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NanoString partners with Celgene

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Singapore: NanoString Technologies, a provider of life science tools for translational research and molecular diagnostic products, has collaborated with biologics firm Celgene. The companies will develop a companion diagnostic assay using nCounter Analysis System to support the clinical validation of REVLIMID for treatment of Diffuse Large B-Cell Lymphoma (DLBCL).

Under the terms of collaboration agreement, NanoString will develop, seek regulatory approval for, and commercialize the diagnostic test and is eligible to receive payments totaling up to $45 million of which $5.75 million is an upfront payment, $17 million is for potential success-based developmental and regulatory milestones, and the remainder is for potential commercial payments.

DLBCL is a heterogeneous group of cancers classified together on the basis of morphology, immunophenotype, genetic alterations and clinical behavior, and represents the most common form of Non-Hodgkin Lymphoma.

According to the National Cancer Institute, DLBCL will represent approximately 37 percent of the 70,000 new cases of Non-Hodgkin Lymphoma in a year. The subtypes of DLBCL have long been known to have varying prognoses. Accordingly, the accurate and precise assignment of subtype has the potential to become increasingly important with the emergence of novel therapies, and repurposing of existing products, that have selective clinical activity in specific subsets of patients.

Under the collaboration agreement with Celgene, NanoString will work to develop an in vitro diagnostic (IVD) companion test to REVLIMID that will be used to screen patients who are being enrolled in a pivotal study of REVLIMID for the treatment of DLBCL. Upon successful completion of the study, NanoString will pursue regulatory approval of the IVD in key global markets. Pursuant to the terms of the agreement, NanoString retains the flexibility to independently develop and commercialize additional indications for the IVD assay.

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"Biomarker-driven clinical trials are the future of clinical oncology. Our collaboration with NanoString exemplifies our commitment to be at the forefront of science. The nCounter platform is expected to enable reproducible subtyping of patients in our pivotal REVLIMID DLBCL study and will form the basis for companion diagnostic development," said Mr Jean-Pierre Bizzari, executive vice president of clinical development at Celgene. "We are excited to work with NanoString's experienced team to aid us in the development of a targeted treatment for patients with DLBCL."

The upfront payment and a portion of the success-based milestone payments are intended to cover NanoString's costs for clinical development of the IVD. Included in such $45 million, NanoString may receive potential commercial payments in the event sales of the IVD do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval.

"We are excited to work with Celgene to help improve the lives of patients," said Mr Brad Gray, president and chief executive officer, NanoString Technologies. "Similar to our development of the ProsignaBreast Cancer Prognostic Gene Signature Assay, which is based on the PAM50 gene signature, this new collaboration demonstrates the power of our business model to leverage biomarker discovery and advance the treatment paradigm, bringing the right therapy to the right patient at the right time. In addition, this collaboration further validates the nCounter Analysis System as the platform-of-choice for development of IVDs based on multi-gene expression assays, as well as the quality of our clinical and regulatory capabilities."