



Request for Information
for the award
of commercial sublicense agreement for
Zoliflodacin in Brazil

Date: 01 September 2025

Subject: Request for Information for the award of commercial sublicense agreement for Zoliflodacin

1. Summary

This Request for Information Document is to solicit information for selection of partner for commercialization of a first-in-class antibiotic - Zoliflodacin Powder for Oral Suspension - the only drug being developed specifically to treat resistant strains of gonorrhoea (“Product”).

The partner must have a demonstrable capacity to implement an introduction plan - as well as prior experience in successful commercialization of oral / injectable antibiotic, antiviral & anti-HIV products, preferably for Sexually Transmitted Diseases targeting the community-care settings.

The goal of this request for information is to identify a commercial partner (“Distributor”) to market & distribute the Product in the country of Brazil, the (“Territory”) in alignment with GARDP’s Market Access Plan.

2. BACKGROUND

In 2017, GARDP partnered with Entasis Therapeutics Limited, now a subsidiary of Inoviva, to carry out the phase 3 trial at 16 sites across 5 countries (Belgium, the Netherlands, South Africa, Thailand and the US), comparing zoliflodacin to a globally recognized regimen (500mg ceftriaxone plus 1g azithromycin) for the treatment of uncomplicated gonorrhoea. A total of 958 patients were recruited, making it the largest clinical trial ever conducted for a new treatment against gonorrhoea infection.

In November 2023, the positive results of the pivotal phase 3 trial were announced. A single dose of oral zoliflodacin was found to meet the primary endpoint when compared against the combination of injectable ceftriaxone and oral azithromycin, a current international standard of care.

The New Drug Application (NDA) for the product is currently filed with the USFDA and received the USFDA New Drug Application Acceptance in June 2025.

Please refer to Annex 1 for more information about GARDP and its partners on this project.

3. Summary of Product

The target product for this Request for Information Document is Zoliflodacin powder for oral suspension in a sachet form.

Zoliflodacin is under development for the treatment of drug-resistant uncomplicated urogenital gonorrhoea. It is administered through oral route as an antimicrobial amorphous nonsterile powder dissolved in water. It is a benzisoxazole derivative and it acts by targeting ATP pocket of DNA gyrase and topoisomerase IV.

4. Scope of Work

This scope of work includes the following activities:

GARDP is looking for Commercial Sublicensee to commercialize the Product in the country of Brazil ("Territory"). The commercial sublicense will be granted on a non-exclusive basis.

The commercialization of the Product shall comprise following activities:

- i) **Commercial Strategy:** prepare and implement a commercial strategy for the Product in the Territory, including but not limited to the positioning, affordable access-oriented pricing, distribution, logistics, life cycle management.
- ii) **Market Intelligence generation:** generate market intelligence in the Territory, including but not limited to the market potential, competition, optimal pricing, with a focus on public health access, and distribution channels for the Product.
- iii) **Distribution and Logistics:** implement an import, distribution and logistics strategy in the Territory, supported by an effective ordering and forecasting process, to ensure cost effective, affordable, timely and uninterrupted availability of the Product to patients. In addition to the distribution of the Product through own/contracted distribution network, facilitate the supply of Product, within the Territory, to International Procurement Agency(s), using the Commercial Sublicensee's label.
- iv) **Regulatory:**
 - o update and implement the regulatory strategy and liaison with regulatory authorities at country level;
 - o submit regulatory dossiers to the regulatory authorities intended for obtaining regulatory approvals for the Product in the Territory, and provide regulatory support in the Territory.
- v) **Pharmacovigilance:**
 - o comply with all applicable laws and regulations in the Territory, including but not limited to risk management systems, drug safety and pharmacovigilance;
 - o enter into Safety Data Exchange Agreement(s) with GARDP and Innovia prior to Product commercialization; manage the PV database and reporting to GARDP and Innovia for the Product distributed by the Commercial Sublicensee and/or other appointed entities (International Procurement Agency etc.) within the Territory.
- v) **Market Access and Territory Business Plan:** develop business plans to be approved by GARDP, for the Territory, which shall include:

- registration requirements and timing;
 - identification of local stakeholders and partners,
 - in-country efficient logistics structure, including a pre-launch centralized stockpiling in order to ensure timely and uninterrupted availability of the Product to the patients;
 - pricing considerations: distribution margins, differentiation between private & public market.
- vi) **Information Reporting to GARDP:** report to GARDP on a quarterly basis via a report in writing covering topics including but not limited to net sales data, inventory report, regulatory activities undertaken, completed/ in-progress work towards commercialization plan, local medical affairs plan and ESG matters.

