Protocol Title: A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 3 Trial of Quemliclustat and Chemotherapy Versus Placebo and Chemotherapy in Patients With Treatment-Naive Metastatic Pancreatic Ductal Adenocarcinoma	
Protocol Number:	PRISM-1
Pharmacy Manual Version Number:	2.0
Sponsor:	Arcus Biosciences, Inc.

CONFIDENTIALITY STATEMENT

Version	Summary of Changes
1	Initial Version
2	Updated protocol title, list of acronyms, administration time of nab-paclitaxel, removed dose levels from AB680 Dose Level table, updated product description to remove unnecessary language, clarified language in section 10.3.2.3 for stable temperatures for reconstitution, updated section 11.3 to include additional instruction.

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1. LIST OF ACRONYMS

Acronym	Definition
AB680	quemliclustat
CRA	Clinical Research Associate
CRO	Contract Research Organization
EDC	Electronic Data Capture
Gem	Gemcitabine
IB	Investigator's Brochure
IP	Investigational Product
IRB / EC	Institutional Review Board / Ethics Committee
IRT	Interactive Response Technology
NP	Nab-paclitaxel (Abraxane®)
SDS	Safety Data Sheet
PDAC	Pancreatic Ductal Adenocarcinoma
PI	Principal Investigator
TE	Temperature Excursion
USB	Universal Serial Bus

2. PURPOSE

This Pharmacy Manual provides instructions for the management of the Investigational Product(s) (IP) to be administered to PRISM-1 patients.

IP that that will be administered to patients are as follows:

- **Central Sourced:** Quemliclustat (AB680) will be supplied by the Sponsor ('Arcus') by way of a central drug depot. If unable to be sourced by the site, the Sponsor will also provide nab-paclitaxel (NP) and gemcitabine (Gem) from the central depot.
- **Site Sourced:** Commercially available therapies, gemcitabine and nab-paclitaxel, will be provided by the Trial Site, a site subsidiary or designee, depending on local country operational or regulatory requirements. Product information for those locally supplied treatments, such as description, storage, preparation, and administration, are not included in this manual and should be obtained from the product package inserts. If required based on Regulatory or Institutional requirements, these products may be supplied by the Sponsor ('Arcus') by way of a central drug depot.

This Pharmacy Manual should be reviewed by and be accessible to Trial Site staff involved in the receipt, storage, dispensation, preparation, administration, accountability, and destruction of IP. Pharmacy staff should review the Study Protocol, the Investigator's Brochure (IB), and this Pharmacy Manual (all applicable revisions) carefully before engaging in activities related to IP. Training should be documented as per Trial Site process and be made available to the Clinical Research Associate (CRA) upon request. The CRA is the primary contact for IP related questions.

3. SITE PERSONNEL RESPONSIBILITIES

Arcus recommends that the Principal Investigator (PI) assigns IP management to one primary unblinded study staff member (i.e., a licensed pharmacist). It is also recommended that a back-up be identified to cover in the absence of the primary study staff member. All Site staff involved in IP management should be documented on the Trial Site Signature and Delegation Log (or equivalent).

If IP preparation is delegated to a non-pharmacist, such as a nurse, that individual MUST:

- Meet local regulations for IP preparation,
- Be appropriately trained in IP preparation that maintains trial blinding,
- Have adequate access to IRT system
- Be identified on the Trial Site Signature and Delegation Log, and
- Have documented training on their responsibilities defined in Delegation Log.

Before dosing a patient, the following must be completed:

- Confirm patient has signed the appropriate Informed Consent Form,
- Assignment of a patient identification number,
- Confirm patient is deemed eligible, and
- Confirm treatment assignment by the Sponsor or designee.

An accurate and timely record is required for tracking IP through receipt, storage, dispensation, preparation, administration, accountability and destruction/return. This includes:

- Documentation of receipt (confirmation of receipt of accompanying shipments, IRT confirmation notices, packing slips, in-transit temperature monitoring reports) to include quantity, material status, signature and date
- Maintenance of Drug Accountability Logs
- IRT Randomization, if applicable, and IP assignments
- IP Destruction/return forms

All IP shipment, accountability, preparation and destruction documentation should be filed appropriately in the Pharmacy Binder.

The unblinded CRA will routinely review the IP records to ensure compliance with the Study Protocol for treatment group assignment, preparation, correct administration of IP (including treatment, dosage and treatment interval), accountability, and return/destruction. Trial Site personnel must document any discrepancies on the appropriate log and take appropriate corrective and preventive action, as required, including reporting to Institutional Review Board (IRB)/Ethics Committee (EC) if applicable.

4. STUDY OVERVIEW

This is a randomized, placebo-controlled, double-blind, 2-arm, global, multicenter, Phase 3 study to evaluate the overall survival (OS) of quemliclustat (AB680) versus placebo when each is given in combination with standard-of-care (SOC) NP-Gem in patients with confirmed mPDAC previously untreated in the metastatic setting.

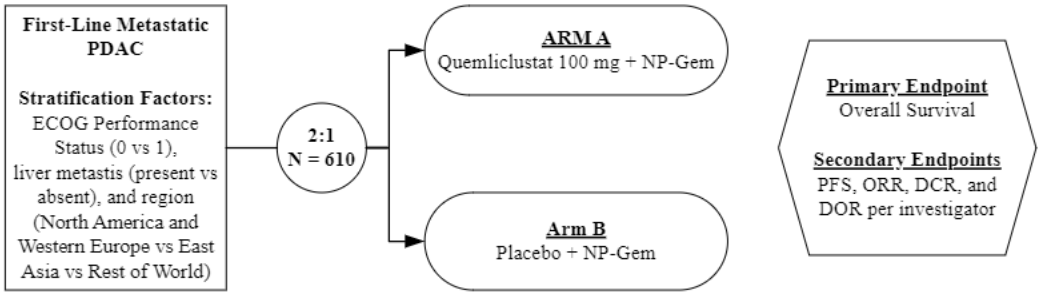
Approximately 610 patients will be enrolled in the study and randomized 2:1 to Arm A or Arm B. Patient randomization will be stratified by presence or absence of liver metastases; Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) (0 versus 1); and region (North America and Western Europe versus East Asia versus Rest of World). A patient is considered enrolled after completing the informed consent process, meeting all eligibility criteria, none of the exclusion criteria, and being randomized.

Crossover between the experimental and comparator arms is not allowed. Patients should continue treatment until permanent treatment discontinuation criteria are met. In addition,

the maximum treatment duration for quemliclustat (AB680)/placebo is 2 years from the initial dose.

The study schema is depicted in Figure 1.

Figure 1. PRISM-1 Study Schema



Arm A (Experimental Arm)

Doses and administration of quemliclustat (AB680), nab-paclitaxel and/or gemcitabine will be administered using a 28-day Cycle for up to 2 years:

- Quemliclustat (AB680) administered at 100 mg intravenously (IV) over 30 minutes (±5 minutes) on Days 1 and 15 of each cycle
- Nab-paclitaxel administered at 125 mg/m2 IV over 30 minutes (±5 minutes) on Days 1, 8, and 15 of each cycle
- Gemcitabine administered at 1000 mg/m2 IV over 30 minutes (±5 minutes) on Days 1, 8, and 15 of each cycle

Arm B (Comparator Arm)

Doses and administration of placebo, nab-paclitaxel and/or gemcitabine will be administered using a 28-day Cycle for up to 2 years:

- Placebo administered every 2 weeks IV over 30 minutes (±5 minutes) on Days 1 and 15 of each cycle
- Nab-paclitaxel administered at 125 mg/m2 IV over 30 minutes (±5 minutes) on Days 1, 8, and 15 of each cycle
- Gemcitabine administered at 1000 mg/m2 IV over 30 minutes (±5 minutes) on Days 1, 8, and 15 of each cycle

5. INVESTIGATIONAL PRODUCT(S)

The IP for PRISM-1 includes:

- Quemliclustat (AB680)
- Nab-paclitaxel – Abraxane®
- Gemcitabine

Abraxane® is the brand of nab-paclitaxel that must be used even if nab-paclitaxel is locally sourced by the site. If Abraxane® is unavailable due to supply shortage in countries where Pazenir® is approved, then Pazenir® may ONLY be used in place of Abraxane® in consultation with the sponsor. Patients who begin treatment with either Abraxane® or Pazenir® must continue to use the same brand of nab-paclitaxel for the duration of their treatment with nab-paclitaxel. However, if the brand of NP the patient initiated treatment on becomes unavailable, the alternative brand of NP (i.e., Abraxane® or Pazenir®) may be used upon approval from the sponsor.

