

Diagnostic for Progression of MDS to AML Using PD-1 or PD-L1 Expression



PD-1 and PD-L1 levels have been found to be significantly different between patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML). To more accurately assess the risk of MDS patients progressing to AML, PD-1 and PD-L1 levels might be usefully incorporated into the International Prognostic Scoring System (IPSS). Such prognostic measurements could result in patients being identified who would benefit from intensive therapy including bone marrow transplantation, but whose risk would otherwise be underestimated.

COMMERCIAL OPPORTUNITY

- The American Cancer Society predicts nearly 20,000 patients will develop AML in 2016 with a 5-year survival for the average patient of 5-10%. The standard method of assessing patient mortality risk is the International Prognostic Scoring System (IPSS) which assigns patients to one of several risk categories. Although certain risk categories are associated with increased likelihood of progressing to AML, the IPSS underestimates the risk of major symptoms by up to 20%. Genetic data are thought to better inform the risk of MDS patients progressing to AML.
- The expression of PD-1 has been shown to be elevated five-fold in MDS patients and elevated up to 5-fold further in AML patients, while that of PD-L1 decreases nearly 450-fold between MDS and AML patients. Ongoing clinical trials have shown anti-PD-1 therapeutics caused a remarkable decline in peripheral blood blasts in a single case of AML, a reversal of the hallmark criterion for disease progression.
- The market is attractive for genetic MDS categorization as evidenced by the MDS Molecular Profile available from Genoptix[®], a gene sequencing test that provides genetic mutation data that can be integrated into the IPSS to better assess prognostic risk. Mutations in one of the tested genes, *RUNX1*, are prognostic for rapid progression to AML.

TECHNOLOGY

This risk stratification tool measures the expression of PD-1 on CD71⁺ and CD34⁺ progenitor cells or the expression of PD-L1 on CD33⁺ myeloid-derived suppressor cells, utilizing an increase in PD-1 or a decrease in PD-L1 levels to indicate risk of progression from MDS to AML. This method is based on data illustrating that PD-1 levels are elevated nearly 5-fold in CD71⁺ PD-1⁺ progenitor cells from AML compared to MDS patients, while PD-L1 decreases nearly 450-fold in CD33⁺ CD14⁺ myeloid-derived suppressor cells in AML compared to MDS patients.

PUBLICATION/PATENT

- A provisional patent application was filed for Drs. List & Wei on March 16, 2016.

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LICENSING OPPORTUNITY

