Feasibility of Real-Time Subtype Identification by Gene Expression Profile in the Phase 3 Trial of Lenalidomide Plus R-CHOP vs. Placebo Plus R-CHOP in Patients With Untreated G-Type Diffuse Large B-Cell Lymphoma

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Abstract

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ABSTRACT

• Use of NanoString LST in clinical studies is expected
• Until recently, real-time subtype identification of Diffuse large B-cell lymphoma (DLBCL), the most common non-Hodgkin lymphoma (NHL), was limited due to the need for technical expertise and reagents
• The DLBCL Lymphoma Subtyping Test (LST) was developed based on large-scale gene expression profiling and validated in multiple studies
• NanoString® nCounter® Analysis System9,10 may enable real-time subtype identification by cell-of-origin (COO)
• The DLBCL LST assay20

BACKGROUND

Recent advances in tumor biology have allowed for a more precise classification of lymphomas, particularly of diffuse large B-cell lymphoma (DLBCL). Until recently, the cell-of-origin (COO) classification of DLBCL was performed in research settings using complex and time-consuming microarray techniques because it requires fresh frozen biopsy samples and cannot be performed on formalin-fixed paraffin-embedded (FFPE) samples. The DLBCL Lymphoma Subtyping Test (LST) was developed based on large-scale gene expression profiling and validated in multiple studies9,10. NanoString® nCounter® Analysis System9,10 may enable real-time subtype identification by cell-of-origin (COO). 

OBJECTIVE

Evaluate the handling LST assay performance, including turnaround time from receipt of sample to identification of DLBCL subtype. In the context of the phase 3 R2-CHOP vs. R-CHOP vs. patients with previous untreated G-type COO, LST assay

METHODS

- R2-CHOP (GCB and Non-GCB) is endorsed by ASH and NCCN guidelines, and enrolled on the ROBUST study
- These findings have important implications for the design
- As of April 8, 2016, 139 patients have met all inclusion criteria and are enrolled
- Mean turnaround time for identification of DLBCL subtype was 2.29 days
- A total of 576 patients were screened and subtype assessed per NanoString
- The LST assay20
- NanoString assay performance was evaluated in 14 different clinical centers in Europe, Asia, and the United States
- A total of 225 patients were enrolled and assessed

RESULTS

- The LST assay20
- NanoString assay performance was evaluated in 14 different clinical centers in Europe, Asia, and the United States
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CONCLUSIONS

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- NanoString assay performance was evaluated in 14 different clinical centers in Europe, Asia, and the United States
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REFERENCES