Expression of Interest : SANAC 001032026

Invitation to South African manufacturers to accelerate access to quality-assured Lenacapavir (Injection, Tablet, Active Pharmaceutical Ingredient)

Issuance Date: 5th March 2026

Closing/submission: 7th April 2026 @ 16H00

Briefing Session will be held online on 17th March 2026 @ 15:00

Link:
https://teams.microsoft.com/meet/31149912943512?p=XxWzD6GLd5pZxLbaBr

1. Introduction

The South African National AIDS Council (SANAC), as the highest national coordinating body for the HIV, TB, and STI response, is mandated to convene government, civil society, private sector and development partners, to advance South Africa's national health priorities. Central to this mandate is ensuring that policy, scientific evidence, and implementation strategies align to enable equitable access to life-saving innovations.

In collaboration with the National Department of Health (NDoH), Department of Trade, Industry and Competition (DTIC), Department of Science Technology and Innovation (DSTI) and National Treasury (NT), SANAC is leading a coordinated national process to position South Africa for future manufacturing opportunities and to strengthen readiness for local production of lenacapavir injection, tablet, and Active Pharmaceutical Ingredient (API). This process includes structured engagement with Gilead Sciences to pursue the issuance of a voluntary license (VL) for lenacapavir Injection, tablet, and/or API, a critical step for the successful progression of this initiative. In this context, SANAC has also invited technical partners, including Unitaid, United States Pharmacopeia (USP), and the Medicines Patent Pool (MPP), to collaborate in advancing regional manufacturing capacity in sub-Saharan Africa.

Through this Expression of Interest (EOI), SANAC invites South Africa–based manufacturers with potential capability and capacity to produce lenacapavir injection, tablets, and/or API to submit their applications. The EOI aims to identify and shortlist qualified manufacturers with the technical capability and production capacity to support potential regional supply. The resulting shortlist will inform subsequent engagements with Gilead as part of efforts to secure a seventh voluntary license agreement that supports regional manufacturing and equitable access.

2. Overview of Expression of Interest

The specific products under consideration are:

2.1 Lenacapavir solution for subcutaneous injection, 463.5 mg, 1.5 mL vial (309 mg/ml).

2.2 Lenacapavir tablet, 300 mg.

2.3 Lenacapavir API.

3. Respondents Requirements and Assessment Scope

Applications will be assessed based on potential technical manufacturing capabilities, quality assurance systems, regulatory compliance, and strategic commitment to equitable access and implementation. The EOI submission must include comprehensive and verifiable documentation as outlined in Annexure 1, Annexure 2 and/or Annexure 3.

The scope of the work will include:

- API and key input material supplier selection and review of the Active Pharmaceutical Ingredient Master File (APIMF) and related documentation to ensure the quality of input materials and components.
- API characterization and specification development; analytical method development and method validation.
- Finished pharmaceutical product (FPP) development including formulation, manufacturing process development, packaging development/validation, analytical method development/validation and FPP specification development. and bioequivalence requirements
- Manufacturing process scale-up, key production equipment qualification, and development and improvement of process and procedures.
- Stability studies of the finished product to demonstrate shelf life at an acceptable recommended storage condition.
- Manufacturing facility gap assessment and technical support for compliance with GMP requirements.
- Product dossier compilation in line with the submission requirements of the approving authority for registration and marketing authorization of the product.

- Establishing procedures and processes to promote climate smart manufacturing practices through optimizing material handling and costs and safe waste management
- Where applicable, sourcing of input materials, reference standards, and comparators to conduct formulation and manufacturing process development including the study required to demonstrate the quality, effectiveness, and interchangeability of the product.
- Design and execution of a regulatory strategy for target market penetration product registration, namely including the path for regulatory filing, approval, and maintenance of approval status by working with WHO prequalification and WHO Listed Authorities (WLA) through the collaborative registration process (CRP) with a single filing of product dossier for submission and approval.
- Design and implementation of a market access strategy, offering the product at an agreed set of access terms (including price, volumes, regulatory approval/commercial footprint, etc.) through public and private commercial channels across a target set of Low and Middle-Income Countries (LMICs).

