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*APPLICATION NUMBER:*

**125388Orig1s000**

**MEDICAL REVIEW(S)**

## CLINICAL REVIEW

Application Type BLA  
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Review Completion Date 8/1/2011

Established Name Brentuximab vedotin  
Trade Name Adcetris<sup>TM</sup>  
Therapeutic Class Antibody-drug conjugate  
Applicant Seattle Genetics, Inc.

Formulation 50 mg single use vial  
Dosing Regimen 1.8 mg/kg intravenously every  
3 weeks  
Proposed Indication Treatment of patients with  
Hodgkin lymphoma who have  
relapsed after autologous stem  
cell transplant  
Intended Population(s) Adults >18 years of age

Template Version: March 6, 2009

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