Moonlight Therapeutics Receives FDA Clearance of IND Application for MOON101 and Announces New Funding

NEWS PROVIDED BY
Moonlight Therapeutics, Inc.
16 Oct, 2025, 16:30 EDT

Moonlight is developing MOON101 as a treatment for peanut allergy and has received clearance from the FDA to proceed clinical testing of MOON101 in peanut allergic adults and children as well as new funding.

Atlanta, GA, October 16, 2025 /PRNewswire-PRWeb/ --

Moonlight Therapeutics, Inc., a biotechnology company developing a platform to treat food allergies, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for MOON101 to initiate its first clinical trial in individuals with peanut allergy. In addition, Moonlight has raised private funds to support clinical development of MOON101 and received a new grant from the U.S. Defense Health Agency (DHA)'s Congressionally Directed Medical Research Programs (CDMRP) to expand its pipeline beyond MOON101.

Last year, Moonlight raised its first equity round of $2.4 million in Seed funding from Portal Innovations, Allerfund, and Invest Georgia that would enabled the company to initiate its first clinical trial, SURVEYOR. The FDA clearance of the IND application for MOON101 will now enable the start of the SURVEYOR trial whose aim will be to evaluate the safety of MOON101 in peanut allergic adults and children. The trial will be funded through a $3 million cooperative grant from the National Institute of Allergy and Infectious Diseases and new private funding from SOSV, a global deep tech venture capital firm.

"This FDA clearance marks a pivotal milestone for Moonlight and for families living with peanut allergy," said Samir Patel, co-founder and CEO of Moonlight Therapeutics. "We are now positioned to move MOON101 into the clinic and evaluate its safety in peanut allergic individuals with the eventual goal of demonstrating that MOON101 can modulate the immune system of a peanut allergic person away from anaphylactic reactions that can occur from even small amounts of exposure to peanuts."

MOON101 uses Moonlight's proprietary intradermal allergen immunotherapy platform to desensitize individuals with a food allergy. The platform delivers allergens directly into the skin using a small, minimally invasive dermal stamp. The treatment is designed for at-home self-administration that requires less than five minutes of wear time of the stamp and has shown promising results in preclinical studies of peanut allergies. The new grant from the DHA's Congressionally Directed Medical Research Programs (CDMRP) will support the company's broader pipeline development, enabling advancement of its proprietary intradermal allergen immunotherapy platform beyond MOON101.

The upcoming clinical trial will be conducted in collaboration with leading food allergy centers in the United States. "There are over six million people in the United States with a peanut allergy, but the vast majority of patients are not pursuing treatment and unmet need remains high," said Dr. Brian Vickery, Chief, Division of Allergy/Immunology, Children's Healthcare of Atlanta, Marcus Professor of Pediatric Immunology, Emory University School of Medicine and lead clinical investigator on the trial. "We are excited to begin testing the safety and tolerability of MOON101 in peanut-allergic individuals and evaluate its potential as a patient-friendly and convenient treatment option."

"For too long, peanut allergy has been overlooked rather than recognized as a frontier of medicine," said Stephen Chambers, General Partner at SOSV and Managing Director at startup development program IndieBio. "In reality, peanut-allergic individuals are overdue for the kind of innovation we've already unleashed in other immune-mediated diseases. This is exactly why SOSV invests: to back the science and founders in transforming overlooked populations into the next wave of breakthrough therapies."

About Moonlight Therapeutics
Moonlight Therapeutics is an early-stage biotechnology company based in Atlanta, Georgia. The company is developing an intracutaneous, allergen-specific immunotherapy platform to treat food allergies. Food allergies affect more than 30 million people in the United States. Moonlight's proprietary platform is designed to deliver allergens directly to immune cells in the skin and can be used for single or multiple allergens. This technology was invented at Texas Tech University and is supported by the Georgia Research Alliance. To learn more, visit moonlighttx.com.

Forward-Looking Statements
This press release contains certain forward-looking statements, including statements regarding Moonlight's clinical development plans, expected outcomes in clinical trials, regulatory interactions, and potential impacts of its technology. These forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including but not limited to the progress of drug development, availability of funding, regulatory decisions, clinical trial outcomes, and other factors that could cause actual results to differ materially. Moonlight undertakes no obligation to update or revise any forward-looking statements.

Disclaimer
This work is supported in part, as detailed above, by the Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense (DOD), in the amount of $3,309,999.00, through the Peer Reviewed Medical Research Program under Award No. HT9425-25-1-0548. Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DOD.

MOON101 will be evaluated in the clinic in peanut allergic individuals with the eventual goal of demonstrating that this therapy can modulate the immune system of a peanut allergic person away from anaphylactic reactions that can occur from even small amounts of exposure to peanuts.

Media Contact
Samir Patel, Moonlight Therapeutics, Inc., 1 4043488294, ir@moonlighttx.com, https://moonlighttx.com

SOURCE Moonlight Therapeutics, Inc.