4. Post-Selection Collaboration and Support (Indicative Scope of Work)

Following evaluation and shortlisting, selected manufacturers will undergo a structured technical due diligence process, including a detailed gap analysis and capital expenditure (CAPEX) assessment. The assessment will evaluate manufacturing capability, quality management systems, regulatory readiness, infrastructure requirements, and investment needs in relation to the proposed development pathway. Based on the outcomes of these assessments, manufacturer-specific remedial action plans and investment roadmaps may be developed. Subject to agreed implementation plans, regulatory requirements, and financing viability, SANAC and its partners may facilitate access to a tailored package of technical assistance and catalytic support for shortlisted manufacturers. This support may include:

- Technical support towards product development and process optimization, manufacturing site compliance with International GMP and WHO-PQ standards, quality

assurance, optimization of production capacity and efficiency, market access strategy, design, execution, and procurement;

- Financial subawards for product development, and regulatory filing;
- Demand generation and procurement facilitation support, which may include advanced market commitments and appropriate incentive mechanisms to support sustainable volumes and access objectives.

5. EOI and Selection Process

5.1 Step 1: Submission of Expressions of Interest (EOIs) by Manufacturers.

Manufacturers submit EOIs and all required documentation as specified in this EOI Annexures 1, 2 and 3 to the designated inbox **(tenders@sanac.org.za)** by the stated deadline **(7th of April 2026 by 16H00).**

5.2 Step 2:

- **Evaluation and shortlisting** The evaluation team will conduct a prequalification process against the published evaluation criteria.
- **Due Diligence (On-Site Assessments) on the shortlisted manufacturers -** shortlisted manufacturers will undergo on-site assessments including GMP/quality system reviews, facility walkthroughs, technical interviews, and verification of submitted evidence.
- Development of Corrective and Preventive Action (CAPA) plans where gaps are identified.

5.3 Step 3: Shortlisting and Recommendation to Gilead

- Manufacturers will be evaluated against the published technical and access criteria, and those meeting the requirements will be shortlisted.
- Following shortlisting, a recommendation of qualified manufacturers will be made.
- All supporting documentation of the recommended manufacturers will be submitted to Gilead for consideration.

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5.4 Step 4: Gilead Assessment and Licensing Decision

Gilead will conduct its own assessments on the recommended manufacturers and identify manufacturers eligible to enter voluntary license negotiations for Lenacapavir (injection, tablet, and/or API).

5.5 Step 5: Negotiation between manufacturer and Gilead

License terms are negotiated between Gilead and the selected manufacturers (which may include but not limited to pricing, volumes, markets, timelines).

5.6 Step 6: Technical Assistance and Implementation

Technical assistance will be provided through SANAC Partners to support the development of quality-assured, timely, and affordable supply. This support may include, but is not limited to, product development and scale-up, GMP readiness and quality system strengthening, regulatory dossier preparation and submissions (including WHO PQ, CRP, and WLA pathways), and market access preparation.

6. How to Submit Application

Manufacturers intending to respond to this EOI must demonstrate their capabilities in API Tablet and sterile product manufacturing and provide all supporting documentation as outlined in Annexures 1, 2 and 3.

Submissions must:

- Clearly indicate the dosage form(s) of interest and/or interest in manufacturing the active pharmaceutical ingredient (API). Manufacturers may apply for injectable, tablet, and/or API.
- Present the current state of manufacturing for drug products or drug substances, and fully address the requirements specified in this EOI.
- Include verifiable evidence of relevant experience, such as registration footprints for other sterile injectable products, experience with manufacturing or supplying products approved by WHO Listed Authorities (WLA), and participation in WHO Prequalification

(PQ) or the Collaborative Registration Procedure (CRP), along with demonstrated manufacturing capacity and compliance with applicable quality and regulatory standards.