Generic gemcitabine will be centrally sourced and provided by Arcus to sites who are unable to source on their own. If locally sourced, sites must use Gemzar® or a generic gemcitabine that has been approved by the local Health Authority in the country of randomization.

Detailed information is included in this Pharmacy Manual, the IBs, and Safety Data Sheets (SDS) located in Appendix 1.

5.1 Product Description(s)

5.1.1 Non-marketed Products

Quemliclustat (AB680) is a potent, selective, and reversible inhibitor of CD73, and blocks the generation of adenosine from AMP and reverses the immune-inhibitory effects of AMP/adenosine. Quemliclustat (AB680) is supplied as a sterile lyophilized powder in a single-use, glass vial with a white flip-off cap which must be reconstituted and further diluted for IV injection. The quemliclustat (AB680) vial, stopper, and cap are latex free.

Quemliclustat (AB680) Powder for Solution for Injection	
Vial Contents	107.5 mg/vial
Route of Administration	Solution for Injection
pH	6.8 – 7.6
Formulation Component	Arginine, mannitol and phosphoric acid
Reconstitute with	8.6mL of normal saline (0.9% sodium chloride)
Appearance of Reconstituted Solution	Clear, colorless to yellow solution, essentially free from visible particulates

5.1.2 Central Sourced Marketed Products

SmPC's for centrally sourced marketed products can be found at:
https://arcusbio.egnyte.com/fl/4tEQtTuL8M

Nab-Paclitaxel

Compound	Presentation	MA Holder	License/MA Number
Nab-Paclitaxel (Abraxane)	100mg Single Dose Vial	Bristol-Myers Squib Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867 IRELAND	EU/1/07/428/001

Gemcitabine

Compound	Presentation	MA Holder	License/MA Number
Gemcitabine (Ribozar)	1g Powder for Solution for Infusion Vial	Hikma Farmaceutica (Portugal) SA Estrada do Rio da Mo 8, 8A-8B, Fervenca 2705-906 Terrugem SNT Portugal co Distributor: Hikma Pharma GmbH Lochhamer Stre. 13 82152 Martinsried Germany	ZUL 73878.00.00 (Germany)
Gemcitabine (Gemcitabine Powder AqVida)	1g Powder for Solution for Infusion Vial	AqVida GmbH, Kaiser-Wilhelm-Str., Hamburg, Germany	ZUL 79590.00.00 PZN 16758495 (Germany)
Gemcitabine (Gemcitabine Hikma 38 mg/ml)	Concentrate for solution for infusion 1000 mg, 38mg/mL	Hikma Farmaceutica (Portugal) SA Estrad do Rio da Mo 8, 8A-8B, Fervenca 2705-906 Terrugem SNT Portugal co Distributor: Hikma Pharma GmbH Lochhamer Stre. 13 82152 Martinsried Germany	ZUL 2203452.00.00 (Germany)

5.2 Product Packaging and Labelling

For Arcus Sponsored Trials, each vial of quemliclustat (AB680) is provided in a white carton, where it must remain until use. The vial and the carton will be labeled according to local regulatory requirements. Each vial will contain a unique kit ID for purposes of dispensation and accountability. Complete any additional information, as required or applicable, by country regulations:

- Carton: Subject No., Dispense Date, Investigator, Site No., Visit No.
- Vial: Subject No., Dispense Date, Visit No.

Nab-paclitaxel and gemcitabine labeling will be according to the commercially available presentations, as supplied centrally or locally for each country. Labeling will be in the appropriate languages for each country and an investigational label will be applied to the drug packaging if required by a country's regulations. Each vial will contain a unique kit ID for purposes of dispensation and accountability. Complete any additional information, as required or applicable, by country regulations:

- Carton: Subject No., Dispense Date, Investigator, Site No., Visit No.
- Vial: Subject No., Dispense Date, Visit No.

6. INTERACTIVE RESPONSE TECHNOLOGY (IRT)

The IRT system, YPrime, contains information related to the trial site, patients, and IP inventory, and will be used for the following:

- IP Shipment Requests
- IP Shipment Receipt Acknowledgement
- Patient Randomization/ Enrollment
- IP Assignment (including lot and quantities)
- IP Inventory Management, including Expiration and Quarantine
- Patient Treatment Discontinuation
- Temperature Excursions
- IP Returns and Accountability

For details on IRT system access, training, the website URL link, etc., reference the IRT Quick Reference Guide.

7. CENTRAL SOURCED IP INVENTORY

Shipments of IP will be sent to the address provided by the Trial Site staff to the CRA. Trial Site staff should immediately alert the CRA if the IP shipment address changes at any point during the study.

IP will be shipped according to the shipping schedule for the Central Depot.

A USB temperature monitoring device will be included in each shipping box. Instructions on how to stop, read, and download the temperature monitor are included in each shipment.

Each shipment of quemliclustat (AB680) will include:

- IP
- Packing slip
- USB temperature monitoring device

Each shipment of gemcitabine and nab-paclitaxel will include:

- IP
- Packing slip
- USB temperature monitoring device

7.1 Initial Shipment

Initial Shipments will be triggered in YPrime after all essential documents have been received and upon site activation. IP requirements for the initial shipment will be defined in the IRT.

7.2 Resupply Shipments

Resupply Shipments will be triggered automatically in YPrime based on a resupply algorithm that considers patient visit schedule(s), current inventory levels, inventory expiration and other factors. It is important that inventory and statuses are appropriately captured in IRT per the IRT Quick Reference Guide and in a timely manner to ensure the resupply algorithm functions as designed. If there is a need for a resupply shipment based on patient schedules, holidays, etc., please contact your CRA to coordinate with Sponsor or designee.

8. CENTRAL SOURCED IP SHIPMENTS

8.1 Shipment Receipt

The unblinded pharmacist or designee is responsible for proper inspection of each IP shipment received. Shipments should be opened immediately upon receipt at Trial Site. The temperature monitor should be located, and the included instructions (Appendix 2) followed to stop recording. **If a Temperature Excursion is noted, reference Section 8.3 (in transit Temperature Excursions) of this manual for further instructions.**

The IP should be removed from the shipper and:

1. Inventoried against the Packing Slip
2. Inspected for damage
3. Transferred for storage in the appropriate storage conditions

All forms accompanying each shipment should be reviewed and filed in the Pharmacy Binder.

Record each IP Shipment receipt on the respective Drug Accountability Log(s) or sponsor approved site accountability system. Sample Drug Accountability Logs are included in Appendix 6.

8.2 IRT Shipment Receipt Confirmation

Each shipment must also be confirmed as received in YPrime to ensure the IRT resupply function triggers appropriately and to avoid issues when dispensing in IRT.

For details on how to receive shipments in IRT, including how to note any as damaged, missing, etc., reference the IRT Quick Reference Guide.

