

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

214621Orig1s000

Trade Name: Orgovyx

Generic or Proper Name: relugolix

Sponsor: Myovant Sciences GmbH

Approval Date: December 18, 2020

Indication: For the treatment of adult patients with advanced prostate cancer.

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APPROVAL LETTER

NDA 214621

NDA APPROVAL

Myovant Sciences GmbH
Attention: Carmen Ladner
Vice President, Regulatory Affairs
2000 Sierra Point Pkwy, 9th Floor
Brisbane, CA 94005

Dear Ms. Ladner:

Please refer to your new drug application (NDA) dated and received April 20, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Orgovyx (relugolix).

This new drug application provides for the use of Orgovyx (relugolix) for the treatment of adult patients with advanced prostate cancer.

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.¹ Content of labeling must be identical to the enclosed labeling text for the Prescribing Information and Patient Package Insert, 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.

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

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>.

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 214621.**” 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 Orgovyx (relugolix) 120 mg tablets shall be 24 months from the date of manufacture when stored at or below 30°C (86°F).

ADVISORY COMMITTEE

Your application for Orgovyx was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

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 necessary studies are impossible or highly impracticable since prostate cancer does not occur in children.

**POSTMARKETING COMMITMENT SUBJECT TO REPORTING REQUIREMENTS
UNDER SECTION 506B**

We remind you of your postmarketing commitment:

- 3962-1 Conduct a pharmacokinetic study to evaluate the effect of P-gp inhibitors when administered after relugolix to further inform dosing strategy. Submit the datasets with the final study report. The study results may inform product labeling.

The timetable you submitted on December 10, 2020, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	03/2021
Final Protocol Submission:	06/2021
Study Completion:	01/2022
Final Report Submission:	04/2022

**POSTMARKETING COMMITMENT NOT SUBJECT TO THE REPORTING
REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitment:

- 3962-2 Submit test report for the currently ongoing study titled “The Zebrafish Extended One-Generation Reproduction Test” to support of the environmental risk assessment for relugolix.

The timetable you submitted on November 20, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 08/2021

Submit clinical protocols to your IND 118736 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol**,” “**Postmarketing Commitment Final Report**,” or “**Postmarketing Commitment Correspondence**.”

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, call the Regulatory Project Manager for this application.

If you have any questions, contact Rashida Redd, Regulatory Project Manager, at 301-796-5489 or Rashida.Redd@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Paul G. Kluetz, MD
Supervisory Associate Director
Office of Oncologic Diseases
Center for Drug Evaluation and Research

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>

ENCLOSURE(S):

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

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/

PAUL G KLUETZ
12/18/2020 10:53:18 AM