

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**212123Orig1s000**

*Trade Name:* Tauvid Injection

*Generic or Proper Name:* Flortaucipir F18

*Sponsor:* Avid Radiopharmaceuticals, Inc.

*Approval Date:* May 28, 2020

*Indication:* For the use of as a radioactive diagnostic agent indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD).

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## 212123Orig1s000

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*APPLICATION NUMBER:*

**212123Orig1s000**

**APPROVAL LETTER**



NDA 212123

**NDA APPROVAL**

Avid Radiopharmaceuticals, Inc.  
Attention: Stephen P. Trucchio, M.S., RAC  
Senior Director, Regulatory Affairs and Project Management  
3711 Market Street  
7<sup>th</sup> Floor  
Philadelphia, PA 19104

Dear Mr. Trucchio:

Please refer to your new drug application (NDA) dated September 29, 2019, received, September 30, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tauvid (Flortaucipir F18) Injection.

This new drug application provides for the use of Tauvid (Flortaucipir F18) Injection as a radioactive diagnostic agent indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD).

### **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 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) as well as annual reportable changes not included in the enclosed labeling. 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 via publicly available labeling repositories.

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

<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>.

## **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “Final Printed Carton and Container Labeling for approved NDA 212123.” Approval of this submission by FDA is not required before the labeling is used.

## **USER GUIDE FOR IMAGE DISPLAY**

Submit the final user guide for image display that is identical to the user guide submitted on May 15, 2020 as soon as it is available, but no more than 30 days after they are printed. For administrative purposes, designate this submission “Final Printed User Guide for Image Display Labeling for approved NDA 212123.” Approval of this submission by FDA is not required before the labeling is used. Please note, changes to the user guide that are minor or editorial may be addressed in your postmarketing annual reports where they can be provided through a summary of any changes to the guide or, if no change, a statement of that fact. More significant changes will need to be addressed in accordance with 21 CFR 314.70, whether as CBE-0s or Prior Approval Supplements.

## **REQUIRED PEDIATRIC ASSESSMENTS**

We are waiving the pediatric study(ies) requirement for this application because necessary studies are impossible or highly impracticable.

## **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>

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

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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>

## **REPORTING REQUIREMENTS**

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

## **MEDWATCH-TO-MANUFACTURER PROGRAM**

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at [FDA.gov](http://FDA.gov).<sup>6</sup>

## **POST APPROVAL FEEDBACK MEETING**

New molecular entities and new biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, call Lisa Skarupa, Regulatory Project Manager, at 301-796-2219.

Sincerely,

*{See appended electronic signature page}*

Charles J. Ganley, MD  
Director, Office of Specialty Medicine  
Center for Drug Evaluation and Research

ENCLOSURE(S):

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<sup>6</sup> <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm>

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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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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CHARLES J GANLEY  
05/28/2020 03:15:24 PM

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