5. Instructions to Participants

a. Participants are requested to provide the following:

- i. Form A (Annex 2) completed and signed by an authorized representative of the Participant;
- ii. Compliance self-declaration (Annex 3) signed by an authorized representative of the Participant;
- iii. RFI Questionnaire (Annex 4) completed;
- iv. A word/powerpoint document describing the Participant's current strategy & operations in the Territory and a high-level commercial strategy for the Product in the territory.
- v. Financial stability confirmation: past 3 years basic financial statements (P&L, balance sheet, cash flow statement).

b. Response submission

- i. All responses shall be submitted in English via email with the subject line *RFI Response_Zoliflodacin_BR* to: kprabhakar@gardp.org
- ii. Responses received after the deadline will not be considered.
- iii. The timeline of the RFI is as follows:

RFI Publication on GARDP Website	September 1 st , 2025
Deadline for receipt of responses	September 22 nd , 2025

c. Costs of preparing documents

All costs associated with the preparation of the responses to the RFI and participation in general will be borne by the Participants.

d. Confidentiality

Information which the Participants consider to be proprietary should be clearly marked as such. All such information will be treated as confidential and used by GARDP for this RFI assessment purposes only.

e. No disclosure

Information relating to the examination, clarification and evaluation of the Participants' responses to this RFI shall remain internal to GARDP.

f. Future Sublicense Agreement

As mentioned hereabove, future Commercial Sublicensee is required to comply with all substantial terms of the commercial sublicense agreement template that will be provided by GARDP. The final Sublicense Agreement will be finalized during the negotiation process after selection of the Participant.

6. Additional Information

Any organization that takes part in the process reserves the right to exit it at there will. No penalty incurred.

GARDP reserves the right to request additional information from, or arrange interviews with Participants, visit the Participants' premises and facilities, and conduct an audit to verify the information provided.

7. Selection process

GARDP will assess each eligible response based on selection criteria that include the overall quality of the commercialization plan provided, timelines, corporate capabilities, proposed geographical coverage, commitment to access and antibiotic stewardship, and demonstrated expertise with similar products. GARDP anticipates that several Participants will be identified for further discussions to refine their responses.

GARDP may engage with a third party to perform a quality audit of the selected Participants.

GARDP anticipates an award of commercial sublicense agreement(s) post completion of evaluation and audits (if required). The final evaluation results and award information will remain confidential and proprietary to GARDP.

Annex 1

Information about GARDP and its partners

- **GARDP:**

The Global Antibiotic Research & Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally founded in 2018 to ensure that everyone who needs antibiotics receives effective and affordable treatment. GARDP is funded by the governments of Australia, Germany, Japan, Monaco, the Netherlands, the Public Health Agency of Canada, South Africa, Switzerland, the United Kingdom, the Canton of Geneva, as well as the European Union, Wellcome Trust and private foundations. GARDP is registered under the legal name GARDP Foundation. (www.GARDP.org)

- **Innoviva Specialty Therapeutics:**

Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc., is focused on delivering innovative therapies in critical care and infectious disease. Innoviva Specialty Therapeutics' products, through its affiliate, La Jolla Pharmaceutical Company, include GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Innoviva Specialty Therapeutics' products, through its affiliate, Entasis Therapeutics Inc., include XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use approved for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). For more information about Innoviva Specialty Therapeutics, please visit [here](#).

Annex 2

Form to be completed by Participants

FORM A: Response to Request for Information Document & Questionnaire- Zoliflodacin

This form must be completed, signed, and returned to GARDP at kprabhakar@gardp.org .

DECLARATION

We, the undersigned, having read the Request for Information Instructions Document for Zoliflodacin, submit our response, which includes the information requested in the Questionnaire and Section 6. We confirm that all the information provided is correct.

We confirm that we are interested to enter into discussions for a possible collaboration with GARDP on the Scope of Work as described in section 4 in accordance with the Evaluation as described in section 7.

We understand that Respondents' issue of the Request for Information Document and the response we submit is not a commitment by either party to enter into such discussions or collaboration. We further understand that GARDP reserves the right to discuss and collaborate with one or multiple parties, no parties, or to cancel the Request for Information Process at their discretion.

The Request for Information Document Package and any response thereto shall be the property of GARDP.

Name of authorized representative:

Title:

Signature:

Date:

Company name:

Postal Address:

Telephone No.:

Email Address:

Annex 3

Compliance self-declaration

As GARDP is using public funding, GARDP must exclude from funding any organization or person having powers of representation, decision-making or control over the organization or a member of their administrative, management or supervisory body if they have been the subject of a final judgment or of a final administrative decision for one of the following reasons¹

- a) bankruptcy, insolvency or winding-up procedures;
- b) breach of obligations relating to the payment of taxes or social security contributions;
- c) grave professional misconduct, including mis-representation
- d) fraud;
- e) corruption;
- f) conduct related to a criminal organisation;
- g) money laundering or terrorist financing;
- h) terrorist offences or offences linked to terrorist activities;
- i) child labour and other trafficking in human beings;
- j) irregularity
- k) creating a shell company;
- l) being a shell company

I, _____, acting as representative of the _____, hereby confirm that none of the above apply to our company or to any persons have powers or representation, decision-making or control of our organization, or is a member of our administrative, management or supervisory body.

Name & Title

Date & Location

¹ Directive 2014/24/EU (repealing Directive 2004/18/EC) shall be considered equivalent to the Financial Regulation of the EU. This section may therefore be checked against systems, rules and procedures applying the above-mentioned Directive or national law transposing the above-mentioned Directive.

Annex 4

RFI Questionnaire

Kindly download the RFI Questionnaire from the RFI link on GARDP website.