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Omnix Medical Announces First Patients Dosed in Phase II Trial of Antimicrobial Lead Compound OMN6

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First-in-class treatment for life-threatening, drug-resistant Acinetobacter baumannii infections advances toward Phase II clinical proof-of-concept

Omnix Medical

Omnix Medical, a biopharmaceutical company developing next-generation anti-infectives for severe multidrug-resistant infections, announced that the first patients in a Phase II trial (NCT06087536) have been dosed with its lead compound OMN6, a first-in-class antimicrobial targeting severe multidrug-resistant Acinetobacter baumannii infections associated with high mortality and limited treatment options. The patients were treated at Rabin Medical Center (Beilinson Hospital), Samson Assuta Ashdod University Hospital, and Shamir Medical Center in Israel.

The ongoing Phase IIa study is a prospective, multinational, multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial evaluating OMN6 in patients with hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by Acinetobacter baumannii complex (ABC), including carbapenem-resistant strains classified by the WHO as critical priority pathogens. The trial is designed to identify safe and well-tolerated doses and to assess the PK profile of OMN6 in patients.

OMN6 is being evaluated as a novel first-line treatment with a membrane-disrupting mechanism of action designed to address severe infections with high unmet medical need and limited available treatment options.

“Mortality rates in critically ill patients infected with carbapenem-resistant Acinetobacter baumannii can reach up to 60%, while treatment options remain extremely limited. The WHO has classified Acinetobacter baumannii as a critical priority pathogen as it causes some of the most difficult multidrug-resistant infections in intensive care medicine worldwide,” said Professor Keith Kaye MD, MPH, Chief of the Division of Allergy, Immunology and Infectious Diseases at Rutgers Robert Wood Johnson Medical School and a member of Omnix’s Clinical Advisory Board. “The growing global spread of multidrug-resistant Gram-negative pathogens underscores the urgent need for novel anti-infective approaches with differentiated mechanisms of action.”

“What makes OMN6 particularly interesting is its differentiated membrane-disrupting mechanism of action, which is specifically designed to selectively target bacterial membranes and rapidly destroy them,” said Professor Yehuda Carmeli, MD, MPH, Head of the National Institute for Antibiotic Resistance and Infection Control, Tel Aviv Medical Center and a member of Omnix’s Clinical Advisory Board. “In severe Acinetobacter infections, where treatment options remain extremely limited and resistance development continues to increase globally, innovative antimicrobial peptides such as OMN6 with a differentiated mechanism of action may offer an important new therapeutic strategy.”

“Dosing the first patient in our Phase II study marks a major milestone for Omnix Medical and advances OMN6 further toward clinical proof-of-concept,” said Dr. Moshik Cohen-Kutner, Co-Founder & Chief Executive Officer of Omnix Medical. “OMN6 was engineered to selectively bind to bacterial membranes and rapidly destabilize them, leading to bacterial cell death while minimizing the potential for resistance development. We believe this novel mechanism could represent a

promising new therapeutic approach for patients suffering from life-threatening multidrug-resistant Gram-negative infections with very limited available treatment options."

OMN6 is a first-in-class, fast-acting antimicrobial peptide (AMP) with a novel mechanism of action designed to rapidly form pores in bacterial membranes, leading to a direct physical destruction of the pathogens. The compound targets multidrug-resistant Gram-negative pathogens, including carbapenem-resistant Acinetobacter baumannii (CRAB), and is derived from naturally occurring insect-derived antimicrobial peptides. OMN6 addresses severe infections with high unmet medical need and limited treatment options. Following successful Phase I development, the compound is currently being evaluated in an ongoing Phase II clinical study.