bioMérieux receives US FDA 510(k) Clearance and CLIA-waiver for the fast and innovative BIOFIRE® SPOTFIRE® System and its BIOFIRE® SPOTFIRE® Respiratory (R) Panel and will be submitting the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini for 510(k) clearance

Marcy l'Étoile (France) – February 8th 2023

bioMérieux, a world leader in the field of *in vitro* diagnostics, has received U.S. Food and Drug Administration (FDA) 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for the fast and innovative BIOFIRE® SPOTFIRE® System and its BIOFIRE® SPOTFIRE® Respiratory (R) Panel. bioMérieux also announces that it will be submitting a 510(k) for the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini.

The COVID-19 pandemic has demonstrated the need for healthcare professionals to have diagnostic tests available as close as possible to the patient, providing actionable results quickly. With the totally new and innovative BIOFIRE® SPOTFIRE® System and its BIOFIRE® SPOTFIRE® Respiratory (R) Panel, bioMérieux further expands its syndromic testing technology outside traditional clinical laboratories to near patient testing locations such as urgent care in or outside of the hospitals, physician offices including pediatricians, and other healthcare facilities directly in contact with patients.

The BIOFIRE® SPOTFIRE® solution allows care for patients suspected of respiratory tract infections with results delivered during a patient's visit in approximately 15 minutes. CLIA-waiver allows the BIOFIRE® SPOTFIRE® System and the BIOFIRE® SPOTFIRE® R Panel to be used by non-lab professionals at the point-of-care.

"O*ur new system is a true revolution in healthcare with an unprecedented time to result and proximity to the patient. It opens the door for bioMérieux to deliver the proven medical value associated with multiplex panels to many more individuals, in decentralized near-patient settings"* said Mark Miller, Executive Vice President, Chief Medical Officer, bioMérieux.

The BIOFIRE® SPOTFIRE® R Panel detects 15 of the most common bacteria, viruses, and viral subtypes that cause respiratory tract infections*.

To fully address the needs of Point of Care testing, , bioMérieux has also developed the BIOFIRE® SPOTFIRE® R Panel Mini. This Panel is intended to detect 5 of the most common viral causes of upper respiratory tract infections: SARS-CoV-2 (virus associated with COVID-19), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus. The BIOFIRE® SPOTFIRE® R Panel Mini is not yet available for sale.The FDA submission of this panel is anticipated by the end of Q1 2023.

With a system footprint approximately the size of a standard sheet of paper and a scalability up to 4 modules, the system is designed to meet testing volume needs of any size of out of hospital setting.

PRESS RELEASE

*** Viruses**: Adenovirus, Coronavirus (seasonal), Coronavirus SARS-CoV-2, Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B virus, Parainfluenza virus, Respiratory syncytial virus. **Bacteria**: *Bordetella pertussis, Bordetella parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae*

"*We are proud to deliver such an innovative syndromic testing technology at the Point of Care. We believe the* BIOFIRE® SPOTFIRE® *solution is a real game changer in patient care, allowing physicians to give patients an accurate and rapid diagnosis, using only one test, during the actual patient visit. Our syndromic offer will cover most patient care settings in the US -expanding our business coverage and opportunities dramatically,*" declared Pierre Boulud, Chief Operating Officer, Clinical Operations, bioMérieux.

The full commercial launch of BIOFIRE® SPOTFIRE® System and its BIOFIRE® SPOTFIRE® R Panel is scheduled for early April in the US market.

Additional BIOFIRE® SPOTFIRE® panels will be developed to meet other infectious disease patient needs at the point-of-care.

BIOMÉRIEUX GAME CHANGER FOR 60 YEARS

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 45 countries and serves more than 160 countries with the support of a large network of distributors. In 2021, revenues reached €3.4 billion, with over 90% of sales outside of France.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) 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.
www.biomerieux.com.

bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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