NGSgo ONCOdentify® MPN is launched. GenDx' first product of a series of hemato-oncology diagnostic assays

<u>Utrecht, February 02, 2022</u>. In collaboration with University Medical Center of Utrecht (UMCU), GenDx has added a new assay to its product portfolio which is tailored for detecting genetic markers in blood cancers. NGSgo ONCOdentify® identifies mutations within the JAK2, CALR and MPL genes, valuable for the prognosis and selecting treatment options for myeloproliferative neoplasm (MPN).

The MPN kit is the first of a series of assays to detect somatic mutations related to hematological malignancies like acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and chronic lymphocytic leukemia (CLL). The test can be used on Illumina sequencing platforms.

Next generation sequencing (NGS) offers advantages in accuracy, sensitivity, and speed with the potential to significantly impact the field of oncology. Because NGS can cope with a multiplexed approach of genes in a single assay, it reduces the number of multiple tests as an efficient and fast way to identify the causative mutation.

Dr. Wietse Mulder, CEO of GenDx says: 'Anchored on extensive knowledge of developing software and reagents for accurate HLA typing, we can now offer NGSgo ONCOdentify as a highly sensitive assay for detection of mutations in a tumor sample. We are convinced that this assay is a valuable contribution to improve tailor made treatment of blood cancers. ONCOdentify is now launched as Research Use Only (RUO), but we are in the process of validating it for In Vitro Diagnostic (IVD) device'.

About GenDx

Genome Diagnostics B.V., also known as GenDx, is a Dutch company, specialized in molecular diagnostics, focused on development, production and sales of innovative assays and analysis software for transplantation and companion diagnostics.

GenDx specializes in HLA sequencing-based typing strategies and offers reagents and software for both Sanger and NGS approaches. Additional product lines are post transplantation products for chimerism monitoring by qPCR and NGS and personalized diagnostic assays. Thanks to its extensive in-house expertise, GenDx also offers custom laboratory services for basic and clinical research organizations. GenDx Education organizes dedicated HLA sequence based typing and chimerism monitoring training courses worldwide on a regular basis for anyone working in tissue typing or research laboratories, blood banks, and donor registries.

GenDx is based at the Utrecht Science Park, the Netherlands and was founded in 2005 by Erik Rozemuller PhD, Wietse Mulder PhD and UMC Utrecht Holdings B.V. represented by Oscar Schoots PhD and Raoul Linschoten LLM. GenDx has a USA-based office near O'Hare airport, Chicago, IL.

In 2019, Ampersand Capital Partners completed a minority growth equity investment in the company. For further information about GenDx go to www.GenDx.com.

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