- Be organized in the exact order indicated in Annexures 1, 2 and 3.
- Ensure all documents are clearly labeled, legible, and properly referenced.
- Link any supplementary materials to relevant sections of the proposal for ease of review.
- Email the proposal package to tenders@sanac.org.za

7. Evaluation Process

The response to the EOI will be evaluated against the criteria outlined in Annexures 1, 2 and 3. The evaluation will be based on the supporting documents submitted in response to the EOI including manufacturing and regulatory compliance capabilities, product quality, manufacturing process and production capability, access strategy, and experience in performance management.

7.1. EOI Evaluation Framework

A. Technical Manufacturing Capability (60 Points)

Applicants must demonstrate strong technical capabilities across key manufacturing and technology domains, with a particular emphasis on Lenacapavir API, Lenacapavir Tablet, and/or Lenacapavir sterile drug product manufacturing, packaging, and distribution. The proposals should clearly outline the infrastructure, expertise, and processes in place to support efficient scale-up and rigorous quality assurance and control (including post market surveillance). Any gaps should be transparently identified with a proposed cost plan to address them.

The technical manufacturing capability represents 60 Points of the total score, with a minimum threshold of 45 points is required to qualify for assessment under section B. Manufacturers must provide detailed evidence across the following key components, each weighted as outlined in Annexure 1 2 and 3 of the application form:

- Manufacturing Site Regulatory Compliance: Demonstrated adherence to applicable national and international regulatory requirements and standards for sterile product manufacturing.
- API and Input Materials Supplier Quality Control: Robust quality management system to ensure the quality and reliability of Active Pharmaceutical Ingredients and other critical inputs.
- Product Development and Scale-up: Proven expertise in formulation development, technology transfer, and scalable manufacturing processes.
- Commercial Manufacturing and Regulatory Filing Capability: Evidence of operational excellence in packaging, distribution, and large-scale production of quality-assured medicines.
- A clear outline of the corrective and preventive action plan (CAPA) required to rectify gaps to meet the strategic objectives of the project.

B. Access and Implementation Potential (40 Points)

Only the manufacturers who meet the minimum of 45 points under section A above will be evaluated in this section. The total points scored on Section A and B will be used to shortlist the top ranked manufacturers

The overall goal is to expand equitable access to healthcare products, to reduce health disparities, and strengthen regional supply chains. Applicants must outline current and future strategies to expand access, improve affordability, and promote continuous quality improvement. Emphasis should be placed on innovative, climate-smart manufacturing practices that contribute to long-term sustainability and regional resilience. Applicants should also demonstrate a willingness to participate in future regional initiatives, including preparedness and response efforts for public health emergencies.

This category represents 40 points of the total evaluation score, with criteria detailed in Annexure 1, 2 and 3 of the application form:

- **Production Operations and Access Strategy**
  - Strategic approach to ensuring sustainable, equitable, and affordable access to priority health products.
  - Readiness to support emergency response and preparedness initiatives.
  - Commitment to advancing climate-smart manufacturing practices.
- **Project Performance and Implementation Management**
  - Clear project management systems, including financial and human resources, to monitor progress and ensure delivery of expected outcomes.
- **Commercial terms – potential to achieve target terms**
  - Current cost structure and pricing.
  - Capacity.
  - Identification of any technical, financial, or operational support needed to achieve stated access and implementation objectives.

Part C

- Only shortlisted manufacturers will be subjected to due diligence
- Due Diligence will be conducted which will include site assessments and verification of documents submitted
- These assessments will also identify gaps that will require Technical Assistance

8. Confidentiality

Submissions will be treated as confidential and may be accessed only by SANAC and partners and any other authorized evaluators bound by confidentiality. NDAs will be executed prior to deeper due diligence and data exchange.

9. Terms & Conditions

- This EOI does not obligate SANAC and its partners to make any award or to pay any costs incurred in proposal preparation.
- SANAC reserves the right to accept or reject any expression of interest, to negotiate, and/or to cancel this EOI
- Applicants must disclose any conflicts of interest. (Must use SBD 4 attached).
- EOI must remain valid for 180 days from the submission deadline.

