

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217779Orig1s000

PRODUCT QUALITY REVIEW(S)

NDA OPQ Review and Evaluation

NDA 217779 Review # 01

OPQ RECOMMENDATION: APPROVAL

Drug Substance Retest Period:

[^(b)₍₄₎ months stored at ^(b)₍₄₎ °C] proposed shelf-life and storage conditions.

FDA Assessment: An expiration dating period of ^(b)₍₄₎ months may be granted when stored at the proposed storage conditions.

Drug Product Expiration Dating Period:

[Shelf life (unopened) ^(b)₍₄₎ stored at 5°C ± 3°C and In-use (once reconstituted and diluted): 48 hours stored at 2-8°C or 18 hours at room temperature (20-25°C)] proposed shelf life and storage conditions.

FDA Assessment: An expiration dating period of 24 months may be granted when stored at the proposed storage conditions for 188 mg imetelstat powder for injection, and an expiration dating period of 12 months may be granted for 47 mg imetelstat powder for injection.

Drug Name/Dosage Form	Imetelstat Powder for Infusion
Strength	188 mg imetelstat (equivalent to 200 mg imetelstat sodium) 47 mg imetelstat (equivalent to 50 mg imetelstat sodium)
Route of Administration	Intravenous
Rx/OTC Dispensed	Rx
Indication	Treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA)
Applicant	Geron Corporation
US agent, if applicable	Not applicable

[FDA will complete these sections.]

Submit Date(s)	January 27, 2023; June 16, 2023 (Rolling submission 2)

Received Date(s)	January 27, 2023; June 16,2023
PDUFA Goal Date	June 14, 2024
Division/Office	Division of Hematology Malignancies 1/Office of Oncologic Diseases
Review Completion Date	April 19, 2024
Established Name	Imetelstat for injection
(Proposed) Trade Name	
Pharmacologic Class	Telomerase inhibitor
Recommendation on Regulatory Action	Approval

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED
SD 4	06/16/2024	All
SD 5	07/14/2023	All
SD 7	08/02/2023	OPMA
SD 11	08/31/2023	Micro/OPMA
SD 12	09/13/2023	DS and DP
SD 15	09/27/2023	All
SD 18	10/11/2023	DS and DP
SD 22	10/19/2023	DP and OPMA
SD 24	10/23/2023	Micro/OPMA
SD 29	12/21/2023	OPMA
SD 32	01/12/2024	DP and OPMA
SD 37	01/29/2024	OPMA
SD 44	02/22/2024	DS and DP (including Non-clinical)
SD 51	03/29/2024	DP
SD 53	04/19/2024	DP

Quality Review Team

DISCIPLINE	PRIMARY REVIEWER	SECONDARY REVIEWER
Drug Substance	Karina Zuck	Gaetan Ladouceur
Drug Product	Olen Stephens	Shalini Anand
Manufacturing	David Acevedo	Christine Falabella
Biopharmaceutics	n/a	n/a
Regulatory Business Process Manager	Dahlia Walters	
Application Technical Lead	Shalini Anand	
ORA Lead	n/a	
Environmental	Olen Stephens	Shalini Anand
Microbiology	Jason God	Julie Nemecek

ORBIT Partner Agency Quality Review Team (To be redacted for FOIA)- N/A

Agency	PRIMARY REVIEWER	SECONDARY REVIEWER

HC Canada		
HSA Singapore		
TGA Australia		
Swissmedic Switzerland		

RELATED/SUPPORTING DOCUMENTS

DMFs:

[Applicant will complete]				[FDA will complete]	
DMF #	Type	Holder	Item Referenced	Status	Comments
(b) (4)	II				
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs
	III			Adequate	Open, Active, supports many A/NDAs

Other Documents: *IND, RLD, or sister applications*

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	072072	The development of imetelstat was initiated under IND 072072 in 2005 with the first-in-human protocol CP04-151 and all CMC and nonclinical information are included in this IND. Currently, clinical development for myelofibrosis proceeds under this IND.
IND	147027	IND 147027 was opened in January 2020 at the request of FDA in

		November 2019 to administratively split the clinical development of myelodysplastic syndromes to a new IND under the Division of Hematologic Malignancies 1 due to an Agency reorganization. This IND references IND 072072 for CMC, nonclinical and historical clinical information.

CONSULTS

[FDA will complete this section.]

