



BioFire Submits *De Novo* Application to FDA for FilmArray[®] Meningitis/Encephalitis Panel

Marcy l’Etoile, France - April 14, 2015 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire, its molecular biology affiliate, has submitted a *de novo* classification request to the U.S. Food and Drug Administration (FDA) for the FilmArray[®] Meningitis/Encephalitis (ME) Panel. The pioneering FilmArray[®] ME Panel addresses a critical, unmet need for quickly identifying central nervous system infections by utilizing a comprehensive panel to test cerebrospinal fluid (CSF) for the most common bacteria, viruses and fungi responsible for community acquired meningitis or encephalitis. A one-hour turnaround time has the potential to reduce mortality and morbidity from these devastating diseases and to positively impact patient management.

The submission of the FilmArray[®] ME Panel comes after the successful completion of a clinical study that included more than 1,500 prospective samples analyzed at 11 different sites across the United States, including a representative mix of pediatric and adult patients. The FilmArray[®] ME Panel will only be available for sale once the FDA has completed its process. The Panel will be the fourth clinical diagnostic test to run on the FilmArray[®] system, making its syndromic menu the largest commercially available for a multiplexing platform.

“We are excited to lead the fight towards improving clinical outcomes from meningitis and encephalitis by submitting this distinctive diagnostic test for FDA clearance,” said Randy Rasmussen, bioMérieux Corporate Vice President of Molecular Biology and CEO of BioFire Diagnostics. “A fast and accurate diagnosis is key to reducing mortality and morbidity from meningitis and encephalitis and most of all giving physicians timely high medical value information to better manage their patients. With this launch, we will further consolidate our leadership position in molecular syndromic diagnosis of infectious diseases.”

More than 1.2 million people every year are affected by meningitis worldwide, resulting in 120,000 deaths globally from bacterial meningitis. Bacterial meningitis can occur suddenly in healthy people and even with prompt diagnosis and treatment, approximately 10% of patients die and up to 20% or more sustain permanent damage and disability¹. The most common infectious pathogens of meningitis and encephalitis, usually targeted by several labor-intensive, complex and varied laboratory methods, are assayed in the single test format. The FilmArray[®] ME Panel approach is faster, easier and potentially much more efficient than standard methods for diagnosing the most common causes of this syndrome.

Specialized in the molecular and syndromic diagnosis of infectious diseases, BioFire develops, manufactures and markets the FilmArray[®] solution. FilmArray[®] is a CE-marked and FDA-cleared multiplex PCR molecular biology system that is easy to use, accurate and rapid. It makes it possible to identify, in a single reagent or panel, the most frequent disease-causing organisms responsible for a syndrome, whether they are viruses, bacteria, fungi or parasites. FilmArray[®]’s menu currently comprises three panels – respiratory, blood culture identification and gastrointestinal – all of which are CE-marked and FDA-cleared.

¹ <http://www.comomeningitis.org/news-and-events/world-meningitis-day>; accessed April 3, 2015

About bioMérieux

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2014, revenues reached €1,698 million with 88% 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 used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris stock market (Symbol: BIM – ISIN: FR0010096479).
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