Azitra Announces Rare Pediatric Disease Designation for ATR-12 for the Treatment of Netherton Syndrome

-- IND filing for ATR-12 expected by the end of 2020 –

Branford, CT, May 27, 2020 -- Azitra, Inc.**,** a clinical-stage medical dermatology company addressing serious skin conditions by harnessing the microbiome, today announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to ATR-12 for the treatment of Netherton syndrome (NS), a chronic genetic skin disease that can be life threatening.

The FDA grants Rare Pediatric Disease Designation for pediatric diseases affecting a limited number of patients, that are serious or life-threatening, and primarily occurs in individuals from birth to age 18. The goal of FDA's Rare Pediatric Disease Designation and Voucher Programs is to encourage the development of new drug and biological products for the prevention and treatment of rare pediatric diseases.

If ATR-12 is approved, Azitra would be eligible to receive a priority review voucher, which can be used for priority review of a drug marketing application for another product being developed by the company. Alternatively, the voucher could be sold or transferred.

"Currently available treatments for NS have limited efficacy and can cause serious side effects; we are hopeful that ATR-12 will offer a new treatment option to patients suffering from this life-threatening disorder," said Richard Andrews, President and CEO of Azitra. "Obtaining Rare Pediatric Disease Designation is a major milestone for ATR-12, a product candidate based on our core microbiome technology. Azitra has developed a system to engineer commensal skin bacterial to deliver disease-modifying proteins. This designation will significantly expedite the product's clinical development and we expect to enter clinical testing in 2021."

About Netherton Syndrome

NS is a rare autosomal recessive disease of the skin, characterized by severe inflammation, pruritus, scaling, redness, and dehydrated skin. It is estimated to affect one of every 200,000 live births worldwide. It has been reported that one in ten infants with NS die in their first year of life. Patients can suffer lifelong challenges including red, scaly skin, hair defects (bamboo hair) and an ongoing higher than normal risk for infection and allergy. The disease is caused by mutations in the *SPINK5* gene, which encodes the serine protease inhibitor Lympho-epithelial Kazal-type related inhibitor (LEKTI). There are currently few treatment options for NS.

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About ATR-12

ATR-12 is a proprietary strain of *Staphylococcus epidermidis* engineered to express therapeutic levels of LEKTI protein to treat NS. The microbiome-based product is designed to reside on the skin and provide continuous delivery of the missing protein. The function of LEKTI is to regulate protease activity in the epidermis. Proteases in the skin play an important role in the shedding of skin cells in a process known as desquamation. When LEKTI is absent or has reduced activity, excess shedding occurs, and the skin is sensitive, open, and appears red and scaly. ATR-12 will be provided as a non-aqueous ointment for topical application.

About Azitra

Azitra, Inc. is a clinical-stage medical dermatology company that combines the power of the microbiome with cutting-edge genetic engineering to treat skin disease. The company was founded in 2014 by scientists from Yale University and works with world-leading scientists in dermatology, microbiology, and genetic engineering to advance its pharmaceutical programs to treat cancer therapy-associated skin rashes, targeted orphan indications and atopic dermatitis. Learn more at www.azitrainc.com

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