OTR non-lab consult (paper evaluation) to evaluate the suitability of the proposed LC-UV and LC-UV/MS analytical methods for drug substance and drug product analysis.

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List of Acronyms

Acronym	Definition
12mers	FLP lacking a single nucleotide
14mers	FLP with one additional nucleotide
(b) (4)	
CFU	Colony Forming Unit
Da	Dalton
EU	Endotoxin Units
FLP	Full Length Product
(b) (4)	
GC-FID	Gas Chromatography with Flame Ionization Detection
ICP-OES	Inductively Coupled Plasma – Optical Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma – Mass Spectrometry
LC-UV/MS	Ultra-High Performance Liquid Chromatography – Ultraviolet Spectroscopy / Mass Spectrometry

Evaluation of the Quality Information

[Applicant to provide link to the data in m3 sections as appropriate]

DIFFERENCES IN M3 MODULE IN SUBMISSIONS TO DIFFERENT AGENCIES

None. The first application submission for Imetelstat is to the US.

1. EXECUTIVE SUMMARY

Summary of Rationale for Recommendation:

- a. The applicant provided sufficient information to assure the identity, strength, purity, and quality of the proposed drug product. All associated manufacturing, testing, packaging facilities were deemed acceptable. Based on the OPQ review team's evaluation of the information provided in the submission, OPQ recommends APPROVAL of NDA 217779 for Imetelstat Powder for Infusion.
- b. **Is the overall recommendation in agreement with the individual discipline recommendations?** Yes

Recommendation by Subdiscipline:

Drug Substance - Adequate
Drug Product - Adequate
Quality Labeling - Adequate
Manufacturing - Adequate
Biopharmaceutics - Adequate
Microbiology – Adequate

Life Cycle Considerations:

In the quality submission dated April 19, 2024, the Applicant agreed to the following PMCs (post-marketing commitments):

Recommended CMC PMC's:

1. Provide sufficient batch data, justification, and proposed quantitative acceptance criteria for the release specifications for 'reconstituted solution concentration'.
Final Report Submission: One year from the anticipated action date.
2. As additional batch and stability data are obtained, submit a CBE-0 supplement annually (over the next five years) to report interim results that reviews this

new data and tighten specification limits for product related substances by the LC-UV/MS method. Provide a final report of efforts to tighten specification limits for the product related substances and analytical method improvements for the LC-UV/MS method at the end of this five-year period as a CBE-0.

PMC Timelines:
Annual interim reports for five years from the anticipated action date and then a final report at the five-year mark.

2. APPLICATION BACKGROUND

Table 1: Application Background			
Reference	Date	Designation	Comment
Orphan Designation #15-5014	23 December 2015	Orphan Drug Designation	Orphan Drug Designation granted for the treatment of patients with myelodysplastic syndrome (MDS).
IND 072072 Referenced ID: 4173182	27 October 2017	Fast Track Designation	Fast Track Designation granted for MDS that is not associated with the del(5q) cytogenetic abnormality and who are refractory or resistant to treatment with an erythropoiesis-stimulating agent (ESA).

3. SUMMARY OF CMC SPECIFIC PRESUBMISSION AGREEMENTS

The Applicant’s Position:

The development of imetelstat in subjects with advanced hematological and solid tumor malignancies was initiated by Geron Corporation under investigational new drug (IND) 072072 in 2005.

In 2014, Geron entered into a license and collaboration agreement with Janssen Research & Development, LLC (Janssen) and IND 072072 was transferred to Janssen in 2015. Clinical development continued under IND 072072 for myelofibrosis and myelodysplastic syndromes.

In 2018, The Geron license and collaboration agreement with Janssen was terminated and IND 072072 was transferred from Janssen to Geron in 2019.

In January 2020, IND 147027 was opened at the request of FDA in November 2019 to administratively split the clinical development of myelodysplastic syndromes to a new IND under the Division of Hematologic Malignancies 1 due to an Agency reorganization. IND 147027 references IND 072072 for CMC, nonclinical and historical clinical information. A list of relevant regulatory CMC history is provided in [Table 2](#).

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The FDA's Assessment: *Consistent with FDA's records*

4. ENVIRONMENTAL ASSESSMENT

The Applicant's Position:

Geron is requesting categorical exclusion for imetelstat in accordance with 21 CFR 25.31(b). Geron is not aware of any extraordinary circumstances exist with the use of this product that would warrant the preparation of an environmental assessment per 21 CFR 25.15(d) Information to support categorical exclusion under 21 CFR 25.31(b) is provided with the NDA submission.