9.1 Submission of responses to EOI

SANAC invites manufacturers to **complete the application form provided in Annexures 1, 2 and 3 and submit the required supporting documentation by, 7th of April 2026 @ 16H00**. All documents submitted in response to this EOI must be organized in the exact sequence outlined in the application forms (Annexure 1, 2 and 3).

Applicants are responsible for ensuring that all materials are clearly presented, legible, properly numbered, and appropriately annotated. Please note that SANAC will not be liable for any costs incurred by applicants in the preparation, submission, or revision of the application form and its attachments.

All enquiries should be in writing and submitted to tenders@sanac.org.za The closing date for receipt of all enquiries is **31 March 2026 @16H00.** All enquiries beyond the closing date may not be responded to.

10. FORMAT FOR THE EOI SUBMISSION

The following document must be submitted at the closing date and time of the EOI.

- Completed SBD 1 document.
- Company Profile
- Completed SBD 4 document.

All documentation requires as specified in Annexures 1, 2 and or 3

Annexure I: Application Form for submission in response to the EOI

Product Name: **Lenacapavir solution for injection, 463.5 mg/1.5 mL vial (309mg/ml)**
Manufacturer Name: _____
Address: _____
Contact Person Name: _____
Email: _____
Telephone

S/N	Evaluation Criteria	Confirm Submission		Document reference/attachment
		Yes	No	
	A. Manufacturing Capability and Quality (60 points)			
1	**Administrative Information (5).** Please provide the supporting documents and mark "√" under "Yes" of the right columns of this table confirm			
	1.1 Cover Page (signed and dated)			
	1.2 Manufacturer Site Master File (SMF)			
	1.3 Manufacturing License			
	1.4 GMP certificate (s)			
	1.5 Marketing Authorization (registration certificate)			
	1.6 Other certifications (ISO, PIC/S etc.)			
2	**FPP Manufacturing site regulatory compliance (10)**			
	2.1 Summary and conclusion of recent GMP assessment of the FPP manufacturing site.			
	2.2 Summary of any ongoing/pending corrective and preventive action plan (CAPA) from previous inspection.			
	2.3 Has any regulatory authority revoked or cancelled your manufacturing license, GMP certificate, or marketing authorization within the past three years? If yes, please provide details.			
3	**API and Input material supplier quality control (10)**			
	3.1 Access to DMF from the existing API supplier (submit only letter of access)			
	3.2 API manufacturer GMP compliance status and certificates and API supplier qualification procedure			

	3.3 Summary of APIMF approval path and current approval status			
	3.4 FPP manufacturers procedures for API characterization, API analytical method development, specification and control of input materials 3.5 Access to specialized components required for injectable manufacturing – sterile vials, syringes and related packaging. The packaging of the innovator's drug product involves the use of specialized vials (2 vials) and additional components such as 2 vial access devices, 2 syringes and 2 needles per package unit.			
4	**Product development and scale up (15)**			
	4.1 Pre-formulation and formulation development of LEN and/or related injectable formulation products. (provide available reports, protocols/SOPs)			
	4.2 Procedures for selection of components including excipient, primary and secondary packaging materials			
	4.3 Manufacturing process development and qualification - provide a copy of SOP, protocol or equivalent			
5	**Commercial manufacturing and capability (20)**			
	5.1. Manufacturing process validation for sterile product (submit only the approach and validation protocols/SOPs for sterilization of product and components)			
	5.2. Capabilities to conduct stability studies to determine shelf-life of finished product. Provide a copy of stability study protocols and qualification summary of stability chambers.			
	5.3. Scale up of development batches to commercial production of Len injectable (batch size, annual volume, summary of key production equipment capacity)			
	B. Access and Implementation Potential (40 points)			
6	**Commercial Supply and Demand Creation (30)**			
	6.1. Please fill in the following table on CMC development, commercial production, and general one-time costs.			

