Request for Proposals: BPaL introduction planning

Background:
The TB Alliance is a non-profit, product development partnership committed to discovering, developing, and delivering improved regimens to fight tuberculosis. TB Alliance received regulatory approval from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) for a novel, all-oral, six-month regimen combining bedaquiline and linezolid with the new drug pretomanid (BPaL) in 2019 and 2020, respectively. In the Nix-TB Phase 3 trial, this regimen demonstrated efficacy in treating the most intractable drug-resistant TB populations— including patients with XDR-TB and those with MDR-TB that are treatment intolerant or non-responsive (NEJM, 2020). Based on this and other data, WHO endorsed used of the BPaL regimen under operational research conditions in multidrug-resistant tuberculosis (MDR-TB) patients with TB that is resistant to fluoroquinolones or for whom another effective regimen cannot be designed (WHO, 2020). The BPaL regimen is under further clinical development in the Zenix trial that aims to optimize dosing for linezolid and bedaquiline and is expected to read out in the first half of 2021.

The drugs in the regimen are now available for purchase through the Global Drug Facility (GDF) or directly from Mylan. Mylan and TB Alliance's other commercial partners are responsible for the manufacture of pretomanid, ensuring its global availability, and pharmacovigilance.

Lessons learnt from recent launches of TB medicines have highlighted the importance of proactive implementation planning to facilitate smooth and timely scale-up following policy decision. As a product development partnership, TB Alliance relies on not only its commercial partners, but also on a network of public health partners to support planning, sensitization, and roll-out efforts. TB Alliance is currently seeking partner(s) to support efforts to understand pathways for potential programmatic scale-up of the BPaL regimen in select high burden countries. Proactive planning could help reduce potential lag between policy formulation and roll-out and ensure smoother and timely national implementation and scale-up once a country has made the decision to adopt a new life-saving intervention such as BPaL.

Scope of Work:
Through the proposed collaboration, the identified partner(s) will leverage their expertise and strong in-country networks to facilitate development of country specific roadmaps for introduction of the BPaL regimen. These plans will articulate access pathways, outline programmatic and operational considerations, identify enabling conditions, outline potential introduction hurdles and mitigating strategies, and articulate expected roles and responsibilities for different stakeholders—including national programs, patient representatives, manufacturers and distributors, TB Alliance, Ministries of Health, key opinion leaders, WHO, technical partners, and donors— in the introduction process. Important considerations and strategic interventions needed to catalyze uptake and availability will also be addressed in plans. Plans will be developed with appropriate engagement with, feedback and

buy-in from relevant country stakeholders and decision-makers, owned by national programs, and support actual implementation efforts. Plans must include, and integrate across key components to ensure smooth and swift roll out and scale-up following satisfactory experience in initial implementation under conditions such as operations research, pilot, conditional access, or clinical access programs, including:

- Approach to policy change in the national context and developed along with key national stakeholders/opinion leaders, including
    - Diagnostic/treatment algorithm
    - Engagement of patient/advocacy groups
    - Updates to national training materials
    - Integration into NSPs
- Practical strategies for supporting rapid transition in the areas of:
    - Integration into workplans and budgets
    - Integration into national policy, algorithms, and EMLs
    - Phase in/phase out stock transition
- Identification of both one time and incremental clinical and lab/diagnostic training, capacity, and infrastructure needs to support regimen introduction, including in the areas of treatment administration, monitoring, and pharmacovigilance
- Determination of the budget, additional incremental resources and financing sources that might be needed to shepherd regimen transition
- Recommendations for supporting integration of the regimen into procurement and supply channels, and for supporting availability of pretomanid and companion drugs (bedaquiline, linezolid) in the regimen
- Articulation of key risks and proposed mitigation strategies

The above is an illustrative list.

Target countries for this effort will be chosen from the following list: South Africa, Peru, Ukraine, China.

TB Alliance expects to support this work in 1-3 countries, to be selected based on strength of proposals received and cost involved.

Deliverables will be a report submitted in narrative form with an accompanying PowerPoint presentation for each individual country, and country-owned implementation plans. The proposed work is to be completed by Q3 2021.

If mutually agreed upon, the collaboration may be extended to include additional scopes of work related to implementation of recommendations in the proposed introduction plans, including support in organizing joint stakeholder meetings and trainings, as well as providing technical support for country level roll out of new regimens. Any further extensions to the scope of the collaboration would be contingent upon adequate funding.

Partners will be expected to proceed in a manner that is transparent and non-promotional.

Format and Requirements:

Proposals should include the following components:

- Description of the services to be provided, including the scope of activities, approach, milestones, and timelines
- Justification for the countries proposed for inclusion, including:
    - Description of why the proposed countries are strong candidates to choose to adopt the regimen (e.g., their disease burden and interest in adopting new tools) and indication of national program counterpart willingness to participate in early planning
    - Information on existing country networks and platforms that will be leveraged to expeditiously deliver the work, and discussion of how this project will link to and complement other related initiatives
- Description of the plan for ensuring adequate coordination with TB Alliance, commercial partners, and other relevant stakeholders to ensure complementarity and alignment of efforts
- Overview of the roles, responsibilities, and relevant experience of project personnel and of the organization
- Detailed budget, disaggregated by country if more than one is proposed. Should include the following categories: travel, meetings, staff/FTE, any outsourcing, any sub-contracting, etc. Names and bios of the project team, along with expected level of effort should also included

Evaluation Criteria:

Proposals will be evaluated based on the following criteria:

- Strength of proposal and responsiveness to RFP
- Existing in-country networks and local knowledge. The ability to leverage networks, KOL relationships, and strong baseline knowledge to deliver the work expeditiously and effectively
- Track record advising development of national level plans for treatment introduction, particularly with respect to TB in respective countries
- Cost effectiveness and value for money (breadth and anticipated quality of proposed deliverables relative to budget requested)
- Ability to meet ambitious timelines for proposed deliverables.

Deadline for communicating intent to submit is October 23, 2020. Full proposals are due to the TB Alliance by email by close of business on November 23, 2020.

All inquiries and completed documentation should be directed electronically to:

Sarah Cook-Scalise and Aastha Gupta
sarah.cook-scalise@tballiance.org Aastha.gupta-consultant@tballiance.org