**bioMérieux's VIDAS® B•R•A•H•M•S PCT™ becomes the first FDA-cleared procalcitonin assay as an aid for antibiotic stewardship in respiratory infections and sepsis**

**Marcy l'Etoile (France) - February 24, 2017** – bioMérieux, a world leader in the field of *in vitro* diagnostics, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the expanded use of VIDAS® B•R•A•H•M•S PCT™, an automated assay measuring procalcitonin (PCT) levels, to help clinicians make important decisions regarding the optimal use of antibiotics in two common clinical situations: lower respiratory tract infections (LRTI) and sepsis.

With these two new additional claims, VIDAS® B•R•A•H•M•S PCT™ becomes the first and only FDA-cleared procalcitonin test available in the U.S. market to assist physicians in antibiotic management for patients with suspected or confirmed LRTI or sepsis. In the case of patients with LRTI, VIDAS® B•R•A•H•M•S PCT™ will aid physicians in decision-making to safely reduce overall antibiotic use. In the case of sepsis patients, VIDAS® B•R•A•H•M•S PCT™ will aid physicians on deciding when antibiotics can be safely discontinued. Using VIDAS® B•R•A•H•M•S PCT™ in these frequent and important clinical situations will help reduce inappropriate and unnecessary antibiotic use, which may avoid the side effects associated with their use while slowing and preventing the emergence of resistant bacteria.

"*Committed to the diagnosis of infectious diseases for more than 50 years, we are very honored to receive this innovative claim expansion. Antimicrobial resistance is considered as a major threat to public health and this FDA clearance illustrates our capacity to provide clinicians with high medical value tests to help them make important treatment decisions. The goal is to achieve better outcomes for patients and to ensure that each of them receives the appropriate treatment,*" said Mark Miller, Corporate VP, Chief Medical Officer at bioMérieux.

"*True to its pioneering spirit, bioMérieux worked with the FDA to develop a strategy which undertook a comprehensive evaluation of the published literature and conducted an in-depth analysis – termed a meta-analysis – to support the two new indications for use. These studies validated the vital role of VIDAS® B•R•A•H•M•S PCT™ as an aid for antibiotic stewardship and the important role which diagnostic tests can play to curb the rise of multi-resistant bacteria,"* highlighted Sam Bozzette, Medical Affairs Americas at bioMérieux.

Originally FDA-cleared in 2007, VIDAS® B•R•A•H•M•S PCT™ was the first automated test measuring procalcitonin in the U.S. to aid in the risk assessment for sepsis and septic shock on the first day following admission to an intensive care unit (ICU). In June 2016, this test received an additional FDA clearance to aid in assessing the risk of mortality for patients with severe sepsis by monitoring PCT levels serially over 96 hours.

PRESS RELEASE

## About VIDAS®

The VIDAS® automated immunoassay platform, designed for small test series, is well-suited to emergency situations. The very broad menu of tests allows clinicians to provide diagnosis, monitoring and prognosis for a number of diseases, particularly in the field of infectious diseases and emergency testing. Among them, VIDAS® B•R•A•H•M•S PCT™ provides test results in just 20 minutes. With over 30,000 instruments used by clinical laboratory professionals, the VIDAS® range has the largest installed base of automated laboratory immunoassay systems in the world[1], which makes this innovation available to a large number of hospitals.

## About Lower Respiratory Tract Infections

Lower respiratory tract infections (LRTI), are common across all age groups. In 2013, there were about 150 million reported LRTIs[2]. These resulted in 2.7 million deaths, accounting for 4.8% of all deaths in 2013[3]. LRTI represents a leading cause of clinic visits and admissions to the hospital following an Emergency Department visit[4], and collectively includes the syndromes of community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbations of chronic obstructive pulmonary Disease (AECOPD). These three conditions are commonly treated with antibiotics despite the fact that a large proportion are caused by reasons which do not require the administration of antibiotics[5].

## About Sepsis

Sepsis is a severe infection in which the human immune response leads to life-threatening organ dysfunction. Around 27 million people in the world are affected by sepsis each year. In its most severe form, septic shock, there is a 30% mortality. Making the diagnosis as fast as possible, defining and administering the most appropriate antibiotic therapy and knowing when to safely stop antibiotic treatment represent the current major unmet medical needs in this medical condition which could lead to less antimicrobial resistance while safely improving patient outcomes.

## bioMérieux's pledge to fight sepsis

VIDAS® B•R•A•H•M•S PCT™ is part of bioMérieux's sepsis solution range. bioMérieux' offering enables workflow optimization, allowing the sepsis patients' samples to reach the laboratory and be analyzed rapidly. It also comprises: blood cultures with BacT/ALERT® or BacT/ALERT® VIRTUO™, a new fully automated CE-marked blood culture system making 24/7 reception and processing of these urgent samples possible; the molecular syndromic FilmArray® BCID Panel, which in 1 hour, and with only 2 minutes hands-on time, allows pathogen identification; VITEK® MS for automated fast identification of pathogens using MALDI-TOF spectrometry; and VITEK® 2 for automated reliable pathogen identification and antibiotic susceptibility testing.

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[1] *CAP Today, July 2016*

[2] Global Burden of Disease Study 2013, Collaborators (22 August 2015). "Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013.". *Lancet (London, England)*

[3] GBD 2013 Mortality and Causes of Death, Collaborators (17 December 2014). "Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013.". *Lancet.*

[4] http://www.hcup-us.ahrq.gov/reports/statbriefs/sb174-Emergency-Department-Visits-Overview.pdf

[5] Shapiro D J, Hicks L A, Pavia A T, Hersh A L. Antibiotic prescribing for adults in ambulatory care in the USA, 2007–09. Journal of Antimicrobial Chemotherapy 2013

## About bioMérieux

*Pioneering Diagnostics*

A world leader in the field of *in vitro* diagnostics for over 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2016, revenues reached €2,103 million, with more than 90% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the Euronext Paris stock market
(Symbol: BIM/Reuters: BIOX.PA/Bloomberg: BIM.FP – ISIN: FR0010096479).
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