	CMC Development and Manufacturing		
	Activity	**Provide Estimated Cost per Activity in USD**	**Comments**
	Per batch cost for formulation development		
	Proposed batch size for scale up batches (of vials per batch)		
	Total cost of testing for drug product (in-process, release testing)		
	Number of batches to support product development		
	Total cost to manufacture product development batches		
	Total cost of testing to generate primary stability study batches (indicate the cost t_0 from release testing, provide protocol)		
	CMC and Commercial production		
	Per batch cost to run validation batch(es)		
	The cost of producing commercial batches		
	Proposed batch size of validation batch(es) (vials per batch)		
	Proposed batch size of commercial batch(es) (vials per batch). Provide the largest batch size with the current and future expansion		
	The cost of testing (In-Process, Release Testing & Packaging/Labelling)		
	Number of validation batches to support regulatory submission for filing		
	Total cost of validation and commercial batches to support submission batches for filing		
	Total cost to generate stability study on validation batches (t_0 from release testing, indicate protocol)		
	Regulatory submission fee for filing		
	General One-Time Costs		
	Analytical Method Evaluation or Development/Qualification and Validation		
	Cleaning Verification / Validation		
	Compatibility study of manufacturing/filling equipment with drug product		
	Cost of study for extractable and leachability study of silicon tube and connecting tubes		
	Bulk and intermediate product hold time stability		

	study cost			
	Bioburden/Endotoxin/Sterility method suitability study and testing cost			
	The cost of evaluation and validation by terminal sterilization (TS)			
	6.2 Pricing			
	Annual Volume bands of LEN (define bands as applicable to your production) (ex-works in USD)			
	Annual Volume of LEN	Ex works price = $		
	6.3 Types of incentives support required	**Description/Justification**		
	Financial support for product development			
	Collaboration for formulation development			
	Support for regulatory affairs			
	Advance market commitments			
7	**Project performance and Implementation management (10)**			
	7.1. Please provide an overview of your proposed team for manufacturing, project management, quality assurance, regulatory, procurement, sales, tender management, market access and government affairs. Include team composition, roles, and responsibilities relevant to this EOI.			
	7.2. Outline the human and financial resources your organization will allocate to support project implementation and ongoing management. Include any specific commitments.			
	7.3. Describe your internal procedures for monitoring project implementation and performance. Include a summary or example of SOP used for this purpose.			
	7.4 Describe the market access strategy ensuring geographic diversity			
	7.5 Can we also ask questions on Pharmacovigilance, supply chain.			

Annexure 2: Application Form for submission in response to the EOI

Product Name: **Lenacapavir Tablets, 300 mg.**
Manufacturer Name: _____
Address: _____
Contact Person Name: _____
Email: _____
Telephone

S/N	Evaluation Criteria	Confirm Submission		Document reference/attachment
		Yes	No	
	B. Manufacturing Capability and Quality (60 points)			
6	**Administrative Information (5).** Please provide the supporting documents and mark "√" under "Yes" of the right columns of this table confirm			
	1.7 Cover Page (signed and dated)			
	1.8 Manufacturer Site Master File (SMF)			
	1.9 Manufacturing License			
	1.10 GMP certificate (s)			
	1.11 Marketing Authorization (registration certificate)			
	1.12 Other certifications (ISO, PIC/S etc.)			
7	**FPP Manufacturing site regulatory compliance (10)**			
	7.1 Summary and conclusion of recent GMP assessment of the FPP manufacturing site.			
	7.2 Summary of any ongoing/pending corrective and preventive action plan (CAPA) from previous inspection.			
	7.3 Has any regulatory authority revoked or cancelled your manufacturing license, GMP certificate, or marketing authorization within the past three years? If yes, please provide details.			
8	**API and Input material supplier quality control (10)**			
	8.1 Access to DMF from the supplier (submit only letter of access)			
	8.2 API manufacturer GMP compliance status and API supplier qualification procedure			

	8.3 Summary of APIMF approval path and current approval status			
	8.4 FPP manufacturers procedures for API characterization, API analytical method development, specification and control of input materials			
9	**Product development and scale up (15)**			
	9.1 Pre-formulation and formulation development of Lenacapavir tablets. (provide available reports, protocols/SOPs)			
	9.2 Procedures for selection of components including excipient, primary and secondary packaging materials			
	9.3 Manufacturing process development and qualification, provide a copy of SOP, protocol or equivalent			
10	**Commercial manufacturing and capability (20)**			
	10.1. Manufacturing process validation for tablet product (submit only the approach and validation protocols/SOPs for Tablet product)			
	10.2. Capabilities to conduct stability studies to determine shelf-life of finished product. Provide a copy of stability study protocols and qualification summary of stability chambers.			
	10.3. Scale up of development batches to commercial production (batch size, annual volume, summary of key production equipment capacity)			
C. Access and Implementation Potential (40 points)				
11	**Commercial Supply and Demand Creation (30)**			
	11.1. Please fill in the following table on CMC development, commercial production, and general one-time costs.			
	CMC Development and Manufacturing			
	Activity	**Provide Estimated Cost per Activity in USD**	**Comments**	
	Per batch cost for formulation development			

	Proposed batch size of scale up batches for product development (of tablets per batch)		
	Drug Product In-Process, Release Testing & Packaging/Labelling		
	Number of batches to support product development		
	Total cost to manufacture product development batches		
	Total cost of testing to generate primary stability study batches (indicate the cost t_0 from release testing, provide protocol)		
	Cost of dissolution profile study against comparators		
	Cost of pivotal BE study against recommended comparators		
	Cost of souring comparators		
	CMC and Commercial production		
	Per batch cost to run validation batch(es)		
	The cost of producing commercial batches		
	Proposed batch size of validation batch(es) (tablets per batch)		
	Proposed batch size of commercial batch(es) (tablets per batch). Provide the largest batch size with the current and future expansion		
	The cost of testing (In-Process, Release Testing & Packaging/Labelling)		
	Number of validation batches to support regulatory submission for filing		
	Total cost of validation and commercial batches to support submission batches for filing		
	Total cost to generate stability study on validation batches (t_0 from release testing, indicate protocol)		
	Regulatory submission fee for filing		
	General One-Time Costs		
	Analytical Method Evaluation or Development/Qualification and Validation		
	Cleaning Verification / Validation		
	Compatibility testing of API-API and API excipient and packaging materials with the drug product component		
	Mixing stage validation and content uniformity		
	Bulk product hold time study		
	11.2 Pricing		

	Annual Volume bands of Lenacapavir (define bands as applicable to your production) (ex works in USD)			
	Annual Volume of Lenacapavir	Ex works price = $		
	11.3 Types of incentives support required	**Description/Justification**		
	Financial support for product development			
	Collaboration for formulation development			
	Support for regulatory affairs			
	Advance market commitments			
12	**Project performance and Implementation management (10)**			
	12.1. Please provide an overview of your proposed team for manufacturing, project management, and quality assurance. Include team composition, roles, and responsibilities relevant to this EOI.			
	12.2. Outline the human and financial resources your organization will allocate to support project implementation and ongoing management. Include any specific commitments.			
	12.3. Describe your internal procedures for monitoring project implementation and performance. Include a summary or example of SOP used for this purpose.			

Annexure 3: Application Form for submission in response to the RFP

Product Name: Lenacapavir API

Manufacturer Name: _____
Address: _____
Contact Person Name: _____
Email: _____
Telephone _____

S/N	Evaluation Criteria	Confirm Submission		Document reference/attachment
		Yes	No	
Note: Please provide the supporting documents and mark "√" under "Yes" of the right columns of this table confirm and mark "x" if not available				
	C. Manufacturing Capability and Quality (60 points)			
11	**Administrative Information (5).**			
	1.13 Cover Page (signed and dated)			
	1.14 Manufacturer Site Master File (SMF)			
	1.15 Manufacturing License			
	1.16 GMP certificate			
	1.17 Other certifications (CEP, BSE/TSE, ISO, PIC/S etc.)			
12	**API Manufacturing site current regulatory compliance status (10)**			
	12.1 Summary and conclusion of recent GMP assessment of the API manufacturing site.			
	12.2 Summary of any ongoing/pending corrective and preventive action plan (CAPA) from previous inspection.			
	12.3 Has any regulatory authority revoked or cancelled your manufacturing license, GMP certificate, or registration certificate within the past three years? If yes, please provide details.			
13	**Starting Material and Input material supplier quality control (10)**			
	13.1 Access to synthesis process of key starting materials from the supplier (provide tabulated summary of the key starting materials name, chemical name, name of supplier along with synthesis flow chart)			

