CASE STUDY

BRISTOL-MYERS SQUIBB

Empire Genomics Helps Nivolumab Receive Accelerated Approval for Hodgkin's Lymphoma

Background

Bentruxumab vedotin is the only approved treatment for Hodgkin's Lymphoma patients who have relapsed from autologous stem cell transplants (ASCT), but for those who relapse after that, a third line option is needed. Nivolumab produced a high response rate in patients with relapsed Hodgkin's Lymphoma in a phase 1b clinical study and could be an option for this patient population.

Objectives

Further evidence was needed to determine if nivolumab is a viable option for the treatment of patients who have relapsed after receiving ASCT followed by bentruxumab vedotin. This study aims to establish the efficacy of nivolumab as a third line option.

Approach

Classical Hodgkin's lymphoma is characterized by an overexpression of the PD-1 ligands PD-L1 and PD-L2, caused by copy number alterations involving chromosome 9p24.1. To improve the accuracy and success of the study, a mutation profile was established, using Empire Genomics PD-L1 and PD-L2 FISH probes, to measure the copy number variations of over 338 participants from 34 hospitals and academic institutions. Patients with the correct mutation were then recruited for the study.

Results

Empire Genomics' ability to quickly develop a custom PD-L1 and PD-L2 biomarker for the study helped Bristol-Myers Squibb receive accelerated approval for Nivolumab by the FDA in May of 2016, just a few months after the study was closed.

Nivolumab for classical Hodgkin's lymphoma after failure of both autologous stem-cell transplantation and brentuximab vedotin: a multicentre, multicohort, single-arm phase 2 trial

Lancet Oncol July 20, 2016; 17: 1283-94

Lead Organization

Bristol-Myers Squibb

Diseases

- Hodgkin's Lymphoma

Biomarkers Mentioned

- PD-L1
- PD-L2
- PD-1
- JAK2
- STAT3
- PAX5

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