U.S. FDA clearance of new tool for managing the world's most prevalent virus

COPENHAGEN, DENMARK – 2 January 2018 - Immudex has received 510(k) clearance from U.S. Food and Drug Administration (FDA) for its Dextramer® CMV Kit. The assay measures viral immune responses and open doors for personalized treatment of cytomegalovirus in transplant patients.

The Dextramer® CMV Kit is an addition to the current standard of care to aid in differentiating transplant patients that are at elevated risk for Cytomegalovirus (CMV) reactivation from those with a low risk due to a re-established immune response to the virus.

CMV is the most common opportunistic infection in transplant patients, and remains a leading cause of morbidity and mortality. Drug therapy for CMV is typically initiated at first detection of CMV reactivation. However, not all individuals in whom CMV reactivation is detected will develop CMV disease. CMV viremia can spontaneously resolve, with CMV controlled by the immune system. Unnecessary administration of antiviral chemotherapy exposes patients to toxicities, is expensive, increases risk of developing drug resistant viral strains and lowers quality of life.

Immudex' Dextramer CMV Kit provides doctors with the additional quantitative information on the patient immune status and risk of CMV reactivation. Identifying those patients that are at risk, because their immune system is too weak to fight the virus on its own, allow more personalized antiviral treatment.

"We are very excited about the release of the Immudex CMV Dextramer test for measuring the T-cell response to CMV", says Philip McCarthy M.D. Blood and Marrow Transplant Program, Roswell Park Cancer Institute. "We anticipate that this test will be important for monitoring T-cell reconstitution of immunity to CMV and determining if the patient has the ability to respond and control CMV after primary therapy. Further, we may be able to use this test to determine, which patients can eradicate CMV without requiring systemic antiviral therapy. "

"This is Immudex' first diagnostic product cleared for the USA market", says Immudex' CEO, Helene Kähler Hjenner. "It is a nice example of precision medicine and support Immudex ambition of improving immune monitoring through high quality products".

The Dextramer CMV Kit is on the market in Europe and is available in the USA beginning December 2017.

About the CMV Dextramer Kit. *The Dextramer® CMV Kit is a semi-quantitative assay intended for the identification and enumeration of cytomegalovirus (CMV)-specific $CD8^+$ T cells in anticoagulated (Na Heparin) whole blood specimens by flow cytometry. The Dextramer® CMV Kit is indicated for assessment of CMV-specific immune status and risk of CMV reactivation in adult human stem cell transplant patients following immunosuppression and used in conjunction with other laboratory and clinical findings.*

About Immudex

Based in Copenhagen, Denmark, Immudex manufactures MHC Dextramers for the detection of antigen-specific T cells. Immudex MHC Dextramer® products are utilized for the quantification or sorting of antigen-specific T cells in life science research, in vitro diagnostics, as well as in the development of immunotherapeutics and vaccines.