CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214621Orig1s000

PRODUCT QUALITY REVIEW(S)

U.S. FOOD & DRUG ADMINISTRATION

RECOMMENDATION

☐ Approval
☒ Approval with Post-Marketing Commitment
☐ Complete Response

NDA 214621
Assessment #1

Drug Product Name	ORGOVYX relugolix
Dosage Form	Tablet
Strength	120 mg
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	Myovant Sciences GmbH
US agent, if applicable	N/A

Submission(s) Assessed	Document Date	Discipline(s) Affected
Original 0001	4/20/2020	All: DS, DP, OPMA, Biopharm
SND 0002	4/20/2020	All
SND 0008	6/8/2020	All
SND 0009	6/9/2020	All
SND 0010	6/11/2020	All
SND 0013	6/18/2020	All
SND 0015	6/25/2020	All
SND 0019	7/17/2020	All
SND 0022	7/27/2020	All
SND 0024	8/5/2020	All
SND 0025	8/12/2020	All
SND 0031	9/1/2020	All
SND 0032	9/11/2020	All
SND 0033	9/23/2020	All
SND 0034	9/29/2020	All
SND 0037	10/20/2020	All
SND 0040	11/3/2020	All
SND 0043	11/16/2020	All
SND 0045	11/20/2020	All

QUALITY ASSESSMENT TEAM

Discipline	Primary Assessment	Secondary Assessment
Drug Substance	Karina Zuck	Ali Al Hakim
Drug Product	Anamitro Banerjee	Thomas Oliver
Manufacturing	Abdullah Md Mahmud	Bogdan Kurtyka
Microbiology	N/A	
Biopharmaceutics	Gerlie Geiser	Banu Zolnik
Regulatory Business Process Manager	Kristine Leahy	
Application Technical Lead	Xiao Hong Chen	
Laboratory (OTR)	N/A	
Environmental	James Laurenson	Scott Furness

EXECUTIVE SUMMARY

I. RECOMMENDATIONS AND CONCLUSION ON APPROVABILITY

The product quality review team recommends Approval of NDA 214621 based on the adequate CMC information submitted in the NDA and acceptable recommendation from the facilities review.

PMC #3962-1: "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 PMC has been agreed upon by the applicant. The final report date is August 31, 2021.

II. SUMMARY OF QUALITY ASSESSMENTS

A. Product Overview

The 505b1 NDA is for the NME drug, ORGOVYX relugolix tablets. Relugolix is a non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist being developed for the treatment of patients with advanced prostate cancer. The maximum daily dose is 360 mg followed by the proposed regimen of a 120 mg dose once daily. The safety and efficacy of Relugolix for the treatment of advanced prostate cancer is primarily based on a Multinational Phase 3 randomized, open-label, parallel-group study that evaluated the efficacy and safety of relugolix in men with androgen-sensitive advanced prostate cancer who required at least one year of continuous ADT. The drug substance is manufactured (b) (4) All excipients are compendial. Although multiple formulations were used in the development, the Phase 3 formulation has been used for the proposed commercial formulation. The relugolix tablets are packaged in HDPE bottle and Aluminum blister card. Based on the primary and supportive stability data, a 24 month expiry was granted for the drug product stored at (b) (4) °C.

Proposed Indication(s) including Intended Patient Population	ORGOVYX is a gonadotropin releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.
Duration of Treatment	Until disease progression
Maximum Daily Dose	Recommended Dosage: A loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day.

	ORGOVYX can be taken with or without food. Instruct patients to swallow tablets whole and not to crush or chew tablets.
Alternative Methods of Administration	N/A.

B. Quality Assessment Overview

Drug Substance: Adequate

Relugolix is a free base white to off-white to slightly yellow solid, without chiral centers. (b) (4)

(b) (4)

Drug Product: Adequate

The proposed ORGOVYX (relugolix) 120 mg tablet drug product is a light red, almond-shaped, film-coated, immediate-release (IR) tablets debossed with "R" on one side and "120" on the other side. The drug product is packaged in 30 count 75 cc high-density polyethylene (HDPE) bottles with desiccant and closed with an induction-sealed child-resistant cap, or 9 count child-resistant single fold-over Aluminum (Alu) blister card. Each tablet contains compendial inactive ingredients: mannitol, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, ferric oxide red, and carnauba wax.

