



NDA 210951/S-004

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING  
COMMITMENT**

Janssen Biotech, Inc.  
c/o Janssen Research & Development, LLC  
Attention: Elise Mazzola  
Associate Director, Global Regulatory Affairs  
920 US Highway 202, PO Box 300  
Raritan, NJ 08869

Dear Ms. Mazzola:

Please refer to your supplemental new drug application dated and received May 29, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Erleada (apalutamide) tablet.

This Prior Approval supplemental new drug application provides for labeling revisions to the U.S. prescribing information based on results from the final analysis of overall survival, efficacy and safety from the SPARTAN study ARN-509-003.

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the Food and Drug Administration (FDA) automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **FULFILLMENT OF POSTMARKETING COMMITMENT**

We have received your submission dated May 29, 2020, containing the final report for the following postmarketing commitment listed in the February 14, 2018, approval letter.

- 3324-1 Submit the analyses and datasets with final report for the clinical trial entitled "SPARTAN, a phase 3 double-blind, randomized study of apalutamide versus placebo in patients with non-metastatic castration-resistant prostate cancer [ARN-509-003].

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing commitments acknowledged in our February 14, 2018, letter.

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>3</sup>

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at [FDA.gov](http://FDA.gov).<sup>4</sup> Information and Instructions for completing the form can be found at [FDA.gov](http://FDA.gov).<sup>5</sup>

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Fatima Rizvi, PharmD, Regulatory Project Manager, at (240) 402-7426 or at [Fatima.Rizvi@fda.hhs.gov](mailto:Fatima.Rizvi@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Amna Ibrahim, MD  
Deputy Director  
Division of Oncology 1  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

### ENCLOSURE:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/  
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