8.3 In-Transit Temperature Excursions

Temperature Excursions (TEs) should be reported in whole numbers, following USP rounding rules. For example, a temperature of 8.4°C would be considered 8°C but a temperature of 8.5°C would be considered 9°C. Events do not require reporting if the time outside of the labelled storage conditions (including rounding rules above) does not exceed 15 minutes.

All Temperature Excursions will be communicated to Sponsor at productcomplaints@arcusbio.com using Product Complaint and Temperature Excursion Intake Form (Appendix 5) within 1 business day from the date of TE discovery. Trial Site staff must determine whether the TE meets the criteria for quarantining pending Sponsor disposition according to Temperature Excursion Guidance for Investigational Product (IP) Supplied by Arcus (Appendix 4). For a TE that is outside the allowable range, Trial Site staff must quarantine all impacted IP and await disposition by Sponsor.

If the IP meets the criteria for quarantine:

- Remove all IP from the shipper
- Quarantine all IP from the shipper(s) at the labelled storage temperature,
    - Immediately place IP in a quarantined storage area under correct storage conditions clearly identifying Quarantine status of material. Quarantined IP must be physically separated from IP that is approved for use, to avoid accidental dispensation, and labeled as quarantine.
- Quarantine the shipment in IRT according to the IRT Quick Reference Guide,
- DO NOT discard or dispense the affected IP, and
- Notify productcomplaints@arcusbio.com and copy the CRA immediately.

The information provided will be used to determine if the IP is still acceptable for use. The Sponsor, CRA, or designee will notify Site staff within 1-2 business days with the final disposition. The final TE form including Sponsor disposition should be filed in the Pharmacy Binder. If the IP is deemed not acceptable for use, please refer to Section 13, IP Accountability, for instruction on documenting this on Drug Accountability Log and Section 14, IP Disposition, for instruction on destruction and/or return.

9. IP STORAGE

9.1 IP Storage

IP must be stored in a temperature controlled, monitored, secure location with limited access at all times.

Quemliclustat (AB680) will be stored at 2°C–8°C (36°F–46°F), protected from light.

For central sourced marketed products refer to the Clinical Label for storage conditions.

Temperature logs should be maintained for each IP storage location from the time of receipt to return/destruction. Temperature should be monitored at least daily on operating business days. Electronic devices/systems for monitoring temperature for IP storage locations are acceptable if properly calibrated. Data maintained within electronic devices/systems for IP storage temperature monitoring must be complete, accurate, reliable (i.e., data backup) and must demonstrate consistent intended performance (i.e., validation). CRAs must have access to temperature records and calibration reports for review during each monitoring visit.

9.2 On-Site Temperature Excursions

Temperature Excursions (TEs) should be reported in whole numbers, following USP rounding rules. For example, a temperature of 8.4°C would be considered 8°C but a temperature of 8.5°C would be considered 9°C.

Trial Site staff must determine whether the TE meets the criteria for quarantining pending Sponsor disposition according to Temperature Excursion Guidance for Investigational Product (IP) Supplied by Arcus (Appendix 4). All Temperature Excursions requiring notice to Sponsor will be sent to productcomplaints@arcusbio.com using Product Complaint and Temperature Excursion Intake Form (Appendix 5) within 1 business day from the date of TE discovery. For TE that requires quarantine according to the Temperature Excursion Guidance for Investigational Product(IP) Supplied by Arcus (Appendix B), Trial Site staff must quarantine all impacted IP and await disposition by Sponsor.

If the IP meets the criteria for quarantine:

- Quarantine all impacted IP at the labelled storage temperature,
  - Place IP in a quarantined storage area under correct storage conditions, clearly identifying quarantine status of material. Quarantined IP must by physically separated from Ip that is approved for use, to avoid accidental dispensation, and labeled as quarantine.
- Quarantine the IP in IRT according to the IRT Quick Reference Guide,
- DO NOT discard or dispense the affected IP, and
- Notify the CRA immediately.

The information provided will be used to determine if the IP is still acceptable for use. The Sponsor, CRA or designee will notify Trial Site staff of the initial assessment decision or immediate action within 1-2 business days. The final TE form should be filed in the Pharmacy Binder. If the IP is deemed not acceptable for use, please refer to Section 13, IP Accountability, for instruction on documenting this on Drug Accountability Log and Section 14, IP Disposition, for instruction on destruction and/or return.

10. IP DISPENSING AND PREPARATION

IP is to be dispensed in accordance with the Study Protocol and only to patients who meet study eligibility criteria and by appropriately trained staff authorized on Delegation Log (or equivalent).

Trial Sites must document the IP preparation steps in source documentation.

To maintain the blind, quemliclustat (AB680) and placebo will be prepared and dispensed in a blinded fashion by an unblinded pharmacist at the study site. The unblinded pharmacist will obtain each patient's study identification number and study drug assignment from the IRT and prepare study treatment solutions for infusion. The unblinded pharmacist will provide the blinded study site staff with ready-to-use, blinded and identically packaged quemliclustat (AB680)/saline infusion solutions for administration at scheduled infusion visits.

Central Sourced Marketed Products

Gemcitabine and nab-paclitaxel will be prepared in line with SmPC guidelines referenced in section 5.1.2.

Quemliclustat (AB680)

10.1 Quemliclustat (AB680) will be prepared under aseptic conditions on the day administered, preferably within 4 hours of patient dosing. IP vials are preservative free. Therefore, they are single use only. Each vial contains 107.5 mg of lyophilized quemliclustat (AB680) powder.

Note: As a precaution, quemliclustat (AB680) should be protected from direct sunlight exposure during preparation prior to dosing.

10.2 Quemliclustat (AB680) must be reconstituted with 0.9% aqueous sodium chloride and further diluted for patient administration. Use of Polyolefin (PO) IV bags and infusion sets are preferred, however other non-PO infusion supplies may be used as needed. Viaflex or formulated PVC (PL146), and ethylene vinyl acetate (EVA) IV bags are considered to be equivalent. Glass or LDPE IV bottles may also be used.

10.3 Reconstitution Instructions

10.3.1 Allow the vial of quemliclustat (AB680) to reach room temperature for approximately 30 minutes prior to reconstitution.

10.3.2 In a sterile environment, using aseptic technique:

10.3.2.1 Withdraw 8.6 mL of normal saline (0.9% sodium chloride) for the quemliclustat (AB680) reconstitution solution. Use appropriately sized

syringe(s) to obtain the required 8.6mL volume, then slowly inject the saline into the quemliclustat (AB680) vial.

10.3.2.2 Slowly reconstitute, avoiding bubbling and vigorous shaking.

10.3.2.3 After reconstitution, check the vials to ensure that the solution is a colorless to yellow, clear liquid essentially free from visible particulates. If turbidity or foreign materials are observed, the solution must not be used. In this case, obtain replacement for patient dosing and follow appropriate Product Complaint reporting procedure.

Note: Reconstituted quemliclustat (AB680) is stable for up to 4 hours at room temperature or refrigerated (2°C-8°C) storage.

Quemliclustat (AB680) for Dilution	
Reconstitute with	0.9% aqueous sodium chloride solution
Reconstitution solution container	Solution packaged in Polyolefin (PO) IV bag is preferred. However other non-PO infusion supplies may be used as needed. Alternatively, Viaflex or formulated PVC (PL146), and ethylene vinyl acetate (EVA) IV bags are considered to be equivalent. Glass or LDPE IV bottles may also be used.
Appearance of reconstituted solution	Clear, colorless to yellow solution, essentially free from visible particulates

10.4 Dilution Instructions

10.4.1 Reference quemliclustat (AB680) Reconstitution and Dilution by Dose Level table below.

10.4.2 Using appropriately sized syringe(s), withdraw the appropriate volume of 0.9% sodium chloride per table from a 100 mL IV infusion bag (PO and EVA are suitable for use) or equivalent and discard.

