Single Shield Prize Informational Webinar

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Susannah Littlewood, Luminary Labs:

Welcome everyone to the Single Shield Prize Informational Webinar. My name is Susannah Littlewood. I'm an associate at Luminary Labs, the Prize Administrator. The Single Shield Prize is supported by the Biomedical Advanced Research and Development Authority herein referred to as BARDA. Before I begin, I want to share that this session is being recorded and will be available on the Single Shield Prize website shortly. Today's session will provide an overview of the PRIZE and how to participate. At the end, we will also respond to some of the frequently asked questions that were submitted during webinar registration. I'm now really happy to pass over to Sarah Murtaza from BARDA to introduce herself and provide some background on the prize.

Sarah Murtaza, BARDA:

Thank you so much, Susannah, and thank you all for joining us today. We're excited to see the level of interest and engagement in the Single Shield Prize. My name is Sarah Murtaza and I am an interdisciplinary scientist here at BARDA. And in that role, I serve as a program manager for the Single Shield Prize. A big challenge when it comes to improving vaccine dosing has been trying to get down to a single dose vaccine approach for a primary vaccine series in naive individuals. The successful development of a single administration vaccine can improve public health and safety in many ways, including by enabling greater immunization capacity with finite manufacturing resources, reducing the resource burden on healthcare systems, and removing barriers to completing vaccination while achieving protection on a shorter timeline. These benefits are particularly valuable during a pandemic when resources are limited and speed is critical.

Existing approaches have yet to be successfully applied to create a single dose which provides the level of protection we need in terms of pandemic response.

This has led to the launch of the Single Shield Prize, an 80 plus million dollar competition to advance single administration vaccine platforms for pandemic influenza. The prize calls for innovative solutions enabling the development of vaccines that could provide protection in a single administration.

So why H5N1 as a use case? When we think about a prize, one of the most important considerations is being transparent on the process and on the judging criteria which constitutes success. In the case of the Single Shield Prize, we also wanted to consider downstream

long-term transition of successful approaches as well as the ability to more broadly apply successful approaches to other non-influenza vaccines. Pandemic influenza vaccines administered via intramuscular, subcutaneous, transdermal or intradermal enable both of these considerations to be addressed. And based on the following rationale, a known well understood correlate of protection which can be measured using fairly simple immunogenicity assays, well-developed and understood animal models.

The allowable approaches are based on licensed vaccine approaches, so types include both inactivated as well as recombinant protein, providing more flexibility and options for prize participants. Pandemic influenza falls within BARDA's threat space, so successful candidates have the potential to be further supported through advanced research and development by BARDA.

The Single Shield Prize uses a prize competition model to encourage participation from both established and emerging innovators, attract novel scientific approaches, encourage and enable entrants to collaborate on creative solutions that may not be possible to achieve independently and to de-risk early stage development. Through the competition, promising technologies receive support from concept stage through clinical studies. I want to thank you again for your interest in the prize, and I look forward to seeing the innovative approaches proposed. And with that, I will turn it back to Susannah to walk through the structure and details of the Single Shield Prize.

Susannah Littlewood, Luminary Labs:

Thanks, Sarah, for sharing that foundational context and the introduction to the prize. We'll now walk through the structure of the prize. So the prize is structured across three stages designed to advance vaccine candidates from concept to investigational new drug application. The prize launched on August 5th, marking the start of concept stage submissions. That's the stage that we're currently in. On September 29th, we will be hosting a proposer's day in New York City. This will be an opportunity for prospective entrants to meet and foster collaboration. Prospective entrants must first submit a declaration of intent and be approved before they submit a concept paper. Declarations of intent will be reviewed on a rolling basis until January 5th, 2027. The deadline for concept papers is January 15th, 2027. After that, stage one is anticipated to be open from Q2 2027 to mid 2029, and stage two is anticipated to be open from mid 2029 to mid 2031.

So who can participate in the Single Shield Prize? The prize is looking for a diverse array of participation from vaccine developers and researchers to biotech companies and other innovators. Eligible entrants will have the chance to compete for more than $80 million in awards while gaining access to technical support and opportunities to connect with collaborators, industry partners, and potential investors. To be eligible to win an award under the prize, an entrant must be a legal entity such as a nonprofit, for-profit or academic institution

and/or be represented by an individual with the delegated authority to act on behalf of that legal entity.