The estimated highest quantity imetelstat (as active moiety) expected to be produced for direct use in any of the next five years is ^{(b) (4)} kg/year.

As required by 21 CFR §25.31(b), the total amount of the active moiety introduced in the aquatic environment (EIC) as a result of maximum use of this product is estimated as being significantly less than 1 ppb.

The FDA's Assessment: *Adequate*

The applicants request for a categorical exclusion under 21 CFR 25.31(b) is accepted based on the estimated concentration entering the aquatic environment.

5. FACILITIES



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11. BIOPHARMACEUTICS - Injectable formulation, so no biopharmaceutics data was submitted to review.

a. BCS Classification

Applicant to fill:

FDA assessment (FDA to fill):

BCS Classification: Choose an item.

Choose an item.

Information to support the BCS Class I designation request, if applicable.

Link:

Page#:

b. Dissolution Test

[Applicant to fill]

USP Apparatus	Paddle Rotation Speed	Medium Volume	Temperature	Medium	Acceptance Criterion

Biopharmaceutics Figure 1: Dissolution Profiles as a function of:

a. Impact of medium pH on dissolution	
Applicant to insert figure here:	Applicant's comments:
FDA Comment:	
b. Impact of paddle Speed on dissolution	
Applicant to insert figure here:	Applicant's comments:
FDA Comment:	
c. Impact of parameter X on dissolution (add as appropriate)	
Applicant to insert figure here:	Applicant's comments:
FDA Comment:	
d. Impact of parameter Y on dissolution (add as appropriate)	
Applicant to insert figure here:	Applicant's comments:
FDA Comment:	
e. Impact of parameter Z on dissolution (add as appropriate)	
Applicant to insert figure here:	Applicant's comments:
FDA Comment:	
f. Justification for selection of the acceptance criteria (or criterion)	
Applicant to indicate whether complete dissolution profile data are available for all	Applicant's comments:

stability timepoints. Applicant to insert multipoint dissolution profile in a graphical format from clinical/PK and primary registration batches figure(s) here:	
FDA Comment:	

	Applicant to fill:	FDA assessment:
The dissolution method is discriminating for:		
i) Particle size distribution (PSD) Link ¹ :	Choose an item.	Choose an item. Page#:
ii) Polymorph/solid state form Link ¹ :	Choose an item.	Choose an item. Page#:
iii) Formulation variations Link ¹ :	Choose an item.	Choose an item. Page#:
iv) Manufacturing process variations Link ¹ :	Choose an item.	Choose an item. Page#:
v) Other (specify): Link ¹ :	Choose an item.	Choose an item. Page#:

¹The applicant to provide link to the appropriate section in the submission. FDA reviewer may update the link as needed.

c. Bridging Throughout Drug Product Development (Formulation, Process, or Site Change)

[To the Applicant: Include a schematic representation of the development of your proposed drug product from initial IND-product to the to-be-marketed product. Include all the formulation/manufacturing/process/etc. changes that occurred throughout development, the studies (in vitro or in vivo) bridging those products, and the PK, clinical, stability-registration studies in which those products were used. Applicant provide supporting data/Figure(s) here:]

Link: Page#:

[To the Applicant: Insert text here]

The FDA's Assessment: Choose an item. Not Applicable.

d. Biowaiver Request

The Applicant's Position:

The NDA Choose an item. contain a biowaiver request

[To the Applicant: Explain the reasons why biowaiver is not needed for the proposed drug product. If biowaiver request is made, provide information to support the biowaiver request, if applicable (compositional proportionality, PK linearity, comparative dissolution profiles with f2 analysis)]

Link:

Page#:

[To the Applicant: Insert text here]

The FDA's Assessment: Choose an item.

Not Applicable

e. Data to Support IVIVC and/or PBBM Modeling, If Applicable.

[To the Applicant: Provide summary of the objective of the model, model development and validation, and outcome. Insert additional text, graphs, and table here to support the information provided above as necessary]

Link:

Page#:

[To the Applicant: Insert text here]

The FDA's Assessment: Choose an item.

Not Applicable

12. LABELING

USPI

Highlights: *Adequate*

TRADENAME (imetelstat) for injection, for intravenous use.

- For injection: 47 mg (b) (4)-powder in a single-dose vial for reconstitution. (Error! Reference source not found.)
- For injection: 188 mg (b) (4)-powder in a single-dose vial for reconstitution. (Error! Reference source not found.)