The proposed specification for the drug substance includes tests for appearance, identification (two nonspecific tests: UV and HPLC retention times), assay, related substances, dissolution, content uniformity, water content, and microbiological examination. The proposed acceptance criteria for all the attributes are reasonable from the Quality perspective (as well as nonclinical perspective for the related substances). The batch data for the registration batches as well as supportive clinical batches all conform to the specifications and have low impurity levels.

The drug product is packaged in child-resistant 30 count bottles and 9 count blister cards. The applicant indicated that the materials used for manufacture of the container closure conform to relevant regulations on indirect food additives and relevant USP chapters. The applicant also verified that both the container closures meet the 16 CFR 1700 special packaging requirements.

In the initial submission, the applicant provided stability data for 3 batches of drug product manufactured using drug substance provided by (b) (4). As the applicant withdrew the drug substance manufacturer, (b) (4), due to facility issues, the applicant provided 6 months of long term and accelerated data for 1 batch and release data for 2 additional batches of drug product manufactured using the (b) (4) drug substance supplier, as agreed in a TCON during the review. The data shows that the drug substance manufactured at (b) (4) (b) (4) sites as well as the drug product batches manufactured using them are equivalent. The stability data provided by the applicant show no major trends or out of specification data. Based on the information provided by the applicant, A 24-month expiry dating period is granted for the drug product stored at or below 30°C (86°F).

Labeling: Adequate

The container carton labels and the labeling for the Prescribing Information are deemed acceptable after the applicant revised the labeling based on FDA's comments.

Manufacturing: Adequate

(b) (4)

Biopharmaceutics: Adequate

The proposed dissolution method and acceptance criterion [USP Apparatus 2 (paddle) at 50 rpm, 900 mL of 50 mM citrate buffer, pH 5.5, 37 ± 0.5°C; "Q = (b) (4) % at 30 min"] are adequate for the routine quality control (QC) of Relugolix (Immediate-Release) Tablets/120 mg at batch release and during stability/shelf-life testing. The dissolution method was demonstrated to be capable of detecting intentionally aberrant batches such as those manufactured with (b) (4) API particle size, or with no disintegrant (b) (4) and with higher than tablet hardness, and longer-than target disintegration time.

Overall, the provided data are adequate to bridge the final proposed-to-be-marketed drug product to the drug product that was evaluated in pivotal clinical and stability studies.

The Applicant classified relugolix as a BCS-4 (Biopharmaceutics Classification System-4) (low solubility/low permeability) drug substance. The biopharmaceutics reviewer agrees with the classification.

Microbiology (if applicable): Choose an item.

N/A

C. Risk Assessment

From Initial Risk Identification	Review Assessment

Attribute/ CQA	Factors that can impact the CQA	Initial Risk Ranking*	Risk Mitigation Approach	Final Risk Evaluation	Lifecycle Considerations/ Comments**
Assay, Stability	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	L	(b) (4)	Acceptable	(b) (4)
Physical stability (solid state)	• Formulation • Raw materials • Process parameters • Scale/equipments • Site	M		Acceptable	
Content uniformity	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	L		Acceptable	
Moisture content	• Formulation • Container closure • Process parameters • Scale/equipment • Site	M		Acceptable	
Microbial limits	• Formulation • Container closure • Process parameters • Scale/equipments • Site	L		Acceptable	
Dissolution – BCS Class II & IV	• Formulation • Container closure • Raw materials • Process parameters	M		Acceptable	

	• Scale/equipments • Site		(b) (4)		

D. List of Deficiencies for Complete Response

None.

Application Technical Lead Name and Date:

Xiao Hong Chen December 1, 2020

Xiao Chen

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FDA U.S. FOOD & DRUG ADMINISTRATION

QUALITY ASSESSMENT DATA SHEET

1. RELATED/SUPPORTING DOCUMENTS

A. DMFs:

DMF #	Type	Holder	Item Referenced	Status	Date Assessment Completed	Comments
(b) (4)	III		(b) (4)	Adequate	11/18/2020	No DMF review is necessary since adequate information provided in the NDA.
	III			Adequate	11/18/2020	No DMF review is necessary since adequate information provided in the NDA.
	III			Adequate	11/18/2020	No DMF review is necessary since adequate information provided in the NDA.
	III			Adequate	11/18/2020	No DMF review is necessary since adequate information provided in the NDA.
	III			Adequate	11/18/2020	No DMF review is necessary since adequate information provided in the NDA.

