bioMérieux receives US FDA 510(k) clearance for the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini and will apply for CLIA-waiver

Marcy-l'Étoile (France), April 13, 2023 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the fast and accurate multiplex PCR*-based BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini. bioMérieux will immediately apply for Clinical Laboratory Improvement Amendments (CLIA) waiver for the test.

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. The BIOFIRE® SPOTFIRE® R Panel Mini is the second multiplex PCR-based test cleared for use on the BIOFIRE® SPOTFIRE® System. Both this system and its 15-target BIOFIRE® SPOTFIRE® Respiratory Panel received FDA-clearance and CLIA-waiver in February 2023.

The new BIOFIRE® SPOTFIRE® R Panel Mini detects five 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, in about 15 minutes.

"We know that in the post-pandemic world patients justifiably demand diagnostic results which are important to them and their families. The inclusion of Rhinovirus into this syndromic panel increases clinicians' ability to provide their patients with a definitive result compared to the other respiratory tests available in the United States which contain only the other 1-4 viruses" declared Mark Miller, Executive Vice-President, Chief Medical Officer, bioMérieux.

The BIOFIRE® SPOTFIRE® System is a small, scalable, multiplex PCR platform designed to bring central laboratory diagnostic results to the decentralized point-of-care (POC) clinical setting. It is the first FDA-cleared PCR system to provide results in under 20 minutes and can run both a large multiplex respiratory test in the 12-25 pathogen target range, and a small multiplex respiratory test in the 3-5 pathogen target range. The BIOFIRE® SPOTFIRE® system with both panels is expected to further expand bioMérieux's presence in the United States outpatient market.

"FDA-clearance of the BIOFIRE® SPOTFIRE® R Panel Mini strengthens our belief that the BIOFIRE® SPOTFIRE® solution is a real game changer in patient care, allowing physicians to give patients an accurate and rapid diagnosis, tailored to their needs be it a large multiplex panel or a more targeted one, while leveraging the same BIOFIRE SPOTFIRE platform." declared Pierre Boulud, Chief Operating Officer, Clinical Operations, bioMérieux. "*Our expanded offer covers both front-line testing as well as second-line testing in the United States, expanding our business coverage and opportunities dramatically*."

The filing for CLIA-waiver of the BIOFIRE® SPOTFIRE® R Panel Mini will immediately follow FDA-clearance. The BIOFIRE® SPOTFIRE® System and the 15-target Respiratory Panel are currently available for sale in the United States.

** Polymerase Chain Reaction*

PRESS RELEASE

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 2022, revenues reached €3.6 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 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

CONTACTS

INVESTORS RELATIONS

Franck Admant
Tel.: +33 (0)4 78 87 20 00
investor.relations@biomerieux.com

MEDIA RELATIONS

CORPORATE
Romain Duchez
Tel.: +33 (0)4 78 87 21 99
media@biomerieux.com

UNITED STATES
Chuck Hester (SEEZ)
Tel. : 919-607-1522
chuckh@seeztoday.com

FRANCE
Claire Doligez (Image 7)
Tel.: +33 (0)1 53 70 74 48
cdoligez@image7.fr

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