10.4.3 Using appropriately sized syringe(s), withdraw the appropriate volume of the reconstituted quemliclustat (AB680) solution, per table below, and slowly inject into the 100 mL IV infusion bag containing 0.9% sodium chloride.

10.4.4 Gently invert the IV bag to ensure complete mixture. Do not shake the bag.

10.4.5 After dilution, check to ensure that the solution is a colorless, clear liquid free from suspended or other foreign materials. If turbidity or foreign materials are observed, the solution must not be used. In this case, obtain replacement for participant dosing and follow appropriate Product Complaint reporting procedure.

10.4.6 Following dose preparation, any quemliclustat (AB680) solution remaining in the vial must not be used for subsequent doses or another participant.

Quemliclustat (AB680) (AB680) vials should be returned to carton for accountability or destroyed on site if authorized by the Sponsor.

Quemliclustat (AB680) for Infusion	
Dilute with	0.9% sodium chloride
Preparation Supplies	100 mL IV infusion bag (PO preferred, though Viaflex or formulated PVC (PL146), and ethylene vinyl acetate (EVA) IV bag, glass or LDPE IV bottles may also be used)
Appearance of diluted solution	Colorless, clear liquid free from suspended or other foreign materials

Quemliclustat (AB680) Reconstitution and Dilution by Dose Level

Dose Cohort	Reconstitution				IV Bag Preparation				Final Dose	
Strength	Number of AB680 vials	AB680 (mg) per Vial	Saline Reconstitution Volume per Vial (mL)	Concentration in vial (mg/mL)	Reconstituted Solution Volume Extracted (mL)	Calculated dose (mg/bag)	Saline Volume Withdrawn from Bag	AB680 Concentration (mg/mL)	Dose Volume to Prepare in Infusion Bag (mL)	Dose Volume to Administer
50 mg	1 vial	107.5 mg	8.6 mL	12.5 mg/mL	4.0 mL x 1 = 4.0 mL	50 mg/ bag	4.0 mL	0.50 mg/mL	100 mL	100 mL
75 mg	1 vial	107.5 mg	8.6 mL	12.5 mg/mL	6.0 mL x 1 = 6.0 mL	75 mg/ bag	6.0 mL	0.75 mg/mL	100 mL	100 mL
100 mg	1 vial	107.5 mg	8.6 mL	12.5 mg/mL	8.0 mL x 1= 8.0 mL	100 mg/ bag	8.0 mL	1.00 mg/mL	100 mL	100 mL

11. IP ADMINISTRATION

Quemliclustat (AB680)

11.1 Quemliclustat (AB680) prepared infusions may be stored for up to a total cumulative time of 4 hours at room temperature (preferred) or a total cumulative time of 24 hours refrigerated (2°C-8°C; 36°F-46°F). Total storage time should not exceed cumulative of 4 hours at room temperature (preferred) and 24 hours refrigerated (2°C-8°C; 36°F-46°F), which is defined from time of preparation (vial seal broken) to the time of infusion start. If the dose solution is stored refrigerated, it should be allowed to reach room temperature for approximately 30 minutes prior to administration.

11.2 Prior to the start of the infusion, allow IV bag/bottle(s) containing IP to come to room temperature (for approximately 30 minutes).

11.3 Quemliclustat (AB680) is administered as separate IV infusion over approximately 30-minutes (+/-5 minutes) using an infusion pump. Quemliclustat (AB680) should be administered through large bore peripheral lines or via central-line access. The end of infusion is defined as the time when the infusion pump is stopped. The infusion line should be further flushed and the line flush volume must not exceed 50 mL. The infusion line must contain 0.2 or 0.22 micron in-line or add-on filter to remove any particulates that may be present. The entire contents of the IV bag/bottle(s) will be administered.

11.4 A physician must be present at the site or immediately available to respond to emergencies during all administrations of study drug. The duration of study drug

administration must be recorded. The patient will be monitored closely during the infusion for any adverse reactions. Once the infusion is complete, it is recommended the infusion line be flushed with the same diluent used to prepare the infusion in section 10.4.2, to ensure any remaining drug be delivered to the patient.

11.4.1 DO NOT co-administer other drugs through the same infusion line as quemliclustat (AB680) (AB680).

11.5 The infusion line must contain 0.2 or 0.22 micron in-line or add-on filter, to remove any particulates that may be present.

11.6 Administration of 0.9% sodium chloride hydration in the same line with quemliclustat (AB680) is an option if the study drug is diluted in 0.9% sodium chloride.

11.7 Treatment modification should be managed as described in the study protocol.

If quemliclustat (AB680)/placebo is administered on the same day as NP and Gem, the study treatments must be administered in the following order as described:

- Administer 100 mg quemliclustat (AB680)/placebo IV over a 30-minute (± 5 minutes) period followed by a 30-minute (+ 15 minutes) rest interval
- Administer NP 125 mg/m2 IV over a 30-minute (± 5 minutes) period or per institutional guidelines
- Administer Gem 1000 mg/m2 IV over a 30-minute (± 5 minutes) period or per institutional guidelines immediately after NP

If only NP and Gem are administered on a given study day, the study treatments must be administered in the following order as described:

- Administer NP 125 mg/m2 IV over a 30-minute (± 5 minutes) period or per institutional guidelines
- Administer Gem 1000 mg/m2 IV over a 30-minute (± 5 minutes) period or per institutional guidelines immediately after NP

Gemcitabine and nab-paclitaxel will be prepared in line with SmPC guidelines referenced in section 5.1.2 or in the relevant prescribing information according to institutional standard practice.

Note: Should an overdose occur, this should be reported per the Study Protocol, section 7.2.3.

12. IP BLINDING

This is a double-blinded study. To maintain the blind, quemliclustat (AB680) and placebo will be prepared and/or dispensed in a blinded fashion by an unblinded pharmacist at the study site. The unblinded pharmacist will obtain each patient's study identification number and study-drug assignment from the IRT and prepare study treatment solutions for infusion. The unblinded pharmacist will provide the blinded study-site staff with ready-to-use, blinded, and identically packaged quemliclustat (AB680)/placebo infusion solutions for administration at scheduled infusion visits. The sponsor and its personnel (except for select designated agents such as the IRT service provider, Clinical Supply personnel, Safety users, PK/PD laboratory personnel, IDMC members, etc.), the study site personnel (excluding the unblinded pharmacist), and the patient will be blinded to quemliclustat (AB680) versus saline placebo administration.

In the event of a medical emergency or pregnancy in which knowledge of the investigational product (i.e., quemliclustat (AB680) versus placebo) will alter the immediate medical management of the patient, emergency unblinding of the patient may be performed by the investigator. Although not required, it is also strongly recommended that the decision to unblind a patient's treatment assignment first be discussed with the medical monitor. Patients whose treatment assignment is unblinded will be discontinued from further treatment with quemliclustat (AB680)/placebo. However, patients will be allowed to continue with NP-Gem following resolution of the AE to baseline or Grade ≤ 1 if the AE is unrelated to NP-Gem per investigator assessment and the medical monitor has reviewed and agreed with the lack of causality for NP-Gem. If these conditions for continuing NP-Gem are not met before the patients exceeds the maximum 28-day treatment delay allowed for NP-Gem, NP-Gem will be permanently discontinued. Please consult the IRT manual regarding how to unblind the patient's treatment assignment in IRT.

