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Unitaid is hosted by the
World Health Organization (WHO)

Dear Manufacturer,

Participation in the Bundibugyo **R**esponse for **I**mproving **D**iagnostic **G**lobal **E**quitable Access **(BRIDGE-Access) platform: Access Commitments**

We are pleased to inform you that your product has been selected to participate in the Bundibugyo ebolavirus (BDBV) diagnostic evaluation platform supported by Unitaid, following the Expression of Interest process led by Africa CDC and WHO, with technical support from PATH, and FIND as part of the Continental preparedness and response plan and within the interim-Medical Countermeasures Network (i-MCM Net) response framework.

Prior to commencing any procurement of products or initiation of evaluation activities, Unitaid and platform lead partners (Africa CDC and WHO) wish to ensure that participating manufacturers understand the objectives of this initiative and the principles guiding its support. The current Bundibugyo outbreak in the Democratic Republic of the Congo and Uganda highlights the urgent need for reliable, accessible and affordable diagnostic tools. At present, access to validated diagnostics remains limited. The Bundibugyo Response for Improving Diagnostic Global Equitable Access platform (BRIDGE Access) provides a coordinated mechanism to make financial and technical support available in order to generate independent evidence on the performance of candidate diagnostic products using scarce and highly valuable clinical specimens collected in affected countries. These specimens are a critical public health resource made available through the contribution of affected countries, communities, patients, and health authorities. Unitaid, in support of the Africa CDC/WHO continental plan, seeks to ensure that the evidence and results generated using the support provided through the platform contributes to public health impact and equitable access.

Toward this goal, Unitaid, with the BRIDGE Access platform leads (Africa CDC /WHO), has defined the principles to which each participating company receiving support through the platform should adhere in order to anticipate and secure access should the product be found suitable for the response. This letter articulates these principles as a framework for engagement and partnership. The letter itself is non-binding and does not create contractual obligations; rather, it reflects a shared commitment to good-faith cooperation in service of public health:

- **Access guided by public health risk and need**

Access to validated diagnostic products should be guided by public health risk, need, and vulnerability, with the objective of ensuring timely and equitable availability for populations most affected by, or at risk from, the relevant pathogen, in accordance with WHO guidance. As a general principle, the diagnostic products validated through the platform should be made available preferentially to all countries in need (defined by Africa CDC and WHO), including to countries and populations from which the evaluation specimens originate, which should be among the first to benefit from the availability, registration, and supply of the validated products.

- **Independence of evaluation**

The evaluation protocol, study design, data analysis, interpretation of results, and publication of findings will remain fully independent. The manufacturer will not influence these processes. Results of evaluations will be published by Africa CDC, WHO, Unitaid, and partners (subject to such conditions as WHO and partners may determine).

- **Equitable access**

The manufacturer commits to sharing any relevant information, and engaging with relevant stakeholders, in the interests of ensuring the affordability, availability, and sustainable supply of the validated product. In particular, the manufacturer shall act in good faith and use and demonstrable commercially reasonable efforts to facilitate timely, equitable and sustainable access to the product in affected and at-risk countries, particularly where public health needs have been identified, consistent with applicable policies and global access and benefit-sharing directions. To ensure affordability, the manufacturer will use commercially reasonable efforts to propose a fair and transparent pricing of the evaluated product, preferably at a reasonable margin over the cost of goods, notably for endemic regions.

- **Manufacturing Quality Standards**

The Manufacturer will manufacture the evaluated product under a quality management system certified to ISO 13485 global standard (or equivalent internationally recognized Good Manufacturing Practices standard).

- **Registration and supply readiness**

The manufacturer will use best efforts to actively pursue and, where within its control, complete the necessary regulatory authorizations and registrations of the evaluated product in all countries affected by, or at risk of, Bundibugyo and/or other Ebola outbreaks where registration is legally feasible, and will further use best efforts to communicate and maintain sufficient manufacturing capacity, stock, and distribution arrangements to support rapid deployment and ensure timely, equitable, and sustainable product availability when public health needs arise.

- **Transparency on supply and costs**

The manufacturer will inform the platform partners and countries, prior to any registration, of any known limitations or restrictions in supply, distribution or export, including those resulting from domestic laws or regulations (for example, export restrictions) as soon as reasonably possible. The manufacturer will also provide transparency to potential purchasers on relevant prices and the total costs for implementation and ownership of the diagnostic, including cost of equipment, maintenance, software, training, and other operational requirements.

- **Post-outbreak access and sustainability**

The manufacturer will use commercially reasonable efforts to support sustained access to the validated product during and beyond the immediate outbreak response. This includes maintaining registration where feasible, ensuring continuity of supply, providing reasonable technical support, maintenance, servicing and replacement parts, and avoiding unnecessary withdrawal from affected or at-risk markets. The manufacturer will promptly notify the platform partners and registered countries of any material changes to the evaluated product (including changes to components, software or intended use) or any known issues with the product and will use commercially reasonable efforts to ensure that products supplied remain materially equivalent to the validated configuration. The manufacturer further commits to working with countries and partners to develop plans that support long-term preparedness and enable rapid deployment of the validated product in future BDBV or other Ebola outbreaks.

This letter has been drafted in the interests of ensuring alignment on the key principles set out above. In the interests of transparency, this letter and the commitments it contains may be made public by Unitaid and its partners.

Unitaid, on behalf of the partners in the Platform, is seeking confirmation of alignment with the principles set out herein from all manufacturers benefiting from support through the Platform. We therefore request that you countersign this letter where indicated below and return it to us by email at jeremie.piton@unitaid.who.int.

Yours sincerely,



Philippe Duneton
Unitaid Executive Director

Acknowledged:

For and on behalf of Manufacturer
Name:
Title:
Date: