GNA NOW Open Call

A unique opportunity for the antibiotic community
The GNA NOW Consortium is looking for a novel antibiotic programme to progress to Investigational New Drug
This is a **unique opportunity** for interested candidates to join IMI’s GNA NOW project & **gain access** to some of Europe's best laboratories and antibiotic drug research experts.
The GNA NOW project at a glance
The GNA NOW project
at a glance

Kristina Orrling, Lygature
GNA NOW Coordinator
GNA NOW project at glance

Objectives:
One Phase II ready drug
One Phase I ready candidate drug
One preclinical candidate drug
Programmes in the pipeline

All novel mode of action targeting multiple Gram(-) pathogens
Programmes in the pipeline

Room for one more to de-risk project goals

- Lead optimisation
- Late Lead to candidate
- Investigational New Drug (IND)-enabling studies
- Phase I
- Phase II ready drug
- Clinical candidate

NOSO-502 (WP3)
odilorhabdin

NOSO-2G (WP4)
odilorhabdin

CORRA (WP5)
corrarmycin

NEW (WP7)
Your compound

[Diagram showing the pipeline stages and compounds]
Structure: 3 programmes x 8 enabling platforms

WP1: Incubator Management
- WP3: NOSO-502
- WP4: NOSO-2G
- WP5: CORRA

WP2: Drug Development Platforms
1. Mode of Action profiling
2. Medicinal chemistry and design
3. Microbiological efficacy and resistance \textit{in vitro}
4. Microbiological efficacy and resistance \textit{in vivo}
5. PK/PD profiling
6. PK, Safety and ADME
7. CMC and fermentation
8. Clinical studies & modelling

• Partnership Management (Lygature & Evotec)
• Communication (Lygature)
• Data Infrastructure (Fraunhofer)
• Public-Patient Involvement (Bristol NHS Trust)
How to join GNA NOW?

5 May
Launch of call for additional programme

18 June
Deadline for submission of Expression of Interest (EoI)

7 July
Top 3 EoIs invited submit a full Programme Dossier (CDA needed)

25 Aug
Deadline for submission of full Programme Dossier
What are we looking for?

What’s in it for you?

Eric Bacqué, Evotec
GNA NOW Lead
What GNA NOW is looking for? (1)

- A **lead-to-candidate program or a development candidate** under or ready for preclinical development

- TPP-consistent spectrum, acceptable resistance risk, satisfactory ADME/PK properties, demonstrated *in vivo* efficacy, established IP position and suitable safety profile

- **Addressing severe hospital infections** (HAP/VAP, cUTI, cIAI and BSI) caused by Gram(-)
  - Enterobacteriaceae, *Pseudomonas* or *Acinetobacter*
  - broad spectrum TPPs or single-pathogen, non-fermenter TPPs possible

- **Novel mode of action**
  - no cross-resistance with marketed classes of antibacterials
  - possibly via modulation of a new/underexplored target or via binding to a new site of a known target

- **Directly-acting antibacterial effect or potentiators**
What GNA NOW is looking for? (2)

- **Small molecules**
  - including also natural products and derivatives, small peptides but no biologics

- **Potential for intravenous administration** (mandatory)
  - potential for oral administration required in case of an enterobacteriaceae-only TPP

- **Technically feasible**
  - matching with available GNA NOW resources, capabilities and expertise
  - potential to benefit from industrial discovery and development expertise and capabilities

- Priority might be given to an organization eligible to IMI provisions for beneficiaries or EFPIA
What’s in it for you?

• Resources equivalent to **several million €** (to be defined according to project needs).

• Access to some of the **best laboratories and experts** in antibiotic drug research in Europe today.

• Access to **all the components needed** to progress your compound to the Phase I-ready stage.

• **Partnering contract** with Evotec, a pharmaceutical company with the experience, expertise and resources to bring a drug to the clinical development stage.

• **Continued control** of the development of your project, as a member of the Compound Steering Committee.