Patients with disease progression and who are considering subsequent treatment in a clinical trial that requires knowledge of prior treatment with an adenosine pathway modulator or related mechanism (e.g., immunotherapy), unblinding of the patient's treatment assignment may be allowed following approval from the medical monitor or designee. Upon approval from the medial monitor or designee, the investigator can unblind the patient's treatment assignment through the IRT as described in the IRT manual.

In the event of a patient's unblinding by the investigator, the sponsor will remain blinded.

While the trial is ongoing, requests for unblinding for reasons other than those specified above will not be permitted unless required by regulatory authorities. Any planned or unplanned unblinding, including accidental or emergency unblinding, should be reported, documented, and assessed for impact to trial results.

If emergency unblinding is required, reference Section 17 (emergency unblinding) of this manual for further instructions.

13. IP ACCOUNTABILITY

IP accountability should be maintained in accordance with the Study Protocol. IP will be accounted for in the IRT using a drug accountability module by an unblinded CRA.

The unblinded pharmacist or designee must maintain records of the receipt, usage, and disposal/return of IPs. Refer to Appendix 6 for study specific Drug Accountability Logs. Accountability logs must be kept current and should contain the following information:

- Initial and resupply IP receipt at Trial Site
- On-hand balance of IP inventory at Trial Site
- Patient identification number for IP dispensing
- Quantity of units of IP dispensed at each visit
- Dates of dispensation and lot numbers of IP dispensed
- Final reconciliation of IP at conclusion of the study
- Quantity and lot numbers of IP destroyed
- Quantity and lot numbers of IP returned to drug depot

Trial Sites may use their internal documents or inventory management systems for IP accountability as long as the CRA has reviewed and documented that the system meets the requirements. Requirements include:

1) The same details of accountability are captured,
2) The CRA has access to the forms, reports, or systems for review at each monitoring visit,
3) Any electronic systems have been appropriately validated to meet relevant regulatory expectations for electronic systems used in clinical trials, and documentation of the validation is available for review by the CRA, Sponsor representatives, and Regulatory Authorities; and
4) At the end of the study, a final record can be generated for filing.

All IP records and inventory must be available for inspection by the Sponsor or designee, the CRA, or Regulatory Authorities. The CRA will perform ongoing IP accountability and reconciliation. IP accountability and reconciliation discrepancies should be reported to the CRA once identified by the Trial Site (loss, damage, etc.). Documentation for the discrepancy should be maintained in the Trial Site pharmacy files.

14. IP DISPOSITION

No IP should be disposed of without prior approval of the CRA. Investigational Product disposal or return will be conducted periodically throughout the study and at study close out following CRA accountability and reconciliation unless site has been approved to destroy used IP vials immediately. Used IP vials that are awaiting accountability and reconciliation should be kept within their original cartons and may be stored at room temperature.

14.1 On-Site Destruction

Prior to destruction of any IP at site, the CRA will review the Trial Site's written destruction process to ensure the following requirements are met and documented to support on-site destruction authorization.

- Use of incineration at Trial Site or by a licensed biohazard disposal/destruction facility
- Regular janitorial service or plumbing is not used
- Required destruction documentation for process is completed and minimally includes the following:
    - Destruction date
    - Reference to lot/batch number
    - MedID/Kit Number
    - Quantity destroyed
    - Method of destruction
    - Name/Signature of responsible person

14.2 Returns for Destruction

IP may also be returned to the Sponsor's designated location. The CRA will assist the site with coordination of IP returns to the local central drug depot as required following accountability/reconciliation. Once the drug depot has completed receipt of the returns, the depot (or Designee) will provide the signed returns form as Acknowledge of Receipt. This documentation should be filed in the Investigator Site File.

15. IP EXPIRATION

The Sponsor or designee is responsible for managing all IP expiration dates and communicating relevant changes to the central drug depot and/or Trial Sites as required. Labelled Expiration Dates in the format of MM/YYYY should be interpreted as the last day of the month listed. For example, a labelled Expiration Date of 09/2019 would be usable through 30Sep2019.

Once the Expiration Date for IP has been reached, it should be quarantined at the labelled storage temperature in a secure location. IP cannot be used after the Expiration Date, unless Sponsor provides confirmation of Expiration Date Extension. Sponsor or designee will provide instructions regarding expiration date extensions and relabeling, if required. Investigational Product should not be disposed of until the expiration date has been confirmed by the Sponsor or designee to have not been extended.

16. PRODUCT COMPLAINTS

Product Complaints are any failure of IP to meet any of its specifications or standards of quality, purity, identity, safety, or potency. Product Complaints may include issues with the IP itself (broken vial, visible contaminant, etc.,) or issues with packaging and labelling. For any IP defect observed during transit or site storage, the Sponsor or designee (i.e., CRA), must be notified immediately. Refer to Product Complaint and Temperature Excursion Intake Form, Appendix 5. Communications regarding Product Complaints should be sent to productcomplaints@arcusbio.com.

Place the damaged IP into appropriate Quarantine storage. Do NOT dispense or destroy the IP unless otherwise authorized by the Sponsor or designee (i.e., CRA). Sponsor will use information obtained from the Trial Site to determine if the IP is still acceptable for use and communicate an initial assessment within 1-2 business days. Once a final decision is made regarding the final disposition of any IP placed on quarantine status, further information regarding the usability of the IP will be communicated. Where necessary, a resupply shipment to replace the damaged IP will be generated. If the IP is deemed not acceptable for use, please refer to Section 13, IP Accountability, for instruction on documenting this on Drug Accountability Log and Section 14, IP Disposition, for instruction on destruction and/or return.

If the damaged IP may be potentially hazardous to safely retain on-site (leakage, etc.), notify the CRA, take a photograph, dispose per Trial Site process, and document on Drug Accountability Log.

17. EMERGENCY UNBLINDING

The PI can obtain unblinded treatment assignment information under emergency situations without first notifying the Medical Monitor utilizing the IRT [Patient Unblind Module]. Reference the IRT Quick Reference Guide.

The Medical Monitor should be notified as soon as possible when unblinding due to emergency has occurred.

Note: Should you become aware of an accidental unblinding event, please notify your CRA.

Appendix 1. SAFETY DATA SHEET(S) (SDS)

Safety Data Sheets for centrally provided marketed products (gemcitabine and nab-paclitaxel) can be found, as available, at: https://arcusbio.egnyte.com/fl/ 99ZyiYCb4G

Quemliclustat (AB680)

Safety Data Sheet Page: 1
AB680 Rev.5

Research Compound Solid
Date: June 28, 2024

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product Identifier

PRODUCT NAME:	Quemliclustat (AB680), Drug Substance
SYNONYMS:	A001680
CHEMICAL FORMULA:	C20H24ClFN4O9P2
MOLECULAR WEIGHT:	580.07 g/mol
CHEMICAL NAME:	Proprietary information
CHEMICAL CLASS:	Nitrogen heterocycle; small molecule inhibitor

1.2 Relevant identified uses of the substance

RECOMMENDED USE:	Pharmaceutical, Laboratory
USES ADVISED AGAINST:	No information available

1.3 Company

Company name:	Arcus Biosciences, Inc.
Address:	3928 Point Eden Way., Hayward, CA 94545

1.4 **EMERGENCY PHONE NUMBER:** +1 (510) 694-6200

2. HAZARDS IDENTIFICATION

EYES:	GHS Classification Category 1
SKIN:	Unknown
INGESTION:	GHS Classification Category 3
INHALATION:	Unknown
REPRODUCTIVE TOXICITY:	Category

Hazard Pictograms:

Signal Word : Danger

Hazard Statements: Causes serious eye damage
Toxic if swallowed

Precautionary Statements-
Prevention : Wash hands thoroughly after handling. Do not touch

Arcus Biosciences, Inc.

