NATIONAL CANCER INSTITUTE
Technology Transfer Center

Molecular Classification of Primary Mediastinal Large B Cell Lymphoma Using Formalin-Fixed, Paraffin-Embedded Tissue Specimens

Summary

Researchers at the National Cancer Institute (NCI) have developed a gene-expression profiling-based molecular diagnostic assay to diagnose and classify primary mediastinal large B cell lymphoma (PMBCL) from diffuse large B cell lymphoma (DLBCL). The diagnosis can be done using routinely available formalin-fixed, paraffin-embedded (FFPE) biopsies. The NCI seeks licensees and/or co-development partners to commercialize this technology.

NIH Reference Number

E-172-2017

Product Type

- Diagnostics

Keywords

- Gene Expression, Assay, Primary Mediastinal Large B Cell Lymphoma, PMBCL, Diffuse Large B Cell Lymphoma, DLBCL, formalin-fixed, paraffin-embedded biopsies, FFPE, Staudt

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

Primary mediastinal B-cell lymphoma (PMBCL) is an aggressive type of non-Hodgkin lymphoma that mostly occurs in people between the ages of 30-40. It accounts for 5-7% of all aggressive lymphomas. The diagnosis of PMBCL is challenging as the histological features of PMBCL overlap with diffuse large B-cell lymphoma (DLBCL), another most common type of non-Hodgkin lymphoma. Available evidence suggests that PMBCL responds much more favorably to the DA-EPOCH-R chemotherapy regimen than to the standard R-CHOP regimen used to treat DLBCL. The diagnostic uncertainty of PMBCL can result in delayed and/or inappropriate treatment, serious harm, and even death of the

patient, so there is a need to more precisely diagnose PMBCL.

Researchers at the National Cancer Institute (NCI) have developed a gene expression-based assay comprising a set of 58 nucleic acid probes that measure the abundance of selected mRNA species using the Nanostring platform. This assay can be used successfully to better distinguish PMBCL from DLBCL and applied to further classify DLBCL into well-established cell-of-origin subtypes. This test can be applied by clinicians to support the pathological diagnosis of PMBCL, and therefore identify a group of patients whose tumors are characterized by a distinct underlying biology.

The NCI seeks licensees and/or co-development partners to develop this technology toward commercialization.

Potential Commercial Applications

- Diagnosis of PMBCL
- Distinguishing PMBCL from DLBCL
- The invention could be used:
  - in the near term as a clinical tool in the initial diagnostic evaluation of suspected PMBCL, which is required in the WHO guidelines for diagnosis of hematologic malignancies
  - as an entry criterion for clinical trials in order to include those patients for which the efficacy of a given treatment likely depends on the molecular subtype of their disease
- Targeted therapies appropriate for each DLBCL subtype

Competitive Advantages

- Easy to integrate into current clinical practice of cancer diagnosis as the assay can be performed using routinely available formalin-fixed, paraffin-embedded (FFPE) biopsies
- Superior prognostic ability over traditional histopathological diagnosis

Inventor(s)

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Development Stage

- Pre-clinical (in vivo)

Publications

Mottok A, et al. Molecular classification of primary mediastinal large B-cell lymphoma using routinely available tissue specimens. [PMID 30257882]

Mottok A, et al. Integrative genomic analysis identifies key pathogenic mechanisms in primary mediastinal large B-cell lymphoma. [PMID 31292115]

Patent Status

- **U.S. Provisional:** U.S. Provisional Patent Application Number 62/519,728 , Filed 14 Jun

2017
- **PCT:** PCT Application Number PCT/US2018/036084 , Filed 05 Jun 2018
- **U.S. Patent Filed:** U.S. Patent Application Number 16/713,528 , Filed 13 Dec 2019

Therapeutic Area
- Cancer/Neoplasm

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