B. OTHER DOCUMENTS: *IND, RLD, RS, Approved NDA*

Document	Application Number	Description
Submission and review documents	IND 118736	Original IND submitted to Division of Hematology and Oncology Products for the proposed indication of GnRH antagonist prostate cancer on 12/11/2013

Submission and review documents	IND (b) (4)	(b) (4)

2. CONSULTS
N/A

Discipline	Status	Recommendation	Date	Assessor
Biostatistics				
Pharmacology/Toxicology				
CDRH-ODE				
CDRH-OC				
Clinical				
Other				

Anamitro Banerjee

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Thomas Oliver

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CHAPTER IV: LABELING

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information:

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Information Provided in the NDA	Assessor's Comments
Product Title in Highlights		
Proprietary name	ORGOVYX	Found acceptable by the Agency
Established name(s)	Relugolix	Acceptable
Route(s) of administration	Oral	Acceptable
Dosage Forms and Strengths Heading in Highlights		
Summary of the dosage form(s) and strength(s) in metric system.	Tablets: 120 mg	Adequate
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	NA	NA

1.2 FULL PRESCRIBING INFORMATION

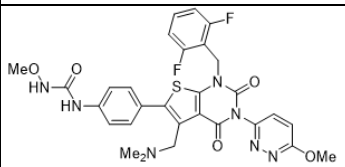
1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents, storage conditions needed to maintain the stability of the reconstituted or diluted product)	NA	NA

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	Tablets	Adequate
Strength(s) in metric system	120 mg	Adequate
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance	NA	NA
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting	light red, almond-shaped, film-coated, and debossed with "R" on one side and "120" on the other side.	Adequate
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	No	NA

1.2.3 Section 11 (DESCRIPTION)

Item	Information Provided in the NDA	Assessor's Comments
DESCRIPTION section		
Proprietary and established name(s)	ORGOVYX, Relugolix	Adequate
Dosage form(s) and route(s) of administration	film-coated tablets for oral administration	Adequate
List names of all inactive ingredients. Use USP/NF names. Avoid Brand names.	mannitol, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, ferric oxide red, and carnauba wax.	Adequate
Pharmacological/ therapeutic class	GnRH receptor antagonist	Adequate
Chemical name, structural formula, molecular weight	 molecular weight: 623.63 daltons molecular formula: $C_{29}H_{27}F_2N_7O_5S$	Adequate
Other important chemical or physical properties (such as pKa or pH)	A white to off-white to slightly yellow solid with a solubility of 0.04 mg per mL in water at 25°C.	Adequate
For oral prescription drug products, include gluten statement if applicable	NA	NA
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity"	NA	NA

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)

Item	Information Provided in the NDA	Assessor's Comments
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s)	Filmcoated tablets	Adequate
Strength(s) in metric system	120 mg	Adequate
Available units (e.g., bottles of 100 tablets)	Bottle contains 30 tablets. Blister cards contain nine tablets.	Adequate
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	The 120-mg tablets are film-coated, light red, almond shaped, and debossed with "R" on one side and "120" on the other side and are supplied in two configurations, bottles (NDC 72974-120-01) and blister packs (NDC 72974-120-02).	Adequate
Special handling about the supplied product (e.g., protect from light, refrigerate). If there is a statement to "Dispense in original container," provide reason why (e.g. to protect from light or moisture, to maintain stability, etc.)	Dispense to patients in original container only. For bottles, keep container tightly closed after first opening. Keep out of reach of children. (b) (4)	Adequate. The applicant provided adequate data to indicate that this is not light sensitive.
If the product contains a desiccant, ensure the size and shape differ from the dosage form and desiccant has a warning such as "Do not eat."	Bottles contain 3 g (b) (4) (b) (4) desiccant in HDPE canisters: 0.99 inch height and 0.762 in diameter	Adequate. No warning statement needed as it differs from the DP: color, weight, and shape.

Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	Do not store above 30°C (86°F).	Adequate The storage temperature of "Do not store above 30ºC (86ºF)" was discussed with Dr. David Claffey, a member of the ONDP labeling workgroup. Dr. Claffey indicated that this storage condition is generally afforded to PEPFAR applications, where the product is used in tropical conditions, however, certain exceptions may be made for critical products that are marketed around the world. This being a critical oncology drug, this storage condition is reasonable.
Include information about child-resistant packaging	Included	Adequate

1.2.5 Other Sections of Labeling

NA

1.2.6 Manufacturing Information After Section 17 (for drug products)

Item	Information Provided in the NDA	Assessor's Comments
Manufacturing Information After Section 17		
Name and location of business (street address, city, state and zip code) of the manufacturer, distributor, and/or packer	Manufactured by Bushu Pharmaceuticals Ltd, Kawagoe-shi, Saitama, Japan Manufactured for Myovant Sciences, Inc., Brisbane, CA 94005	Adequate

2.0 PATIENT LABELING

Assessment of Product Quality Related Aspects of Patient Labeling (e.g., Medication Guide, Patient Information, Instructions for Use):

Patient information provided. CMC sections of the Patient Information:

- **How should I store ORGOVYX?**
  - Store ORGOVYX at room temperature. Do not store ORGOVYX above 30°C (86°F).
  - Keep the bottle tightly closed after you first open it.
  - The ORGOVYX bottle contains a desiccant to help keep your medicine dry (protect it from moisture). Do not remove the desiccant from the bottle.

(b) (4)

Keep ORGOVYX and all medicines out of the reach of children.

What are the ingredients in ORGOVYX?
Active ingredient: relugolix
Inactive ingredients: mannitol, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, ferric oxide red, and carnauba wax.

Manufactured by: Bushu Pharmaceuticals Ltd, Kawagoe, Saitama, Japan

Manufactured for: Myovant Sciences, Inc., Brisbane, CA 94005

For more information, go to www.orgovyx.com or call 1-833-MYOVANT (1-833-696-8268).

The CMC information provided by the applicant in the Patient Information are **adequate**.

Any deficiencies should be listed at the end in the "ITEMS FOR ADDITIONAL ASSESSMENT." NA

3.0 CARTON AND CONTAINER LABELING

The applicant provided updated container and carton labels (for sale as well as not-for sale professional sample pack) for the blister and the bottle configurations via amendment SD#0038(38) dated October 28, 2020.

3.1 Container Label (Blisters)

(a representative example of proposed container: for sale configuration)

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Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Proprietary name, established name, and dosage form (font size and prominence	ORGOVYX (Relugolix)	Adequate
Dosage strength	120 mg	
Route of administration	Not provided in the Carton Container, but provided in the USPI.	Adequate
If the active ingredient is a salt, include the equivalency statement per FDA Guidance	NA	
Net contents (e.g. tablet count)	9 (blisters) 30 (bottles)	Adequate
"Rx only" displayed on the principal display	Yes	Adequate
NDC number	Included	Adequate
Lot number and expiration date	Space provided	Adequate
Storage conditions. If applicable, include a space on the carton labeling for the user to write the new BUD.	Do not store above 30ºC (86ºF)	Adequate
For injectable drug products for parental administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use)	NA	
Other package terms include pharmacy bulk package and imaging bulk package which require "Not for direct infusion" statement.	NA	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	NA	
Bar code	Provided	Adequate

Item	Information Provided in the NDA	Assessor's Comments about Carton Labeling
Name of manufacturer/distributor	Provided	Adequate
Medication Guide (if applicable)	Patient Information Included	Adequate
No text on Ferrule and Cap overseal	NA	
When a drug product differs from the relevant USP standard of strength, quality, or purity, as determined by the application of the tests, procedures, and acceptance criteria set forth in the relevant compendium, its difference shall be plainly stated on its label.	NA	
And others, if space is available	NA	

Assessment of Carton and Container Labeling: ***Adequate***

Any deficiencies should be listed at the end in the "ITEMS FOR ADDITIONAL ASSESSMENT." NA

ITEMS FOR ADDITIONAL ASSESSMENT

NA

Overall Assessment and Recommendation:

Adequate. Recommended for APPROVAL

Primary Labeling Assessor Name and Date: Anamitro Banerjee, Ph.D.

Secondary Assessor Name and Date: Thomas Oliver, Ph.D.

Anamitro Banerjee

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Thomas Oliver

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U.S. FOOD & DRUG ADMINISTRATION

CHAPTER VI: BIOPHARMACEUTICS

Product Information	
NDA Number	214621
Assessment Cycle Number	Original
Drug Product Name/ Strength	Relugolix Tablets /120 mg
Route of Administration	Oral
Applicant Name	Myovant Sciences GmbH
Therapeutic Classification/ OND Division	GnRH receptor antagonist/ Division of Oncology 1
RLD/RS Number	Not Applicable; 505(b)(1)
Proposed Indication/ Proposed Dosage	For the treatment of patients with advanced prostate cancer: single loading dose of 360 mg (three 120 mg tablets), then 120 mg once daily, with or without food; swallow tablet whole

Assessment Recommendation: APPROVAL

Assessment Summary:

The proposed dissolution method and acceptance criterion [USP Apparatus 2 (paddle) at 50 rpm, 900 mL of 50 mM citrate buffer, pH 5.5, 37 ± 0.5°C; "Q = (b)(4)% at 30 min"] are adequate for the routine quality control (QC) of Relugolix (Immediate-Release) Tablets/120 mg at batch release and during stability/shelf-life testing.