• Option to contribute to the GNA NOW project either as a so-called Contributing Third Party, or as a full member* of the consortium

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* Limited to organisations eligible to the IMI provisions for beneficiaries, *ie* academia & SMEs in EU or associated countries, and EFPIA members
Proposals will be scored on a scale of 1-5 in the following four categories:

- **Scope, Innovation and Novelty**
  - Defines the *minimal criteria* for the call
  - Indication, Target Product Profile, development stage, competitor analysis, *etc*

- **Excellence**
  - Technical data of the compound/series
  - Defined with respect to the Lead and Preclinical Candidate criteria

- **Feasibility**
  - How well the programme matches the GNA NOW resources, expertise, and timelines?
  - What can the Compound Owner contribute with?

- **Implementation**
  - How mature and realistic are the project plans and timelines?
Lead criteria, *main thresholds*

- **MIC**<sub>90</sub> ≤ 4 µg/ml for the targeted enterobacteriaceae and ≤ 8 µg/ml for the targeted non-fermenters
- Specific/on-target antibacterial activities demonstrated
- Manageable resistance risk for key TPP pathogens
- Phys-Chem, ADME and eTox properties documented for the lead compound and analogues
  - no more than 3-4 alerts overall.
- PK properties in mice compatible with TPP indications/routes of administration
- *In vivo* efficacy demonstrated in TPP-relevant infection models with concomitant tolerability
- Tractable and scalable chemistry allowing further optimization of the series
- Acceptable IP position
- L2C optimization strategy and flow chart defined, taking into account the liabilities of the series

*The proposed lead criteria are indicative meaning that the Lead compound may not satisfy exactly all the listed quantitative criteria, or a few properties may not be properly documented. The lead dossier will be evaluated as a whole and with respect to the distance with the ideal Lead profile.*
Development candidate criteria, *main thresholds*

- MIC$_{90}$ ≤ 2 µg/ml for the targeted enterobacteriaceae and ≤ 4 µg/ml for the targeted non-fermenters
- Manageable resistance risk for all key TPP pathogens and mechanism(s) of resistance documented
- No major in vitro ADMET warnings
- In vivo efficacy demonstrated for multiple strains and in multiple infection models, representative of the targeted clinical indications.
- PK data available for several species by the intended route(s) of administration
- Acceptable in vivo tox profile and safety margins in rats
- Efficacy driver determined based on first PK/PD studies
- Reasonable projected active doses in human
- Demonstrated capacity to deliver large batches of the candidate
- IP position compatible with future FTO

The proposed candidate criteria are indicative meaning that the candidate may not satisfy exactly all the listed quantitative criteria, or a few properties may not be properly documented. The dossier will be evaluated as a whole and with respect to the distance with the ideal candidate profile.
Selection Criteria – Feasibility & Implementation

Feasibility

• **Resources**
  - Your contribution, including funding
  - Expected support from GNA NOW
  - Additional resources and expertise that are assumed not to be supported by the GNA NOW consortium, including subcontracting

**Contributions from GNA NOW partners are expected to be:**

- MoA and target elucidation (Helmholtz & BioAster)
- In vitro & in vivo microbiology (NBT, INSERM)
- In vivo microbiology & PKPD, allometric scaling, human dose prediction (Erasmus MC & University of Liverpool)
- Medicinal and computational chemistry, structural biology, protein production, ADME, Phys-Chem, CMC, *in vitro*/*in vivo* toxicology, pharmaceutical sciences (Evotec)

• **Budget**
  - Estimated budget for the GNA NOW activities in line with Consortium capacities

Implementation

Proposed plan (to be refined together with GNA NOW partners)

• **Action plan** to reach the next milestone
• **Timelines** (indicative)
• **Assay Cascade**
• **Tasks, deliverables and responsibilities**
Expression of Interest template
Outline of EoI template

Question 1 – Legal entity & primary contact person
Question 2 – Short history of the programme
Question 3 – Target Product Profile (TPP), table provided
Question 4 – Data on target
Question 5 – Chemistry & CMC
Question 6 – Microbiological profile
Question 7 – Phys-chem and ADMET profile
Question 8 – PK properties
Question 9 – *In vivo* efficacy data
Question 10 – *In vivo* toxicity data
Question 11 – PKPD studies*
Question 12 – Known liabilities and risks
Question 13 – Foreseen development pathway