Entrants must not be prohibited from transactions with or import into the United States as designated or sanctioned by the United States Treasury's Office of Foreign Assets Control or include any entities or individuals designated or sanctioned as such in OFAC's list of specially designated nationals and blocked persons. Entrant teams must not involve any judge of the prize or any other party formally involved with the design, production, execution or distribution of the prize or the immediate family of such a party. Each submission must be led by a primary entrant. The primary entrant entity must be US-based at the time the declaration of intent is submitted and remains so through the issuance of prize awards. This means that the entity must be incorporated in the United States, including US-incorporated subsidiaries, even if the parent is foreign-based or unincorporated with principal place of business in the United States. Principle place of business is defined as the primary location where management directs, controls, or coordinates an entity's activities.

Please note that you can submit more than one concept stage entry, but keep in mind that each primary entrant or a team made up of the same partners can only receive one award per stage. Teaming collaborations between diverse innovators are encouraged. Entrants interested in partnering can fill out a teaming form on the Single Shield Prize website to share a participant profile and connect with potential collaborators. Now onto the awards. The total prize pool for the concept stage is $32 million. Up to eight winners will have the opportunity to receive up to $4 million each. The total prize pool for stage one is $32 million. Up to four winners will have the opportunity to receive up to $8 million each. Award details for stage two will be released prior to the launch of the stage, which is anticipated for mid 2029. The awards at each stage are intended to support technology development to fulfill the next stage of prize success criteria.

Now I'll share some more details about the concept stage of the prize specifically. This stage calls on entrants to submit concept papers detailing their respective single administration vaccine technologies and their plan for non-clinical development and evaluation towards submitting an investigational new drug application. The concept paper should outline innovative technical approach and its feasibility to advance a safe, tolerable, and efficacious single administration vaccine. It should address key considerations for product development and formulation, non-clinical evaluation, regulatory engagement and manufacturing. As a reminder, the concept stage opened on August 5th and will remain open until January 15th, 2027. Prospective entrants must first submit a declaration of intent and be approved before submitting a concept paper. Declarations of intent will be reviewed based on the prizes eligibility requirements and product requirements, which we will review shortly. Declarations of intent will be reviewed on a rolling basis until January 5th, 2027.

I'll now go over the product requirements. Submissions from eligible entrants that meet the following product specifications will be considered for evaluation. The proposed vaccine

candidate must be either an inactivated virus vaccine or a recombinant hemagglutinin protein vaccine. Entrants need not have access to an existing approved influenza product themselves. They need to only submit a candidate built on one of these two in scope platforms. The candidate must only be delivered by one of the following methods, intramuscular, intradermal, transdermal or subcutaneous. The candidate must be targeted towards pandemic influenza AH5N1. The vaccine candidate may target other influenza A subtypes concurrently as long as pandemic influenza A H5N1 is included. The candidate must be administered in a single healthcare visit or single self-administration event. The active components may be released over time, for example, via slow release or pulsatile release mechanisms. Strategies that rely on the simultaneous administration of separate doses or on a combination of different routes of administration at a single time point will not be considered for the price competition.

In addition, the vaccine candidate should include a formulation and/or delivery technology intended to enhance antigen persistence, magnitude and durability of immune response or controlled antigen or adjuvant release following a single administration, and it should be an adjuvanted vaccine where the adjuvant is either co-formulated or admixed with the antigen for co-administration or co-delivery.

Submissions will be evaluated across four equally weighted criteria. One, innovative product design and scientific rationale. Two, non-clinical development plan. Three, regulatory engagement and manufacturing strategy. And four, operational readiness and risk mitigation. Each criterion follows a consistent structure with a few related components outlined within its description. Both the innovative product design and scientific rationale and non-clinical development plan criteria reference the desired product attributes. These describe product requirements and target non-clinical metrics aligned with approved two-dose pandemic influenza vaccines and will inform evaluation of submissions. The Single Shield Prize will be unable to provide additional context, detail or clarity regarding the evaluation criteria or desired product attributes at this time, but we encourage you to reference the evaluation criteria page of the website where you can find the full criteria descriptions and the desired product attributes PDF.

Evaluation of the concept stage submissions will follow a two-step process. First, a review panel will score submissions using the concept stage evaluation criteria. Second, based on the scores, up to 15 submissions will be invited to a virtual pitching round with an expert judging panel. Judges will give recommendations to inform the selection of up to eight winners. Following the concept stage, stages one and two will seek to advance vaccine candidates through non-clinical development. Stage one is open to concept stage winners and to new entrants who meet the eligibility requirements. New entrants must first submit a declaration of intent and be approved before they can submit a stage one technical paper.

Stage one aims to identify promising single administration vaccine candidates that demonstrate the technical feasibility of achieving immune response and protection equivalent or superior to

that of a conventional two-dose vaccine. Stage one calls on entrance to submit a technical paper detailing the non-clinical research conducted on the vaccine candidate across formulation, delivery, antigen, and adjuvant where relevant with supporting data. At the end of stage one, the vaccine candidate should be ready to move towards IND enabling studies. Winners who accept stage one awards will be eligible to progress to stage two. Stage two supports the critical transformation from research grade proof of concept to regulatory grade drug product ready for clinical investigation. Entrants must demonstrate manufacturing scalability, product consistency and regulatory compliance to validate their non-clinical drug asset for human testing. Entrants will be required to submit an IND application to the US Food and Drug Administration and provide evidence of filing, as well as providing a comprehensive data package describing manufacturing capabilities and regulatory compliance outcomes based on price specific requirements.

Further details of stage one and two will be announced prior to the launch of each stage.

Next, we'll walk through what it looks like to submit a solution. To submit, you'll register through the submit page on the program website. Entrants must submit a declaration of intent by 4:59 PM Eastern Time on January 5th, 2027. This will include entrant information and a summary of your proposed vaccine candidate. Entrants must then complete their concept stage submission by 4:59 PM Eastern Time on January 15th, 2027. This will include any updates to entrant information, submission details and your concept paper. This is what the registration interface looks like. One member of the entrant team will need to register and create an account and then they can begin the submission.

To start the submission, you'll first provide basic information about the primary entrant, including contact details for the team lead. You'll then be able to add information about any partner organizations that will form part of the entrant team and make substantive contributions to the proposed work. Be sure that all fields are completed before moving forward. You'll then complete the declaration of intent form, which consists of an eligibility checklist for the primary entrant and partners, a brief summary of your proposed vaccine candidate, which is no more than 250 words, and a product profile checklist for the intended vaccine candidate. After submitting your declaration of intent, entrants will be notified by email within five business days whether they have received approval to submit a concept paper. No additional feedback or details will be provided to entrants who do not receive approval.

Once you have received approval, return to the submission form where you will now be able to complete your submission. First, you are invited to provide any updates that may be to the listed partners since your declaration of intent was submitted. If partners have not changed since the declaration of intent, you can just proceed to the next page. If partners have changed, you should add information for all partner entities, including those that were added during the declaration of intent and remain a partner for the concept stage submission and any new partners since the submission of the declaration of intent. Then you'll complete your submission

details, including the submission title, headline, a technical abstract, and you'll complete a product profile checklist.

Next, you will upload your concept paper. The paper should be submitted as a PDF of no more than 15 pages. References do not count towards the page limit. Additional content may be included in an appendix and the appendices do not count towards the page limit. Appendices are not guaranteed to be reviewed, but you may use them to provide helpful context or clarification. To best enable reviewers to evaluate your concept paper, it should address the following: a concept summary, a summary of the vaccine candidate and of the non-clinical development plan, a product description, description of past progress and current status, so a summary of current development status and a description of past progress, including any supporting evidence from development and evaluation efforts to date. This should include a summary of any past funding and how it's been used to advance development to date. The summary should also include a description of any prior interactions with the FDA regarding the proposed product.

You should include a non-clinical development plan, a roadmap for formulation development and optimization, and for validating the proposed product through non-clinical studies with a sound rationale for model selection aligned with the desired product attributes. You should include a regulatory engagement plan, a roadmap detailing a viable plan to engage with the FDA in preparation for seeking investigational new drug authorization. You should include a risk management plan, a summary risk register, and an overview of the organizational or program-based mechanisms that will be used during the execution of product development to assess, monitor, mitigate, and manage risks. You should include a manufacturing plan, a roadmap aligned with FDA guidance on good manufacturing practice and chemistry manufacturing and controls for IND applications. And finally, a description of organizational capabilities, a summary of the team's key personnel, their roles and responsibilities, how decision-making processes will be made, and a description of team expertise and access to required technology.

All of these recommended elements relate to the evaluation criteria and thus will aid reviewers when they are reviewing your submissions. Each entrant must clearly delineate any confidential commercial information contained in the submission that the entrant wishes to protect as proprietary data. Entrants must also demonstrate within their submission that they possess or have a viable pathway to obtain all requisite intellectual property rights. This encompasses both the vaccine antigen component and any other technology needed for the single administration vaccine candidate. Before submitting, take time to review your materials and ensure all required components are complete. Then complete the submission checklist. Once you have submitted, you'll receive confirmation through the platform and also via a confirmation email. If you have any other questions about how to submit, please email hello@singleshieldprize.com. I'm now going to answer some of the frequently asked questions that attendees surface during the registration process for the webinar.