Overall, the provided data are adequate to bridge the final proposed-to-be-marketed drug product to the drug product that was evaluated in pivotal clinical and stability studies.

The risk assessment for dissolution is shown below.

CQAs	Initial Risk Ranking	Comments	Updated Risk Ranking after Original NDA review	Comments
Dissolution	Medium	BCS-4 (low solubility, low permeability) drug substance	Low	The proposed dissolution specification is acceptable for the routine QC testing of the finished drug product.

Submission Documents assessed:

	Date Received
Original (SDN-1)	4/20/2020
Response to Quality Information Request (SDN-10)	6/11/2020
Response to Quality Information Request (SDN-19)	7/17/2020
Response to Quality Information Request (SDN-25)	8/12/2020
Response to Quality Information Request (SDN-30)	8/27/2020
Response to Quality Information Request (SDN-31)	9/1/2020
Response to Quality Information Request (SDN-32)	9/11/2020
Response to Quality Information Request (SDN-37)	10/20/2020
Response to Quality Information Request (SDN-42)	11/16/2020

Concise Description of Outstanding Issues (List bullet points with key information and update as needed):

- None

B.1 BCS DESIGNATION

Assessment:

The Applicant classifies (and this Reviewer agrees) that relugolix could be categorized as a BCS-4 (low solubility/low permeability) drug substance. Per the Applicant, relugolix oral tablets is intended for immediate drug release.

Solubility. *Low solubility in aqueous media with pH >5.5*
Relugolix is an anhydrous crystalline free base. As shown in Table S-1 of the Section 2.3.S (and Table 21 of the IR Response in SDN-10), relugolix exhibits (b) (4) Based on the less than 120 mg amount of drug that can fully dissolve in 250 mL media at final pH above 5.5, relugolix is classified as a low solubility drug substance per BCS criteria (b) (4) (b) (4)

(b) (4)

Permeability: *Low*
Per the proposed labeling, the absolute bioavailability of relugolix (b) (4) is approximately 11.6%. Additionally, based on Caco-2 cell line study data, relugolix exhibits low permeability across the intestinal membrane and is a substrate of the P-glycoprotein drug efflux transporter. Specifically, the Applicant reported that the apparent permeability of relugolix drug substance across Caco-2 cells is (b) (4) cm/s from apical to basal and basal to apical, respectively.

Dissolution: *Rapid in Low pH Media; Slow in pH > 5.5 Media*
Using the proposed dissolution method (900 mL of pH 5.5 citrate buffer; USP Apparatus 2/paddle at 50 rpm), (b) (4) dissolution ((b) (4)% dissolves within 30 min). (b) (4)

B.2 DISSOLUTION METHOD AND ACCEPTANCE CRITERIA

The proposed QC dissolution method consists of USP Apparatus 2 (paddles) at 50 rpm; 900 mL of 50 mM citrate buffer, pH 5.5, maintained at 37 ±0.5 °C. The proposed dissolution acceptance criterion is 'Q = (b) (4)% at 30 min'.

Assessment:

DISSOLUTION METHOD – *Adequate*
Table P-4 of 2.3.P. Drug Product or Table P.2.2-7 of 3.2.P.2 Drug Product summarizes the parameters of the final proposed dissolution method. Note that the original dissolution method (differs only from the final dissolution method in terms of the dissolution medium pH (b) (4), and) was revised for primary and supportive stability testing and for future commercial release to improve the method's discriminating power, as well as to increase analytical efficiency by shortening the HPLC analysis time.