Safety Data Sheet Page: 2
AB680 Rev.5

Wear protective gloves/protective clothing/eye protection/face protection.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.

Precautionary Statements-Response :

IF IN EYES	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	Get medical help Specific treatment (see supplemental first air instructions on this label) Rinse mouth
IF SWALLOWED:	Immediately call POISON CENTER or doctor
IF INHALED:	Do not breathe dust. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms, call a POISON CENTER or doctor/physician.
	See Section 4, 5, 6 for more information.

Precautionary Statements-Storage : Store locked up. See section 7.

3. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENTS:	Not Applicable (Trade Secret)
CONTENT BY WEIGHT:	Not Applicable (Trade Secret)

4. FIRST AID MEASURES

EYE CONTACT:	In case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
SKIN CONTACT:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and wash before re-use. Seek medical attention if symptoms appear.
INGESTION:	If swallowed, seek medical advice immediately. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
INHALATION:	Do not breathe dust. Move to fresh air. Seek medical advice if respiratory irritation or breathing becomes difficult.
NOTES TO PHYSICIAN:	Treat symptomatically.

5. FIRE FIGHTING MEASURES

Arcus Biosciences, Inc.

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FLAMMABLE PROPERTIES:	No information available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
EXTINGUISHING MEDIA:	Use appropriate media, which is suitable for the surrounding fire and materials.
FIRE-FIGHTING INSTRUCTIONS:	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

6. ACCIDENTAL RELEASE MEASURES

Evacuate area until dust settles. Provide maximum exhaust ventilation. Wear skin, eye and respiratory protection. Clean spilled material using HEPA vacuum and/or wet methods. Wash spill area with detergent and water. Dispose in accordance with applicable waste disposal regulations. Do not wash into sewers or waterways.

7. HANDLING AND STORAGE

Precautions for safe handling:	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing dust.
Conditions for safe storage, including any incompatibilities	Store between 2-8 °C protect from light and moisture Store locked up

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS:
Occupational Exposure Limit (OEL): >10 µg/m³ - 0.5 mg/m³

EXPOSURE/ENGINEERING CONTROLS:
In laboratories, use vented enclosures or fume hoods required when weighing, handling, or transferring the material. In pilot or production facilities, use glove boxes or contained processes supplemented with local exhaust at contaminant-release points.

EYE/FACE PROTECTION:
Wear safety glasses with side shields, chemical splash goggles, or a full-face shield to prevent contact with eyes. The choice of protection should be

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based on the job activity and potential for contact with eyes and face. An emergency eye wash station should be available.

HAND PROTECTION
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

SKIN PROTECTION:
Wear gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact and solvents and reagents in use.

RESPIRATORY PROTECTION:
When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of material, an air-purifying respirator with NIOSH approval for dusts and mists may be needed.

ENVIRONMENTAL EXPOSURE CONTROLS:
Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

OTHER/GENERAL PROTECTION:
Wear suitable protective clothing; disposable overall or laboratory coat as required for lab activities. Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking, applying topical products or smoking). Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid
COLOR	Off-white to brown
ODOR	none
MELTING POINT	167 °C
FREEZING POINT	No data available
BOILING POINT	No data available
FLAMMABILITY	No data available
FLASH POINT	No data available
AUTO-IGNITION TEMPERATURE	No data available
pH	No data available
KINEMATIC VISCOSITY	No data available
SOLUBILITY	≥50 mg/mL in water (Citrate buffer pH 5)
SOLUBILITY IN OTHER SOLVENTS	>105 mg/mL (Methanol) >50 mg/mL (Dimethyl sulfoxide) <60 mg/mL (Tetrahydrofuran)
PARTITION COEFFICIENT	No data available
VAPOR PRESSURE	No data available
VAPOR DENSITY	No data available
RELATIVE DENSITY	No data available

10. STABILITY AND REACTIVITY

REACTIVITY:	No information available
CHEMICAL STABILITY:	Stable under recommended storage conditions
POSSIBILITY OF HAZARDOUS REACTIONS:	None under normal processing
CONDITIONS TO AVOID:	No information available
INCOMPATIBLE MATERIALS:	Bases, oxidizing agents, reducing agents
HAZARDOUS DECOMPOSITION PRODUCTS:	No information available

11. TOXICOLOGICAL INFORMATION

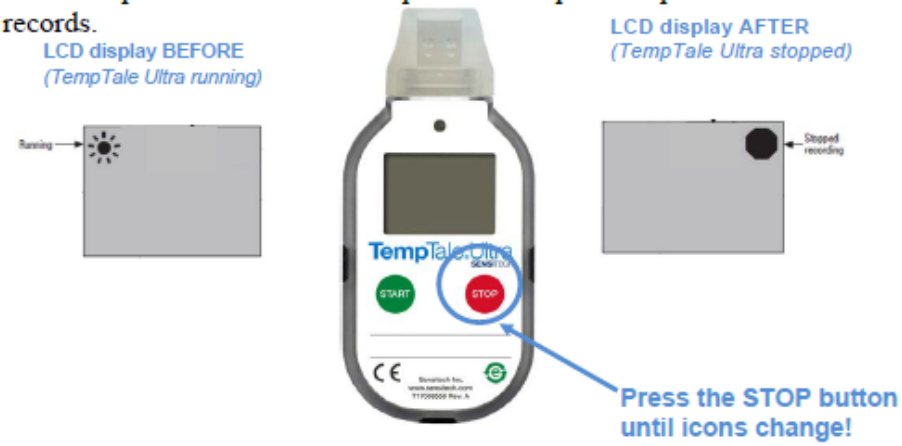
INFORMATION ON LIKELY ROUTES OF EXPOSURE:	Inhalation, skin contact, ingestion, eye contact
ACUTE TOXICITY:	Not available.
SKIN CORROSION/IRRITATION	
Method:	OECD 431
Species/Exposure route:	In vitro
Result:	Negative

Appendix 2. IP SHIPMENT TEMPERATURE MONITOR INSTRUCTIONS

Shipment Receipt Instructions for the TempTale Ultra – vs 1.0

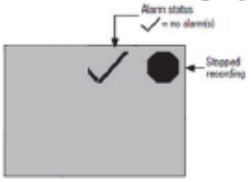
ATTENTION!

- Remove the TempTale Ultra monitoring device from the shipper immediately.
- Press down on the RED STOP BUTTON until the STOP icon appears in the upper right corner of the LCD. This may take several seconds. Plug monitor into USB port and download and print out temperature profile for sites records.

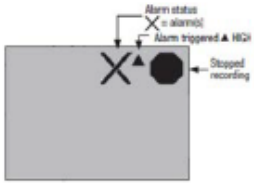


A monitor that is not correctly stopped, will trigger a false alarm. Therefore, please verify that the STOP icon has appeared. If not, press the red stop button again and hold down until the STOP icon has appeared.

- Check the display of the TempTale for the presence of an alarm:



If the Stop icon and the '✓' icon are present, the shipment has arrived in acceptable condition. Store the supplies in the appropriate temperature controlled conditions.



If the '✗' Alarm icon is visible, the temperature has been outside the desired range. Quarantine the supplies in the appropriate temperature controlled conditions and email ONLY the PDF temperature profile and completed Fisher Clinical Services (FCS) Packing List for evaluation to: usall.fcs.novartisincomingtrf@thermofisher.com

- For all shipments (except Toxicology studies), write the consignment number on the TempTale and disposition the TempTale as instructed by the Sponsor.
- Contact your Sponsor with any questions.

