



Sebia enters into agreement with Sanofi to develop multiple myeloma diagnostic test

Test will specifically adjust for isatuximab-induced interference in complete response assessment of multiple myeloma patients

Paris, France, January 7, 2020 – Sebia (Lisses, France), a world leader in multiple myeloma diagnostics and monitoring, announces today that it is entering into an agreement with Sanofi to develop an *in vitro* diagnostic (IVD) test that mitigates the potential interference caused by isatuximab in Immunofixation Electrophoresis (IFE) tests. Sebia will develop the test and act as worldwide supplier. The financial details have not been disclosed.

Isatuximab is an investigational monoclonal antibody (mAb) that targets a specific epitope of CD38 capable of triggering multiple mechanisms of action that are believed to promote programmed tumor cell death and immunomodulatory activity.

New multiple myeloma therapies that use biologics, specifically mAbs, are known to interfere with the patient's monoclonal protein in IFE tests. This can mislead healthcare professionals in interpreting the patient's response to therapy; Immunofixation is one of the tests referenced in the International Myeloma Working Group (IMWG) guidelines to diagnose complete response in a patient with multiple myeloma.

This agreement covers the development of the Hydrashift 2/4 isatuximab IVD kit to be used in conjunction with Sebia's proprietary IFE assay, Hydragel. This IVD test is specifically for patients treated with isatuximab and is only used on Sebia's FDA cleared and CE marked Hydrasys 2 platform.

"We are excited about partnering with Sanofi and further developing our Immunofixation range of products. The future Hydrashift 2/4 isatuximab test is in line with our strategy of developing innovative and advanced products for patient care," said Jean-Marc Chermette, CEO at Sebia. "This development confirms Sebia's commitment and strategic objective to remain the market leader in providing the most advanced diagnostic tools supporting multiple myeloma disease management."

Under the terms of the agreement, Sebia will seek a CE mark for the test in summer 2020 and, subsequently, pursue 510(k) clearance.

About multiple myeloma

Multiple myeloma is the [second most common hematologic malignancy](#), affecting more than [138,000 people worldwide](#). Patients with multiple myeloma continue to relapse over time, making it a difficult to treat and incurable malignancy.

About isatuximab

Isatuximab is an investigational, monoclonal antibody (mAb) that targets a specific epitope of CD38 capable of triggering multiple mechanisms of action that are believed to promote programmed tumor cell death (apoptosis) and immunomodulatory activity. Isatuximab is currently being evaluated in multiple ongoing phase 3 clinical trials in combination with current standard treatments for people with relapsed/refractory or newly diagnosed multiple myeloma. It is also under investigation for the treatment of other hematologic malignancies and solid tumors. Isatuximab is an investigational agent and its safety and efficacy have not been fully evaluated by any regulatory authority.



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 electrophoresis 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 a work cell configuration for up to three instruments with a tube loader, Capillarys 2 Flex Piercing, Minicap Flex Piercing).

Sebia is the world's largest supplier of specialty diagnostic tests based on electrophoresis technology and automation, with more than 75% of the world market and 16,000 laboratories served worldwide.

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