Parameter	**Dissolution**
Apparatus	2 (paddles)
Medium	50 mM citrate buffer, pH 5.5
Volume	900 mL
Temperature	37 ± 0.5 °C
Agitation rate	50 rpm

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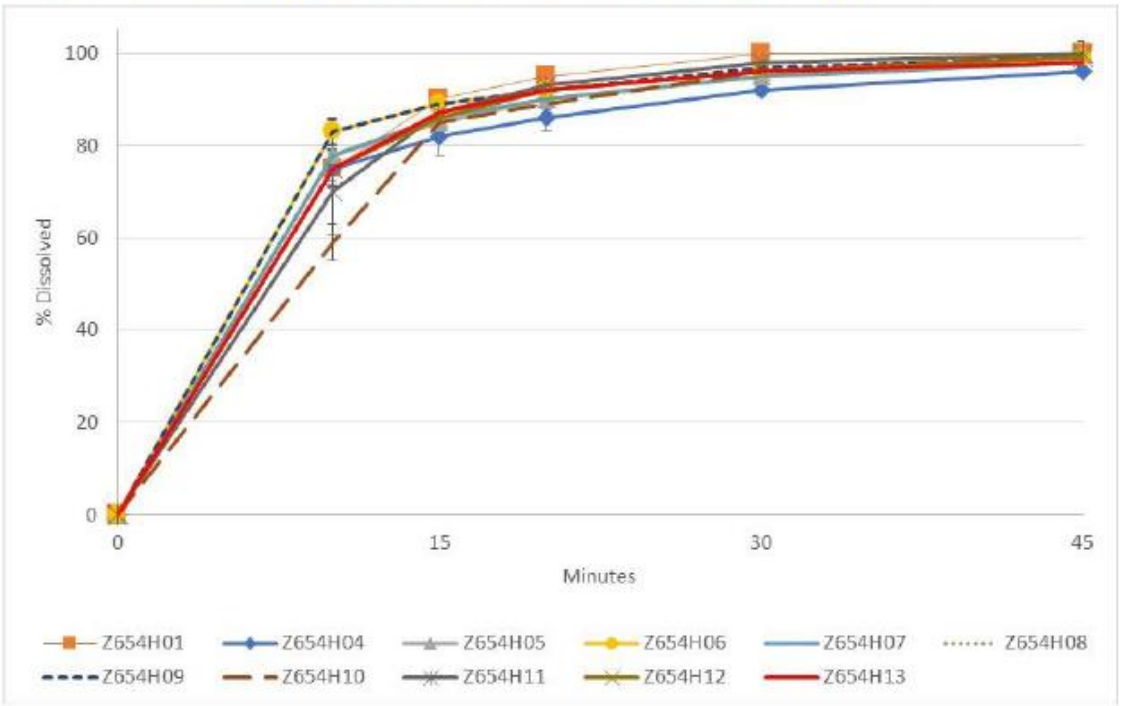
(b) (4)

DISSOLUTION ACCEPTANCE CRITERIA – *Adequate*

(b) (4)

Figure 1. Dissolution of Relugolix Tablets, 120 mg



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Dissolution on Stability

(b) (4)

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(b) (4)

B.12 BRIDGING OF FORMULATIONS

Assessment: *Adequate*

The final proposed to-be marketed *formulation* (T4-B, 120 mg) manufactured by the proposed commercial process and site (b) (4) at the same/similar scale was used in the pivotal Phase 3 study (MVT-601-3201/HERO) and primary/supporting stability studies. PK and PD endpoints were included in the Phase 3 Study.

The proposed commercial drug product batch size (b) (4) is similar to those of the registration/primary stability batches (b) (4) and the Phase 3 clinical trial lots (b) (4)

(b) (4)

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B. 13 BIOWAIVER REQUEST

Assessment: *Not Applicable*

There is only one proposed commercial tablet strength (120 mg) which was evaluated in the pivotal Phase 3 clinical trial. The proposed commercial formulation/process tablet was used in the Phase 3 clinical trial and the registration/stability studies. Formulation changes during clinical development are supported by *in vivo* PK (b) (4) data.

Additional Note:
Per the Applicant, the (b) (4) 120-mg tablet strengths of the (b) (4) formulation are compositionally equivalent on a %w/w basis.

R. REGIONAL INFORMATION

Comparability Protocols

Assessment: *Not Applicable*

Post-Approval Commitments

Assessment: *None*

Lifecycle Management Considerations

(b) (4)

BIOPHARMACEUTICS LIST OF DEFICIENCIES

None

Primary Biopharmaceutics Assessor's Name and Date:
Gerlie Gieser, Ph.D. (11/16/2020)

Secondary Assessor Name and Date (and Secondary Summary, as needed):
Banu Zolnik, Ph.D. (11/17/2020)

Gerlie Gieser

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