Protocol: PRISM-1
Pharmacy Manual

Appendix 3. IP CREDO SHIPPING CONTAINER RETURN PROGRAM

ThermoFisher SCIENTIFIC

Credo Shipping Container Return Program

STOP

Clinical Sites

Please Read Credo Return Instructions carefully

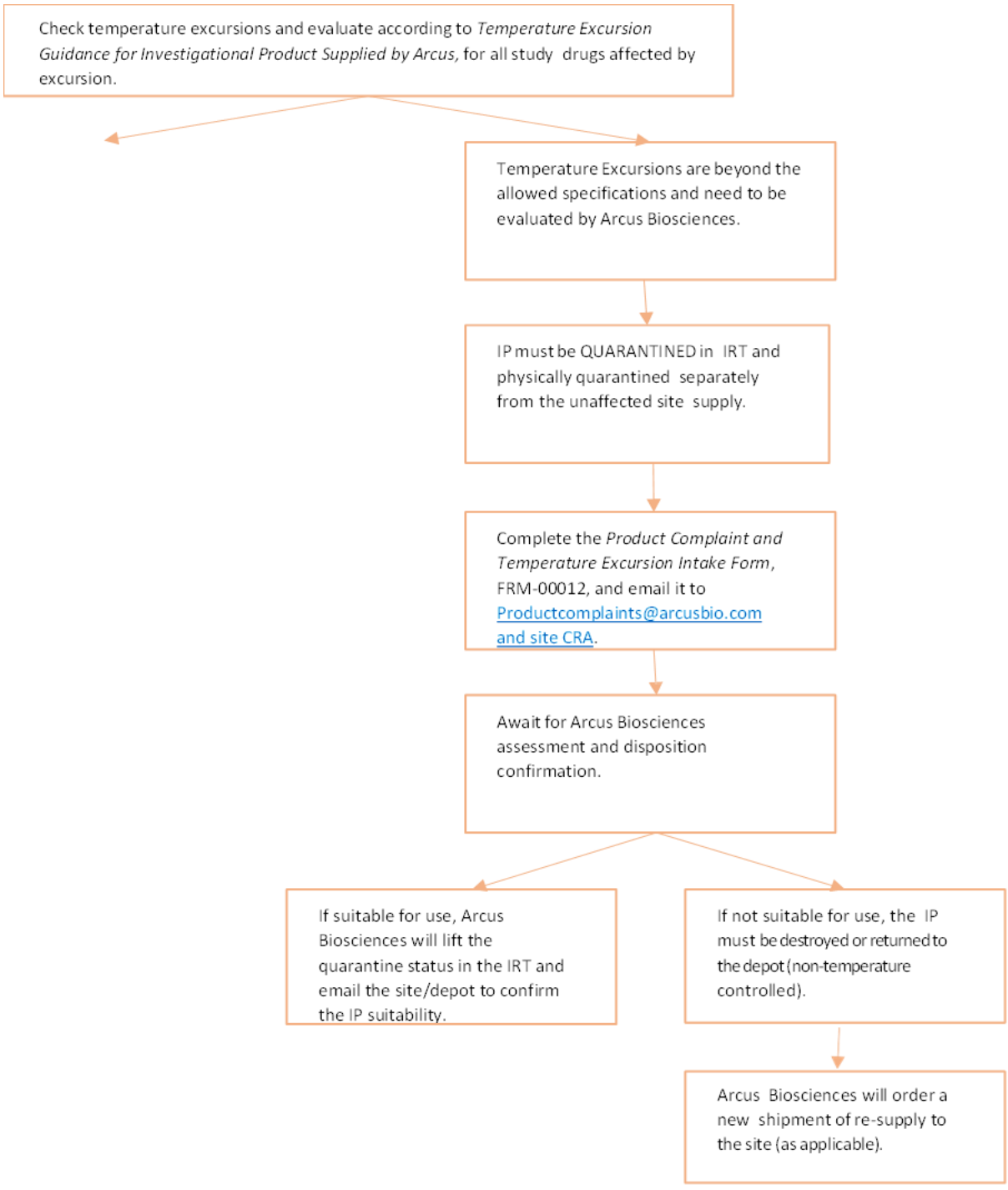
Remove Investigational Medicinal Product
1. Open Credo shipping container
2. De-activate temperature monitoring device as per instructions
3. Store product in a temperature controlled environment as specified on label
Return Credo Shipping Container
1. Remove the courier return shipping label from the document pouch on the top of the inner box lid
2. Ensure the original courier shipping label is marked out or removed from the outer cardboard container
3. Place the pre-printed courier return shipping label on the outer cardboard container or remove step 2 by Placing the new courier shipping label on top of the original shipping label if it has not been removed.
4. Place the downloaded temperature monitor inside the shipping container for recycling **(OPTIONAL)** Note – Please ensure that that all temperature data has been downloaded and monitor is ready for recycling
5. Ensure all components from the Credo shipping container are available for collection. a. Silver vacuum insulation panel lid b. Six (6) white plastic TIC system panels c. Credo shipping container d. Outer cardboard container
6. FedEx Ground will collect the Credo shipping container within (2) days following delivery of the order Note – There is no need to contact FedEx to request a collection. If Collection is not made with (3) days please contact our Logistics Global Helpdesk using the contact information provided below
7. If you currently receive a daily collection from FedEx Ground, just hand the shipping container with all components to the driver.

All freight costs will automatically be billed to Fisher Clinical Services

If you have any questions please contact Fisher Clinical Services Logistics Global Helpdesk at;
Tele: (Toll Free) +1 877 260 3956
(Direct Dial) +1 (484) 538 2168
GL.HD@thermofisher.com

Appendix 4. TEMPERATURE EXCURSION GUIDANCE FOR INVESTIGATIONAL PRODUCT SUPPLIED BY ARCUS

Trial Site Process for Reporting Temperature Excursions



Protocol: PRISM-1
Pharmacy Manual
Temperature Excursion Guidance for Investigational Product Supplied by Arcus

Temperature Reporting Rules: Storage conditions should be reported using United States Pharmacopeia (USP) rounding rules (i.e., to the nearest whole number).

Temp Monitor Value	Reported Value
1.54	2
1.45	1
-0.14	0

Guidance for Arcus Investigational Products that Require Refrigerated Storage: Quemliclustat (AB680)

Excursion	Duration	Action
Below 0°C	Any amount of time	Quarantine and notification to Arcus required.
Between 0°C and 2°C	48 hours or more	Quarantine and notification to Arcus required.
	Greater than 15 minutes and less than 48 hours	Notification to Arcus required. Quarantine not required.
	Less than or equal to 15 minutes	Event is not considered a TE. Notification to Arcus is not required. Quarantine is not required.
Between 2°C and 8°C	Desired Storage Conditions	
Between 8°C and 25°C	Less than or equal to 15 minutes	Event is not considered a TE. Notification to Arcus is not required. Quarantine is not required.
	Greater than 15 minutes and less than 48 hours	Notification to Arcus required. Quarantine not required.
	48 hours or more	Quarantine and notification to Arcus required.
Above 25°C	Any amount of time	Quarantine and notification to Arcus required.

Guidance for marketed products supplied by Arcus: Gemcitabine and Nab-Paclitaxel

Marketed products supplied by Arcus should be stored according to storage conditions within approved labels. Temperature deviations greater than 15 minutes require quarantine and notification to Arcus.

