Sebia announces FDA clearance for its Hydrashift 2/4 daratumumab assay

The *in vitro* diagnostic test, developed in collaboration with Janssen, allows for assessment of response in patients with multiple myeloma by mitigating potential interference induced by daratumumab

Paris, France, January 24 2018 - Sebia, a world leader in multiple myeloma diagnostics testing and monitoring, announces today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its Hydrashift 2/4 daratumumab assay, intended to be used with Hydragel IF, for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. This *in vitro* diagnostic (IVD) reagent mitigates the daratumumab-mediated interference seen in Immunofixation results for patients with multiple myeloma treated with DARZALEX® (daratumumab), a fully human monoclonal antibody that binds to CD38.

The Hydrashift 2/4 daratumumab Immunofixation assay is the result of a collaboration between Sebia (Paris, France) and Janssen Biotech, Inc. (Horsham, PA, Etats-Unis), to provide the clinical community with better tools to monitor patients with multiple myeloma in line with the International Myeloma Working Group's (IMWG) latest recommendations. Sebia received development rights from Janssen and is the worldwide supplier of this assay. Sebia's broad market coverage will enable patients receiving DARZALEX® in many countries throughout the world to have access to testing. The assay received the CE Mark in November 2016.

"Sebia is excited to have developed such a novel and innovative IVD assay," said Jean-Marc Chermette, Sebia's CEO. "Immunofixation is one of the tests referenced in the IMWG guidelines to assess complete response in a patient with multiple myeloma. This development confirms the company's commitment and strategic objective to remain the market leader in providing the most advanced diagnostic tools supporting multiple myeloma disease management."

The Hydrashift 2/4 daratumumab assay is performed on the Sebia Hydrasys 2 agarose gel platform. Sebia has a large established customer base utilizing this platform in academic centers, hospitals and reference laboratories across the world. The implementation of this assay will be easy and seamless in many of these institutions.

About Multiple Myeloma
Myeloma is the second most common blood cancer in the world. Globally, close to 230,000 people live with the disease. More than 110,000 new cases are diagnosed each year. www.myeloma.org/what-is-multiple-myeloma

About Sebia

Sebia a global specialty diagnostic company, develops, manufactures and commercializes IVD tests and analyzers dedicated to the in vitro diagnosis of cancer, inflammatory diseases, diabetes and hemoglobin disorders. Sebia's focus on electrophoresis techniques enables it to maintain a sustained R&D program, providing access to genuine innovations in any lab. Both agarose gel and capillary assays, and their dedicated automation, are designed to be integrated into the same routine workflow; for gel (ASSIST, HYDRASYS 2 SCAN) and for capillary electrophoresis (CAPILLARYS 3 TERA, stand alone or in work cell configuration up to three instruments with tube loader, CAPILLARYS 2 FLEX-PIERCING, MINICAP-FLEX PIERCING).

www.sebia.com

DARZALEX® (daratumumab) is a registered trademark of Janssen Biotech, Inc.

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