Section 2 (if relevant): *Adequate*

This section was revised as below in conjunction with the DMEPA reviewer.

Changes were accepted for clarity of this review:

- Calculate the dose of TRADENAME needed based on the patient’s body weight (kg).
- Determine the number of TRADENAME vials needed to achieve the required dose (total mg) per **Error! Reference source not found.** More than one vial may be needed to achieve a full dose.
- Remove the TRADENAME vials from the refrigerator and allow the vials to sit for 10 minutes to 15 minutes (not to exceed 30 minutes) at room temperature 20°C to 25°C (68°F to 77°F) before use.
- Reconstitute each vial of TRADENAME with the volume of 0.9% Sodium Chloride Injection provided in **Error! Reference source not found.** directly onto the lyophilized powder to obtain a concentration of 31.4 mg/mL of imetelstat.

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Table 21: Reconstitution Volumes

Strength ^a	Volume of 0.9% Sodium Chloride Injection for Reconstitution per Vial	Final Concentration of Reconstituted Solution per Vial	Deliverable Volume per Vial
47 mg	1.8 mL	(b) (4) 31.4 mg/mL ^b	1.5 mL
188 mg	6.3 mL	(b) (4) 31.4 mg/mL ^b	6 mL

^a Recommended to use (b) (4)

^b Each vial contains an overfill to account for loss of liquid during preparation and extraction of the reconstituted solution, resulting in the final concentration, (b) (4)

- Swirl each vial gently to avoid foaming until the powder is fully reconstituted (not to exceed 15 minutes). Do not shake.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The reconstituted solution in each vial should appear as a clear to slightly hazy solution, essentially free of visible contaminants, particles and/or particulates. Do not use if discoloration or particulate matter is present.

- Use the reconstituted solution immediately to prepare the TRADENAME diluted solution in the infusion bag.

Dilution:

- Calculate the required volume of the reconstituted TRADENAME solution needed to obtain the appropriate dose according to the patient's body weight.
- Withdraw a volume equal to the required reconstituted TRADENAME solution from a 500 mL infusion bag of 0.9% Sodium Chloride Injection and discard it.
- Add the required volume of reconstituted TRADENAME solution into the infusion bag so that the total final volume of TRADENAME solution in the bag is approximately 500 mL. Discard any unused portion of the reconstituted solution remaining in each vial.
- Gently invert the infusion bag at least 5 times to ensure that the reconstituted TRADENAME is well-mixed. Do not shake the infusion bag prior to administration.

Diluted TRADENAME Solution Storage:

- If not used immediately, ensure that diluted solution for infusion is used within the total timeframes specified below, according to storage temperature:
  - *When stored at room temperature 20°C to 25°C (68°F to 77°F):*
The total time from the reconstitution of TRADENAME to completion of intravenous infusion should not exceed 18 hours from the time reconstitution.
  - *When stored refrigerated 2°C to 8°C (36°F to 46°F):*
The total time from the reconstitution of TRADENAME to completion of intravenous infusion should not exceed 48 hours from the time reconstitution.

Section 3 Dosage Forms and Strengths: Adequate

- For injection: 47 mg of imetelstat (b) (4) supplied as a white to off-white or slightly yellow lyophilized powder in a single-dose vial for reconstitution.
- For injection: 188 mg of imetelstat (b) (4) supplied as a white to off-white or slightly yellow lyophilized powder in a single-dose vial for reconstitution.

Section 11 Description: Adequate

If the following excipients used in the drug product, include warning/declaration in the USPI:

- FD&C Yellow No.5 or No.6, as a color additive (21 CFR 201.20) is not used.
- Phenylalanine, as a component of aspartame (21 CFR 201.21) is not used.
- Sulfites (21 CFR 201.22) is not used.

The applicant was asked to add additional description of the drug substance physical properties. The applicant added, “Imetelstat sodium (b) (4) is a white to off-white or slightly yellow, amorphous, solid powder. It is highly soluble in aqueous solutions, including in 0.9% Sodium Chloride Injection, (b) (4) at both refrigerated and room temperatures. Imetelstat sodium is hygroscopic.” to section 11.

