FDA Clears First Technology to Distinguish between Bacterial and Viral Infections Using the Body's Immune Response – The MeMed BV® Test and MeMed Key® Platform

- *MeMed BV is a first-of-its kind test that decodes the immune response to accurately distinguish between bacterial or viral infections within minutes*

- *MeMed Key is a pioneering platform that enables rapid and sensitive measurements of multiple proteins at the point-of-need*

- *The MeMed technology suite enables better informed antibiotic treatment decisions, an essential tool in the fight against the global threat of resistant bacteria*

HAIFA, Israel, Boston, MA; September 20th, 2021 – MeMed, a leader in the emerging field of advanced host-response technologies, today announces that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for use of the MeMed BV® test on the point-of-need platform MeMed Key® to help healthcare providers distinguish between bacterial and viral infections. The technology has been cleared for both children and adults.

Bacterial and viral infections are often clinically indistinguishable, leading to the prescription of antibiotics for the treatment of viral infections, for which they are ineffective. Antibiotic misuse drives the emergence of antimicrobial resistance (AMR), one of the biggest healthcare challenges of our time. The novelty of MeMed's technology is that it decodes the body's immune response to infection, the 'host response', rather than focusing on detecting the presence of a microbe. This allows robust diagnosis when the infection site is inaccessible or unknown, even when the pathogen is undetectable using conventional tests, or when the cause of infection are emerging new pathogens. It enables better informed antibiotic treatment decisions, an essential tool in the fight against resistant bacteria.

"For those of us who care for acutely ill children, we have been waiting decades for accurate, rapid diagnostics to confidently guide the care of moderately ill children without a clear focus of infection or recognizable viral illness. This novel test offers promise to help differentiate those children with self-limited viral illness from those with possible bacterial infection, thereby supporting the judicious use of antibiotics," **said Rich Bachur, MD, Professor of Pediatrics and Emergency Medicine, Harvard Medical School, and Chief, Division of Emergency Medicine, Boston Children's Hospital.**

"It has been a decade long journey to reach this point from concept to impacting patient lives," **said Dr. Eran Eden, MeMed's co-founder and CEO.** "This FDA clearance is a breakthrough moment in the field of advanced host-response and could not have been achieved without the dedication of the MeMed team, our clinical partners in the US and around the globe, and the support of the US Department of Defense and EU Commission."

Sergey Motov, MD, Professor of Emergency Medicine, Maimonides Medical Center, New York, said: "Host-response technologies are a new frontier in the management of patients with infectious diseases, with great potential to improve patient outcomes. Every day, I see adults with a complicated medical history presenting to the emergency room with a suspected respiratory tract infection. A technology like MeMed BV can significantly aid in their management."

"We are now using MeMed BV in my department routinely to aid in determining whether a child with fever has a bacterial or viral infection. For example, we recently had a complicated case of a young child with fever but without a clear source. MeMed BV helped in early identification of a severe bacterial infection, that would otherwise be masked by viral PCR detection, lead to a change in the course of treatment, and made a big difference in the patient's outcome," **said Dr Adi Klein, Director of Pediatric Division, Hillel Yaffe Medical Center and Head of the Israeli Clinical Pediatric Society.** "Introducing MeMed's technology has had a significant impact on our medical practice, enabling us to be better stewards of antibiotics and improving patient outcomes."

FDA clearance was based on a multi-center blinded clinical validation study enrolling over 1,000 children and adults and addresses goals laid out in the US National Action Plan for Combating Antibiotic Resistant Bacteria. The test provides highly accurate results with Area Under the Curve of 90% and 97% (primary and secondary endpoints). MeMed has established its US base in Boston and is ramping up commercial activities to ensure broad availability of its products across the US.

About MeMed
Our mission is to translate the immune system's complex signals into simple insights that transform the way diseases are diagnosed and treated, profoundly benefiting patients and society. To learn more about MeMed and our solutions, please visit http://www.me-med.com

About MeMed BV®
MeMed BV® is a first-of-its-kind immune-based protein signature test, developed and validated over the course of decade-long collaborations with leading academic and commercial partners. It provides physicians with an indispensable tool to help distinguish between bacterial and viral infections across multiple pathogens, even if the infection site is inaccessible or unknown. MeMed BV® measures and computationally integrates the levels of three immune system proteins: TRAIL, IP-10 and CRP. When run on the MeMed Key® platform, MeMed BV® provides a result within 15 minutes. MeMed BV® has been independently validated on thousands of patients and the results have been published in leading peer-reviewed journals (including Pediatrics, The Lancet ID, PLOS One, BMJ Peds and European Journal of Clinical Microbiology & Infectious Diseases). The MeMed BV® test has received a CE Mark in Europe and AMAR clearance from the Israeli Ministry of Health.

About MeMed Key®
MeMed Key® is a pioneering technology platform, enabling highly sensitive measurements of multiple proteins, within minutes, at the point of need. It opens the way to quantification of a vast array of human proteins in healthy and disease states, where and when it actually matters. The MeMed Key® development program has been partially funded by the US Department of Defense and the EU Commission. MeMed Key® has received a CE Mark in Europe and AMAR clearance from the Israeli Ministry of Health.

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