Protocol: PRISM-1
Pharmacy Manual

Appendix 5. PRODUCT COMPLAINT AND TEMPERATURE EXCURSION INTAKE FORM

ARCUS BIOSCIENCES	**Product Complaint and Temperature Excursion Intake Form**
Parent Document: SOP-00028 *Management of Product Complaints*	

	Complaint Number: PC- *(To be assigned by Arcus QA)*
Please store the affected Investigational Product (IP) in quarantine under the appropriate storage conditions until the disposition is received from Arcus.	
Part I: *To be completed by Complainant/Reporter (e.g., Trial Site Personnel or Depot)*	
Notification Date:	Date of Occurrence:
Contact Information	
Site or Depot Name:	
Address:	
Site number *(check N/A if not applicable)*:	☐ N/A
Study/Protocol number *(check N/A if not applicable)*: STAR-221	☐ N/A
Name: Phone number: Fax number:	
Title/Role: Email:	
Product Information	
List all Drugs Affected (*Please print this page and attach if additional spaces are needed or N/A unused rows*)	

Product Name	**Dosage Form (Capsule/Tablets/ Vial)**	**Lot Number (or Kit Number)**	**Quantity (e.g., kit, bottles)**	**Site Quarantined? Yes/No**
				☐Yes ☐No
☐N/A				☐Yes ☐No
☐N/A				☐Yes ☐No
☐N/A				☐Yes ☐No
☐N/A				☐Yes ☐No

Complaint Type	
☐ Temperature Excursion – *(Complete Part II A)*	☐ Product Complaint - *(Complete Part II B)*

Company Confidential	Form	FRM-00012	Version 3.0	Effective Date: 21 May 2024	Page 1 of 5

ARCUS BIOSCIENCES	**Product Complaint and Temperature Excursion Intake Form**
Parent Document: SOP-00028 *Management of Product Complaints*	

	Complaint Number: PC- *(To be assigned by Arcus QA)*
Please store the affected Investigational Product (IP) in quarantine under the appropriate storage conditions until the disposition is received from Arcus.	
Part II-A: Temperature Excursion *(check N/A if this is not a Temperature Excursion)*	☐ **N/A**
Note: All Temperature Excursion reporting requires temperature data for proper assessment.	

Type of Excursion	☐ Storage	☐ Shipment		
Required storage temperature:	_____°	☐ Celsius ☐ Fahrenheit		
Duration **above** the limit:	_____ ☐ day(s)	_____ ☐ hour(s)	_____ ☐ minute(s)	☐ **N/A**
Duration **below** the limit:	_____ ☐ day(s)	_____ ☐ hour(s)	_____ ☐ minute(s)	☐ **N/A**
Highest temperature reached:	_____°	☐ Celsius ☐ Fahrenheit		
Lowest temperature reached:	_____°	☐ Celsius ☐ Fahrenheit		
Temperature logs or data logger print-out attached.			☐ Yes	☐ No
Urgency. Next planned dispensation date:				
Completed by Trial Site Personnel or Depot. Name/Title:	Signature and Date:			

ARCUS BIOSCIENCES	**Product Complaint and Temperature Excursion Intake Form**
Parent Document: SOP-00028 *Management of Product Complaints*	

	Complaint Number: PC- *(To be assigned by Arcus QA)*
Please store the affected Investigational Product (IP) in quarantine under the appropriate storage conditions until the disposition is received from Arcus.	
Part II-B: Product Complaint *(check N/A if this is a Temperature Excursion)*	☐ **N/A**
Patient #(s): *(check N/A if not applicable)*	☐ **N/A**
Location of Occurrence/Investigator Site Name (e.g., Pharmacy, at home, etc.):	
Is a sample of the affected product available for return?	☐ Yes ☐ No
Are pictures available?	☐ Yes (Attached) ☐ No
Descriptions and details of the event.	☐ **See Attached**
Completed by Trial Site Personnel or Depot. Name/Title:	Signature and Date:
IMMEDIATELY *(Not More Than 1-2 Business Day(s) from Identification)* SEND COMPLETED PARTS I and II TO ARCUS QUALITY ASSURANCE: **Productcomplaints@arcusbio.com, and copy study assigned CRA.**	

ARCUS BIOSCIENCES	**Product Complaint and Temperature Excursion Intake Form**
Parent Document: SOP-00028 *Management of Product Complaints*	

	Complaint Number: PC- *(To be assigned by Arcus QA)*
Please store the affected Investigational Product (IP) in quarantine under the appropriate storage conditions until the disposition is received from Arcus.	
Part III: *FOR ARCUS USE ONLY*	
Disposition: ☐ Acceptable for Use ☐ Not Acceptable for Use ☐ Other *(Specify in Comments)*	
Comments: ☐ N/A	
QA Approver Name/Title	Signature and Date:

ARCUS BIOSCIENCES	**Product Complaint and Temperature Excursion Intake Form**
Parent Document: SOP-00028 *Management of Product Complaints*	

REVISION HISTORY

Effective Date	Version	Document Owner	Description of Changes
07 Nov 2017	00	Tracy Chen	New document
07 Nov 2017	1.0	Tracy Chen	First version in VVQD. Per numbering convention, the first version of a document in VVQD is version 1.0. Content is unchanged from version 00.
03 Apr 2024	2.0	Jade Huynh	Title changed from Product Complaint and Temperature Excursion "Report" to "Intake Form." Updated to align with major changes to parent SOP-00028. Formatted to current Form template, including addition of this revision history.
21 May 2024	3.0	Jade Huynh	Admin change to allow the Complaint number field to be accessible and populatable. Removed complaint number field from this revision history page.

Protocol: PRISM-1
Pharmacy Manual

Appendix 6. DRUG ACCOUNTABILITY LOG(S)

Quemliclustat (AB680) 107.5mg

Sponsor	Arcus Biosciences	**Protocol Number**	PRISM-1
Principal Investigator		**Site Number**	
Site Name		**Product Description**	Quemliclustat (AB680) 107.5mg/mL Vial
		Batch/Lot Number	
		Expiry	

	Shipment or Subject ID	Quantity	By (Initials)	Date	Site Inventory Running Balance	Disposition Method (D = Destroyed, R=Returned to Depot)	By (Initials)	Date	Verified By (CRA Initials)	Date
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Line	Comment

Line	Comment

Protocol: PRISM-1
Pharmacy Manual

Gemcitabine

Sponsor	Arcus Biosciences	**Protocol Number**	PRISM-1
Principal Investigator		**Site Number**	
Site Name		**Product Description**	Gemcitabine 1000mg
		Batch/Lot Number	
		Expiry	

	Shipment or Subject ID	Quantity	By (Initials)	Date	Site Inventory Running Balance	Disposition Method (D = Destroyed, R=Returned to Depot)	By (Initials)	Date	Verified By (CRA Initials)	Date
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Line	Comment

Line	Comment

Protocol: PRISM-1
Pharmacy Manual

Nab-Paclitaxel (Abraxane® – 100mg)

Sponsor	Arcus Biosciences	**Protocol Number**	PRISM-1
Principal Investigator		**Site Number**	
Site Name		**Product Description**	Nab-Paclitaxel (Abraxane – 100mg)
		Batch/Lot Number	
		Expiry	

	Shipment or Subject ID	Quantity	By (Initials)	Date	Site Inventory Running Balance	Disposition Method (D = Destroyed, R=Returned to Depot)	By (Initials)	Date	Verified By (CRA Initials)	Date
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Line	Comment

Line	Comment

Document Approvals

Approved Date: 30 Sep 2024

Approval Task Verdict: Approve	Lindsay DuBois, Associate Director (ldubois@arcusbio.com) SME Approval 26-Sep-2024 13:42:43 GMT+0000

Approval Task Verdict: Approve	Joe Rosenberg, Clinical Program Manager (jrosenberg@arcusbio.com) SME Approval 27-Sep-2024 15:16:45 GMT+0000

Task: QA Approval Verdict: Approve	Nadine Lee, Sr. Director, GMP Quality (nlee@arcusbio.com) Quality Assurance Approval 30-Sep-2024 21:45:06 GMT+0000