

CENTER FOR DRUG EVALUATION AND  
RESEARCH

*APPLICATION NUMBER:*

**761036Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME MEMORANDUM**

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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**\*\*\* This document contains proprietary information that cannot be released to the public\*\*\***

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<b>Date of This Review:</b>	September 1, 2015
<b>Application Type and Number:</b>	BLA 761036
<b>Product Name and Strength:</b>	Darzalex (Daratumumab) Injection, 20 mg/mL
<b>Total Product Strength:</b>	100 mg/5 mL vial and 400 mg/20 mL vial
<b>Product Type:</b>	Single Ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Janssen
<b>Panorama #:</b>	2015-969480
<b>DMEPA Primary Reviewer:</b>	Michelle Rutledge, PharmD
<b>DMEPA Team Leader:</b>	Yelena Maslov, PharmD

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## **1 INTRODUCTION**

The proposed proprietary name, Darzalex, was found conditionally acceptable in OSE Review # 2015-47910, under IND 100638, dated March 12, 2015. We note that the product characteristics are the same under BLA 761036. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Darzalex, is acceptable from both a misbranding and safety perspective.

If you have further questions or need clarifications, please contact Kevin Wright, OSE project manager at 301-796-3621.

### **1.1 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Darzalex, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your July 15, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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/s/  
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MICHELLE K RUTLEDGE  
09/01/2015

YELENA L MASLOV  
09/02/2015