	13.2 Specification and analytical method for the control of key starting materials, solvents, synthesis reagents, catalysts, and intermediate materials (provide specification, SOP, report, etc)			
	13.3 Key starting materials suppliers' qualification and monitoring			
14	**Final Drug Substance Manufacturing Development and Scale up (15)**			
	14.1 Identification and selection of key starting materials and the route of synthesis path (provide synthesis flow chart with at least two reaction steps before formation of the final Lenacapavir API)			
	14.2 Procedures and strategy on justification for selection of number of reaction steps from physical properties of drug substance, formation, fate and purge of impurities			
	14.3 Strategies for monitoring and control of drug substance manufacturing process based on the manufacturing steps involved that impact on the impurity profile of the drug substance			
	14.4 Drug substance characterization and elemental analysis for the identity and integration of key starting materials for the formation of final drug substance			
	14.5 Impurity profile, API analytical method development, validation, and justification for the development of specification of the final drug substance			
	14.6 Approach and strategy to conduct risk assessment for determination and control of genotoxic impurity, nitrosamine impurity, and elemental impurity			
15	**Commercial manufacturing and capability (20)**			
	5.1. Manufacturing process validation for final Lenacapavir API (submit only the approach and validation protocols/SOPs)			
	5.2. Capabilities to conduct stability studies to determine shelf-life of Lenacapavir API.			

	Provide a copy of stability study protocols and qualification summary of stability chambers.			
	5.3. Scale up of development batches to commercial production (batch size, annual volume, summary of key production equipment capacity)			
D. Access and Technology Transfer (40 points)				
6	**Commercial Supply and Demand Creation (30)**			
	6.1. Please fill in the following table on CMC development, commercial production, and general one-time costs.			
	CMC Development and Manufacturing			
	Activity	**Provide Estimated Cost per Activity in USD**	**Comments**	
	Per batch cost for manufacturing process development			
	Proposed batch size of scale up batches (# Kg per batch)			
	Drug Substance in-Process, Release Testing & Packaging/Labelling			
	Number of batches to support product development			
	Total cost to manufacture final API development batches			
	Total cost of testing to generate primary stability study batches (indicate the cost t_0 from release testing, provide protocol)			
	Technology Transfer and Commercial production			
	Per batch cost to run technology transfer between sending and receiving unit			
	The cost of producing commercial batches			
	Proposed batch size of performance quality batch(es) (Kg per batch)			
	Proposed batch size commercial batch(es) in Kg. Provide the largest batch size with the current and future expansion			
	The cost of testing (In-Process, Release Testing & Packaging/Labelling)			
	Number of qualification/validation batches to support regulatory submission for filing			

	Total cost of validation and commercial batches to support submission batches for filing			
	Total cost to generate stability study on validation batches (t_0 from release testing, indicate protocol)			
	Regulatory submission fee for filing			
	General One-Time Costs			
	Analytical Method Transfer and Evaluation or Development/Qualification and Validation			
	Cleaning Verification / Validation			
	Intermediate product hold time study			
	6.2 Pricing			
	Annual Volume bands of Lenacapavir (define bands as applicable to your production) (ex works in USD)			
	Annual Volume of Lenacapavir in Kg	Ex works price = $		
	6.3 Types of incentives support required	**Description/Justification**		
	Financial support for product development			
	Collaboration for formulation development			
	Support for regulatory affairs			
	Advance market commitments			
7	**Project performance and Implementation management (10)**			
	7.1. Please provide an overview of your proposed team for manufacturing, project management, and quality assurance. Include team composition, roles, and responsibilities relevant to this RFP.			
	7.2. Outline the human and financial resources your organization will allocate to support project implementation and ongoing management. Include any specific commitments.			
	7.3. Describe your internal procedures for monitoring project implementation and performance. Include a summary or example of SOP used for this purpose.			