Sebia signs agreement with Janssen Biotech to develop a multiple myeloma IVD test

Test allows for clear results of multiple myeloma patients' response by eliminating potential interference induced by novel therapeutic antibody

Paris, France, January 30, 2017 – Sebia, a world leader in multiple myeloma diagnostics and monitoring, announces today that it has entered into an agreement with Janssen Biotech, Inc. (Horsham, PA, USA), for the development of an *In Vitro* diagnostic (IVD) test that mitigates the potential interference in visualization of M-proteins in immunofixation electrophoresis caused by DARZALEX® (daratumumab). DARZALEX® is a human monoclonal antibody targeting CD38 that has been shown to provide superior clinical benefit as monotherapy in heavily pre-treated multiple myeloma patients and when combined with standard of care regimens for the treatment of MM in patients with the earlier disease (.e.g, >1 prior line of therapy). This agreement is the first collaboration of its kind for Sebia. The financial details were not disclosed.

The agreement covers the development of the Hydrashift 2/4 daratumumab IVD reagent kit for use with Sebia's proprietary immunofixation (IF) test, Hydragel. Janssen granted Sebia development rights, allowing Sebia to be the worldwide supplier, able to provide the IVD solution to remove the daratumumab interference from the IF test. Sebia's broad market coverage guarantees that patients using DARZALEX® in many countries throughout the world will have access to testing.

It is well known that the newer treatments for multiple myeloma that use humanized monoclonal antibodies (mAbs) can interfere with the patient's native antibodies in immunofixation tests. This can mislead the pathologist in interpreting the patient's response to treatment. Immunofixation is one of the tests referenced in the IMWG (International Myeloma Working Group) guidelines to establish the diagnosis of complete response in a patient with multiple myeloma.

This IVD test is specific for patients treated by DARZALEX®, to be used only on Sebia's FDA cleared and CE marked Hydrasys 2 agarose gel platform. It cannot be used for other patient samples with any other interfering monoclonal antibodies or any other immunofixation test.

"We are excited about partnering with Janssen and further expanding our reach in the international diagnostic market," said Benoit Adelus, CEO at Sebia. "This is great news for patients around the world who will now have access to a reliable IVD test. Hydrashift 2/4 daratumumab is in line with our strategy of developing innovative and advanced products for patient care."

This standardized IVD technique will be sold in those countries where regulatory market approval will be obtained. The product was CE marked in December 2016. The US, Canadian and Japanese market entry and regulatory operations are ongoing.

"Sebia's Hydrashift 2/4 daratumumab will allow for a clear reading of the patient's results, with no interference from daratumumab on immunofixation," said Dr. Thomas Dejoie, laboratory pathologist at the Nantes University Hospital (France), using the test for evaluation purposes.

"Sebia's test has great medical potential. It is a key product in making diagnostics more efficient, precise and accurate for multiple myeloma patients treated routinely with DARZALEX®," said Pr. Philippe Moreau, head of the hematology department at the Nantes University Hospital (France).

The hematology department team at the hospital presented a poster on the product during the recent ASH 2016 congress[1] in San Diego (USA).

Sebia is the world's largest supplier of specialty diagnostic tests, based on electrophoresis technology and automation, with more than 70% of the world market and 15,000 laboratories served worldwide.

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.
https://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).
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[1] https://ash.confex.com/ash/2016/webprogram/Paper96550.html