NDA 214793

NDA APPROVAL

Progenics Pharmaceuticals, Inc.
Attention: Ms. Nancy Blair
One World Trade Center, 47th Floor - Suite J
New York, NY 10007

Dear Ms. Blair:

Please refer to the New Drug Application (NDA) dated and received on September 29, 2020, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PYLARIFY (piflufolastat F 18 injection).

Reference is also made to your clinical pharmacology response of November 19, statistical response of December 23, clinical response of December 29, 2020, statistical response of January 12, chemistry response of January 22, clinical pharmacology of January 26, clinical response of February 2, chemistry responses of February 5, 19, March 1, 3, 22, clinical response of March 26, label response of April 12, clinical-statistical response of April 14, and chemistry responses of April 20 and May 7 and labeling and label response of May 24, 2021.

This New Drug Application provides for the use of PYLARIFY (piflufolastat F 18 injection) for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

APPROVAL & LABELING

We have completed our review of this application. 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.[1]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Content of labeling must be identical to the enclosed labeling 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.*[2]

The SPL will be accessible via publicly available labeling repositories.

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 214793**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for PYLARIFY (piflufolastat F 18 injection) shall be 10 hours from the date and time of manufacture when stored between 20-25 °C.

ADVISORY COMMITTEE

Your application for PYLARIFY was not referred to an FDA advisory committee because this drug is not the first in its class.

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.

We are waiving the pediatric study requirement for this application because studies would be impossible or highly impracticable because prostate cancer rarely or never occurs in the pediatric population.

[2] 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.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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

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, submit a formal official Meeting Request to the FDA.

SUBMISSION REQUIREMENTS

All formal official submissions should be submitted electronically with a cover letter and applicable FDA Forms, as follows:

The Electronic Common Technical Document (eCTD) is CDER and CBER standard format for electronic regulatory submissions.

For eCTD submissions, the FDA Electronic Submissions Gateway (ESG) is the central transmission point, and you should obtain an ESG account. For additional information, see FDA.gov.7F[6]

Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: http://www.fda.gov/ectd.

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[6] http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway

SECURE EMAIL

Secure Email is required for all email communications from the FDA to the Sponsors and / or Sponsor's Authorized Representatives when confidential information is included in the message.

Sponsors and Sponsor's Authorized Representatives must each establish a Secure Email account with the FDA to receive email communications from the FDA that include confidential information (e.g., information requests (IRs), meeting responses, courtesy copies of FDA letters, labeling revisions, trade secrets, manufacturing, or patient information, etc).

To establish a Secure Email with the FDA, send an email request: SecureEmail@fda.hhs.gov.

Note: A secure email may not be used for formal official regulatory submissions.

If you have any questions regarding this NDA, please contact Ms. Thuy M. Nguyen, MPH, Senior Regulatory Health Project Manager at: Thuy.Nguyen@fda.hhs.gov or (301) 796-1427.

Sincerely,

{See appended electronic signature page}

Alex Gorovets, MD
Office Deputy Director
Office of Specialty Medicine (OSM)
Center for Drug Evaluation and Research
US Food and Drug Administration

Enclosures:

- Prescribing Information (Labeling)
- Carton and Container Label

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.

/s/

THUY M NGUYEN
05/26/2021 05:45:07 PM

ALEXANDER GOROVETS
05/26/2021 06:22:19 PM