Section 11 includes the pharmaceutical class, the structure, formula, and molecular weight. The excipients are only pH adjusters, (b) (4)

Section 16 How Supplied/Storage and Handling: Adequate
This section was edited with DMEPA to the following:

TRADENAME (imetelstat) for injection is a preservative free, white to off-white or slightly yellow, lyophilized powder available as:

Carton Contents	NDC
One TRADENAME 47 mg single-dose vial	82959-112-01
One TRADENAME 188 mg single-dose vial	82959-111-01

Storage

Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton.
 Do not freeze.

16.1. Storage

Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton.
 Do not freeze.
 No preservative.

Manufacturer Information (Name and Address): Provided: Adequate

Manufactured for:
 Geron Corporation
 919 E. Hillsdale Blvd., Suite 250
 Foster City, CA 94404

Manufactured by (188 mg vials):
Catalent Indiana, LLC
1300 S Patterson Drive
Bloomington, IN 47403

Manufactured by (47 mg vials):
Patheon Italia, S.p.A
2° Trav. SX Via Morolense, 5
03013 Ferentino (FR), Italy

Carton/Container Label *Adequate*

The representative 47 mg vial and 188 mg carton label are presented below to demonstrate that the nonproprietary name, dosage form, strength, salt equivalency statement, storage conditions, contents, NDC number, lot, expiry, and barcode information are provided.

(b) (4)



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Final Risk Assessments

Lyophilized Powder for Injection

Initial Risk Identification			Review Assessment		
Attribute/ CQA	Factors that can impact the CQA	Risk Ranking	Risk Mitigation Approach	Final Risk Evaluation	Lifecycle Considerations/ Comments
Sterility	• Formulation • Container closure • Process parameters • Scale/equipments • Site	High		Low	
Endotoxin Pyrogen	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Medium		Low	
Assay (API), stability	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Low		Low	The Applicant agreed to a PMC to evaluate the available batch release and stability data over the period of next 5 years and tighten specification limits for product related substances by the LC-UV/MS method.
Physical stability (solid state) lyophilized small molecule products	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Low		Low	
Uniformity of Dose (Fill Volume/deliverable volume)	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	Low		Low	
Leachable extractables	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Low		Low	
Re-dispersability /reconstitution time	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipments • Site	Low		Low	
Moisture content (lyophilized)	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Low		Low	
Osmolality	• Formulation • Container closure • Process parameters • Scale/equipments • Site	Low		Low	

Recommendation Page

Drug Substance: Approval

Primary Reviewer: Karina Zuck
Secondary Reviewer: Gaetan Ladouceur

Date: April 8, 2024
Date: April 8, 2024

Drug Product: Approval

Primary Reviewer: Olen Stephens
Secondary Reviewer: Shalini Anand

Date: March 23, 2024
Date: April 12, 2024

An expiration dating period of 24 months may be granted for the 188 mg strength when stored at the proposed storage conditions.

An expiration dating period of 12 months may be granted for the 47 mg strength when stored at the proposed storage conditions.

At the time of this review, there are several deficiencies that should be addressed through CMC Post-Marketing Commitments. Additionally, there are analytical method improvements that can be communicated through the action letter. These are post-marketing commitments.

Recommended CMC PMC's:

1. Provide sufficient batch data, justification, and proposed quantitative acceptance criteria for the release specifications for 'reconstituted solution concentration'.
2. As additional batch and stability data are obtained, submit a CBE-0 supplement annually (over the next five years) to report interim results that reviews this new data and tighten specification limits for product related substances by the LC-UV/MS method. Provide a final report of efforts to tighten specification limits for the product related substances and analytical method improvements for the LC-UV/MS method at the end of this five-year period as a CBE-0.

Method Development Comments (not approvability issues):

FDA is conveying the following comments regarding your analytical methods in an effort to collaboratively improve product control:

(b) (4)

Quality Microbiology: Approval

Primary Reviewer: Jason God

Date: April 24, 2024

Secondary Reviewer: Nemecek, Julie

Date: April 24, 2024

Application Technical Lead: Approval

Shalini Anand

Date: April 18, 2024

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/

SHALINI ANAND
04/30/2024 10:40:26 AM

KARINA M ZUCK
04/30/2024 11:22:01 AM

GAETAN LADOUCEUR
05/05/2024 02:55:38 PM

OLEN M STEPHENS
05/06/2024 07:07:31 AM

DAVID A ACEVEDO SANTANA
05/07/2024 07:38:39 AM

CHRISTINE A FALABELLA
05/20/2024 09:52:43 AM

JASON M GOD
05/20/2024 09:59:11 AM

JULIE C NEMECEK
05/20/2024 10:03:57 AM