- No confidential information
- Max 5 pages
- Adjust the answers to the stage of your programme
- Indicate if you have relevant data that you’ll include in the Dossier
- Contact the GNA NOW Office in case of questions

gnanow@lygature.org
Dossier template
The GNA NOW Incubator Management Office will guide you through the process. Before submitting, a CDA (Confidentiality Disclosure Agreement) has to be established.
Application Process

Kristina Orrling, Lygature
GNA NOW Coordinator
Submit your proposal (EoI) to
gnanow@lygature.org

Involve GNA NOW Office when preparing the EoI!
Process, deadlines and timelines

- **5 May**: Launch of call for additional programme
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Review Scoring & ranking
CDA With GNA NOW signed

CDA NOW signed
After submitted dossier

15 Sep

#1 proposal invited to sign contracts with Evotec & GNA NOW

Define new programme together with GNA NOW partners (who will do what when?)

Establish Core Team, Steering Committee, external experts etc

Define Go/No-Go criteria

Submit revised Description of Action to IMI
How it works?

• Submission to gnanow@lygature.org of a non-confidential Expression of Interest (EoI)
  - no more than 5 pages using the provided template.

• Submission evaluated and scored by the GNA NOW Review Committee (RC)
  - RC members are a diverse set of industry, independent and academic experts in antibiotic drug discovery and development.

• Top three proposals invited to sign a CDA with GNA NOW.

• Confidential dossiers provided by selected applicants and then reviewed by the RC
  - applicants to answer to Reviewers’ questions in written prior to an oral defence.

• Highest ranked dossier invited to sign partnering agreements with Evotec and with the GNA NOW Consortium.

• Project plans and deliverables (DoA) to be defined jointly between applicant and Consortium
# IP – Access Rights

<table>
<thead>
<tr>
<th><strong>Background</strong>*</th>
<th><strong>Project Execution</strong> (IMI2 JU &amp; GNA NOW)</th>
<th><strong>Research Use</strong></th>
<th><strong>Direct Exploitation</strong></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Exclusive owner</td>
<td>• Access on request (license on fair &amp; reasonable terms - non exclusive)</td>
<td>EVT option for direct exploitation in the field of treatment of infections caused by Gram(-) bacteria + bilateral agreement with EVOTEC</td>
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<td>• Ownership transferred to cpd owner</td>
<td>• Access on request for beneficiaries (Research license – royalty free-non exclusive)</td>
<td>• Rights/licences with a third party to be negotiated</td>
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<td>• Ownership of beneficiaries generating results</td>
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*Background: In appendix 3, exclusion of background from Access Rights

**each Beneficiary are granted Access Rights to the Results/background of any other Beneficiaries and/or CTP solely to the extent Necessary to undertake its own Allocated Work (for GNA-NOW projects execution)**
## Compound Owner status

<table>
<thead>
<tr>
<th>New Compound Owner status</th>
<th>Beneficiary</th>
<th>Contribution Third Party</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligibility</strong></td>
<td>Must qualify as a Beneficiary receiving IMI2 JU funding*</td>
<td>Any legal entity</td>
</tr>
<tr>
<td><strong>Agreement to be signed</strong></td>
<td>IMI2 GNA NOW Consortium and Grant agreements</td>
<td>Contributing Third Party Agreement (appendix of the CA)</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>GNA NOW in-kind activities</td>
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<td></td>
<td>Potential for funding</td>
<td>No funding</td>
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<td><strong>Governance within the consortium</strong></td>
<td>Part of the governance of the entire GNA NOW project</td>
<td>Limited to its program</td>
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<tr>
<td><strong>Bilateral agreement with EVT</strong> (IP, access right, exploitation)</td>
<td>Mandatory</td>
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</tbody>
</table>

Submit your EoI before 18 June
Thank you for your attention

You are invited to apply and to join a dynamic and skilled Consortium that will help you, in a collaborative spirit, to progress your asset to the next level!
Questions?

contact us via:
gnanow@lygature.org