Sebia launches M-inSight®, a test for monitoring multiple myeloma patients

Corgenix, a Sebia Group company, CAP/CLIA clinical laboratory, positions Sebia to globally commercialize M-inSight®, a novel non-invasive liquid biopsy assay for Minimal Residual Disease (MRD) monitoring in multiple myeloma

Paris, France, September 27, 2023 – Sebia, a world leader in multiple myeloma diagnostics and monitoring, today announces the launch of its serum based Minimal Residual Disease (MRD) test for monitoring in multiple myeloma. M-inSight® is a Laboratory Developed Test (LDT) being offered by Corgenix, College of American Pathologists (CAP)-accredited, Clinical Laboratory Improvement Amendments (CLIA) - licensed clinical laboratory and part of the Sebia Group.

M-inSight® is a personalized, targeted mass spectrometry assay, to detect with unprecedented sensitivity the monoclonal protein (M-protein) secreted by the patient's tumor cells in serum. The technology is based on clonotypic peptides mass spectrometry, which avoids the interference with the polyclonal background leading to an ultra-sensitive test.

MRD describes the low levels of myeloma cells that persist in the bone marrow after treatment but cannot be detected with conventional outcome measures and eventually lead to relapse. MRD status is an important prognostic marker and studies have shown its potential as a surrogate endpoint for progression-free survival. MRD testing monitors the effectiveness of a treatment and could be a driver in treatment decisions.

As new therapies emerge to treat patients suffering from multiple myeloma, there is an urgent need for high sensitivity MRD testing in serum to track disease burden and treatment efficacy, without the limitations of current bone marrow-based assays. These are typically invasive, painful and not suited for frequent measurement.

M-inSight® was developed in partnership with Erasmus Medical Center, Rotterdam and Radboud University Medical Center, Nijmegen, both in The Netherlands.

"We are proud to launch M-inSight® to improve the management of multiple myeloma and quality of life for patients, as well as assisting in the drug development and validation process", said Dr Pierre Sonigo, chief scientific officer at Sebia. "By testing in serum with equivalent sensitivity to bone marrow, we will solve current challenges in multiple myeloma MRD-testing, allowing for a more frequent and reliable monitoring of response to treatment."

Sebia is currently the only global partner covering the process of M-protein testing from initial detection to MRD and is committed to developing other liquid biopsy tests such as Circulating Tumor Cells (CTC) and new biomarkers.

About multiple myeloma

Multiple myeloma is the second most common blood cancer in the world, affecting more than 170,000 people worldwide. Multiple myeloma is the cancer of plasma cells characterized by the clonal expansion of plasma cells that predominantly reside in the bone marrow. Each year over 32,000 new cases are diagnosed in the United States, and almost

13,000 patients die of the disease. Patients with multiple myeloma continue to relapse over time, making it a difficult to treat and incurable malignancy.

About M-inSight®
M-inSight® is a Laboratory Developed Test (LDT) validated for clinical use, offered by Corgenix, a Sebia Group company, a CAP-accredited CLIA-licensed clinical laboratory. Patients suffering from multiple myeloma can now have access to M-inSight®. Pharma companies developing and commercializing drugs in multiple myeloma can also benefit from this innovative assay to get deeper insights in their drug development and clinical trials.
www.minsight-mrd.com

About Corgenix
Corgenix is a CAP/CLIA accredited laboratory based in Colorado, USA. Founded in 1990 and part of the Sebia group, it is specialized in clinical trial management and physician-ordered patient testing.
The company also has CDMO capabilities catering to clients in the biotechnology and pharmaceutical industry, cancer centers and academic laboratories.
www.corgenix.com

About Sebia
Founded in 1967, Sebia is a world-leading provider of clinical protein electrophoresis equipment and reagents, a technology used for in vitro diagnostic testing. Its systems analyze proteins in order to screen and monitor various diseases and conditions; primarily oncology (multiple myeloma), metabolic disorders, hemoglobinopathy, rare diseases and more recently autoimmunity. Sebia is offering the largest range of analytical solutions in diagnosis and monitoring of multiple myeloma, including serum and urine protein(s) electrophoresis (SPE/UPE) for screening and identification (Immunotyping / Immunofixation), measurement of FLC and follow-up monoclonal antibody therapy with HYDRASHIFT portfolio.
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