INT301's unique formulation is designed to desensitize an individual with peanut allergy using a toothpaste delivery system.

The active IND enables Intrommune to initiate its clinical program to assess the tolerability, safety, and efficacy of INT301 in peanut allergic patients.

"The FDA's acceptance of our IND validates our novel OMIT platform -- marking a significant milestone for Intrommune and enabling INT301 to advance into the clinic," said Michael Nelson, CEO, Intrommune Therapeutics. "We look forward to initiating our clinical programs to confirm the power of our OMIT toothpaste to potentially transform the lives of patients with peanut allergies."

Approximately 6 million people, including an estimated 1.7 million children, have peanut allergy in the U.S. If approved, INT301 has the potential to be the first allergy immunotherapy treatment that easily integrates into a person's daily routine as both first-line and long-term maintenance therapy for peanut allergy.

"The OMIT platform is expected to improve allergy immunotherapy by increasing the precision of treatment delivery and promoting treatment adherence," said Erick Berglund, PhD, Chief Scientific Officer, Intrommune Therapeutics. "OMIT delivers immunotherapy to the oral mucosa, which has the highest likelihood of initiating allergy desensitization. Targeted delivery of medication is expected to decrease the rate of side effects linked to swallowing food allergy proteins, including eosinophilic esophagitis, gastrointestinal discomfort and potentially life-threatening anaphylaxis that requires the use of emergency epinephrine."

"Today marks an inflection point in the treatment of the historically high unmet patient need area of peanut allergies with a targeted approach to desensitization -- via this simple and elegant solution of a fully-functional toothpaste which has daily adherence and compliance conveniently 'baked' into the platform. Furthermore, I expect the absence of a restrictive REMS (Risk Evaluation and Mitigation Strategy) for the administration of INT301, providing ease-of-access for patients," said Abhit Singh MD, Chief Regulatory Officer, Intrommune Therapeutics.

About Peanut and Other Food Allergies
Food allergies affect an estimated 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 many such foods such as 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 promises advantages over other approaches to allergy immunotherapy due to its targeted delivery, simplified administration, and support of reliable, long-term 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 offers a potential a long-term, patient-friendly, disease-modifying solution for the 220 million people, including approximately 32 million people in the U.S., who suffer from life-altering food allergies. Intrommune's lead product, INT301, is expected to be 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

Cautionary Statement Regarding Forward Looking Statements

This release may contain "forward-looking statements." Forward-looking statements are identified by certain words or phrases such as "may," "will," "aim," "will likely result," "believe," "expect," "will continue," "anticipate," "estimate," "intend," "plan," "contemplate," "seek to," "future," "objective," "goal," "project," "should," "will pursue" and similar expressions or variations of such expressions. These forward-looking statements reflect the companies' current expectations about their future plans and performance. These forward-looking statements rely on a number of assumptions and estimates which could be inaccurate, and which are subject to risks and uncertainties. Actual results could vary materially from those anticipated or expressed in any forward-looking statement made by the companies. The

companies disclaim any obligation or intent to update the forward-looking statements in order to reflect events or circumstances after the date of this release.

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Contact:
John F. Kouten
JFK Communications, Inc.
609-241-7352
jfkouten@jfkhealth.com