bioMérieux submits for FDA Clearance of the BIOFIRE® FILMARRAY® Pneumonia Panel

Marcy l'Étoile, France – April 19th, 2018 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces that BioFire Diagnostics, its molecular biology affiliate, has submitted to the Food and Drug Administration for 510(k) clearance of the BIOFIRE® FILMARRAY® Pneumonia Panel. This new panel will aid in the diagnosis of specific agents that cause infections of the lower respiratory tract.

BIOFIRE builds upon its 25 years of molecular diagnostics expertise with the development of its most advanced panel to date, the BIOFIRE® Pneumonia Panel. BIOFIRE® tests have changed lab workflow and patient management across multiple disease states. The BIOFIRE® Pneumonia Panel will complement the existing BIOFIRE® Respiratory Panel and BIOFIRE® Respiratory Panel 2 to provide a comprehensive diagnostic solution for respiratory infections.

Randy Rasmussen, CEO of BioFire Diagnostics and Executive VP Molecular Biology of bioMérieux said: "*Pneumonia is one of the most common reasons patients go to the hospital, yet the underlying cause of the infection is rarely identified. This leads to over-treatment of the patient and overuse of antibiotics. Using the BIOFIRE® Pneumonia Panel the hospital will be able to rapidly identify the cause of a patient's pneumonia allowing targeted, effective treatment.*"

The BIOFIRE® Pneumonia Panel seeks authorization from the FDA to identify 33 targets in Sputum (including endotracheal aspirate) and Bronchoalveolar Lavage (including mini-BAL) sample types. The target list includes: 18 bacteria, 8 viruses and 7 antibiotic resistance genes. Fifteen of the bacterial targets will be reported with information about the abundance of organism in a given sample. This is a novel feature for a molecular diagnostic panel and is analogous to the semi-quantitative reporting that is traditionally done with culture in the clinical laboratory. bioMérieux plans on pursuing registration in other parts of the world.

The BIOFIRE® Pneumonia Panel is compatible with all existing instrumentation including the FILMARRAY® 1.5, FILMARRAY® 2.0, and FILMARRAY® TORCH systems.

PRESS RELEASE

ABOUT THE BIOFIRE® FILMARRAY® PLATFORM:

The BIOFIRE® FILMARRAY® System is an FDA-cleared and CE-marked multiplex PCR system that integrates sample preparation, amplification, and detection into one closed system. The BIOFIRE® FILMARRAY® System requires only two minutes of hands-on time and has a total run time of about 45 to 65 minutes, depending on the panel. The BIOFIRE® FILMARRAY® System has the largest infectious disease pathogen menu commercially available composed of:

- BIOFIRE® FILMARRAY® Respiratory Panel, a comprehensive panel of 20 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in viral transport media.
- BIOFIRE® FILMARRAY® Respiratory Panel 2 (RP2), a comprehensive panel of 21 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® FILMARRAY® Respiratory Panel 2 *plus* (RP2*plus*), CE marked and FDA cleared, a comprehensive panel of 22 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® FILMARRAY® RP EZ for the detection of 11 viral and 3 bacterial pathogens associated with respiratory infections. FDA cleared and CLIA-waived for use in the US only.
- BIOFIRE® FILMARRAY® Blood Culture Identification (BCID) Panel, capable of identifying 27 of the most common causes of bloodstream infections and associated antimicrobial resistances directly from positive blood culture.
- BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel, for identification of 22 of the most common viral, bacterial, and parasitic causes of infectious diarrhea directly from stool in Cary Blair transport media.
- BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

As of March 31, 2018, the number of BIOFIRE® FILMARRAY® Systems installed globally reached more than 6,500 units.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 43 subsidiaries and a large network of distributors. In 2017, revenues reached €2.3 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, 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 - ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

Corporate website: www.biomerieux.com. Investor website: www.biomerieux-finance.com.

CONTACTS

Investor Relations
bioMérieux
Sylvain Morgeau
Tel.: + 33 4 78 87 22 37
investor.relations@biomerieux.com

Media Relations
bioMérieux
Aurore Sergeant
Tel.: + 33 4 78 87 20 53
media@biomerieux.com

Image Sept
Laurence Heilbronn
Tel.: + 33 1 53 70 74 64
lheilbronn@image7.fr

Claire Doligez
Tel.: + 33 1 53 70 74 48
cdoligez@image7.fr

BioFire Diagnostics, LLC
Wade Stevenson
Tel.: +1 801-736-6354 x1463
wade.stevenson@biofiredx.com