

B·R·A·H·M·S PCT Joins the Fight Against Antibiotic-Resistant Organisms **Expanded FDA clearance results in an effective, new tool for reducing antibiotic exposure in patients with lower respiratory tract illnesses and sepsis**

WALTHAM, Mass., July 18, 2017 /PRNewswire/ -- [B·R·A·H·M·S GmbH](#), a part of Thermo Fisher Scientific Inc., today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for expanded use of the [B·R·A·H·M·S PCT sensitive KRYPTOR](#) assay. The assay helps hospital clinicians decide whether to initiate antibiotic therapy in patients with suspected or confirmed lower respiratory tract infections (LRTI) and when to safely discontinue antibiotics in patients with LRTI and sepsis.

The new clearance provides clinicians in emergency departments, intensive care and other hospital units with an effective tool for antibiotic stewardship, identified by the Centers for Disease Control (CDC) as a key strategy for addressing the problem of antibiotic resistance.¹ It is estimated that at least 30 percent of antibiotics prescribed in the U.S. are unnecessary,² contributing to the spread of antibiotic-resistant bacteria.

As a sensitive and specific biomarker of the presence and severity of bacterial infection, B·R·A·H·M·S PCT sensitive KRYPTOR has been shown to reduce antibiotic prescription rate and duration in patients with LRTI, defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD). Evaluating the decline in [B·R·A·H·M·S PCT levels over time](#) aids clinicians in determining whether to discontinue antibiotic therapy for patients with LRTI or sepsis, without compromising patient safety.

"We are thrilled that the FDA has expanded the use of B·R·A·H·M·S PCT sensitive KRYPTOR to include antibiotic therapy decision-making," said Patrick Durbin, senior vice president and president of specialty diagnostics at Thermo Fisher Scientific. "Clinicians in the U.S. now have an important tool to support their antibiotic stewardship efforts, benefiting their patients as well as the community at large."

About B·R·A·H·M·S PCT (Procalcitonin) sensitive KRYPTOR

B·R·A·H·M·S PCT sensitive KRYPTOR is the first and leading procalcitonin (PCT) assay cleared for clinical use in the U.S. In use in many European countries since 1996, the value of B·R·A·H·M·S PCT in supporting care of critically ill and septic patients has been reinforced through more than 3000 publications in the U.S. and in Europe. PCT is included in antibiotic stewardship guidelines issued by IDSA (Infectious Disease Society of America) and the Surviving Sepsis Campaign.^{3,4}

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with revenues of \$18 billion and more than 55,000 employees globally. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics and increase laboratory productivity. Through our premier brands – Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific and Unity Lab Services – we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive support. For more information, please visit www.thermofisher.com.

¹ Centers for Disease Control and Prevention. *Antibiotic resistance threats in the United States, 2013* Atlanta, GA: CDC;2013

² Fleming-Dutra et al., Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care

Visits, 2010-2011, JAMA. 2016;315(17):1864-1873. doi:10.1001/jama.2016.4151.

³ Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016.

⁴ Barlam T, et al., Guideline for Implementing an Antibiotic Stewardship Program, Infectious Diseases Society of America, CID 2016:62.

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