We'll start off with a couple of questions about entrant eligibility. The first question is, is a team which includes partners based outside of the US eligible? Yes, the primary entrant must be US based, but the primary entrant can team up with foreign-based partners provided that the partners meet the eligibility requirements.

The second question is what types of entrants are eligible? So an entrant must be a legal entity and/or be represented by an individual with the delegated authority to act on behalf of that legal entity. The entity could be a nonprofit, for-profit, or academic institution, for example.

Next, we had a question related to teaming. What is the ideal composition for an entrant team? There is no prescribed team composition and what is ideal may vary depending on the entrance proposed approach and needs. Whether an entrant chooses the team or not will not be a factor within evaluation. Submissions will be evaluated based on entrant's ability to execute the proposed approach in accordance with the concept stage evaluation criteria. But those interested in partnering can fill out the teaming form on the website and also register for the September 29th proposers day to connect with other prospective entrants and partners.

We now have a number of questions about product requirements. First, does the prize have a preferred route of administration? So to reiterate this, the proposed candidate must be delivered by one of the following routes of administration, intramuscular, intradermal, transdermal, or subcutaneous.

Can the vaccine candidate employ controlled release, self-boosting or pulsatile release technologies delivered in a single encounter? Yes, these technologies are in scope.

Which types of platforms are being considered? The proposed vaccine candidate must be either an inactivated virus vaccine or a recombinant hemagglutinin protein vaccine. Examples of in-scope approaches include egg-based, cell-based recombinant protein subunit or self-assembling scaffolded protein nanoparticles displaying HA antigens.

An additional note here, we had a number of questions about acceptable models, desired duration of protection, and which arms of the immune system should be targeted. Entrants should refer to the desired product attributes found on the prize website for more details in relation to these. The attributes will inform evaluation of the submission and they serve as a guide to entrance for what is expected during non-clinical studies.

Now we have a number of questions related to stage of development of candidates. First, what stage of development does a vaccine candidate need to have reached to enter the concept stage? The candidate doesn't need to have reached a particular stage of development to submit a concept paper, but if an entrant or team does have preliminary data, they're encouraged to share that as part of their concept stage submission.

Can the proposed candidate incorporate multiple novel approaches? Yes, a proposed candidate can incorporate multiple novel elements provided that the candidate aligns with the product requirements.

Can a team enter at a later stage if they have already conducted certain non-clinical studies? Yes, an entrant or team could choose to skip the concept stage and enter a submission at stage one, but stage two will only be open to winners of stage one, so new entrants couldn't enter at that stage. Do entrants need to have access to commercially available antigen for use during non-clinical studies? This isn't a requirement. At the concept stage, entrants are asked to indicate the intended source of the antigen to be used during non-clinical studies and the antigen may be commercially available or sourced or produced through other means. Submissions will be evaluated on the degree to which the primary entrant and any included partners possess the capabilities required to successfully execute the proposed non-clinical studies in accordance with the concept stage evaluation criteria.

We next have a question related to evaluation. Are entrants required to source and use FDA-approved pandemic vaccines as control arms for animal studies? No, this is not a requirement. The prize is not seeking a head-to-head comparison with existing vaccines. Instead, vaccines will be evaluated against the desired product attributes which describe target non-clinical metrics which are aligned with approved two-dose pandemic influenza vaccines.

Finally, we have a few questions related to prize rules and context. First, how will the funds be dispersed and are there any conditions of receiving funding? The stage awards are paid to entrants who are selected as winners under the prize rules, terms and conditions. Unlike a grant or a contract, a prize is not a cost reimbursement mechanism and it's not based on direct, indirect, proposed or incurred costs. It's expected that winners will use the prize funds to further development and participation in subsequent stages of the prize or towards execution of a phase one clinical trial in the case of stage two winners.

How does this program relate to other BARDA pandemic influenza programs? The Single Shield Prize compliments, but doesn't overlap with several other BARDA-related efforts looking at improving vaccine formulation and delivery. Pandemic influenza falls within BARDA's threat space, so following stage two completion, successful candidates could be further supported through advanced research and development by BARDA as funding and priorities allow.

If you have any other questions, anything that we haven't covered, please reach out to hello@singleshieldprize.com.

So what are the next steps? We encourage you to complete the teaming form on the Single Shield Prize website and share a participant profile and connect with potential collaborators to register on the submission platform, review all the program materials on the website, and sign up for the prize newsletter if you haven't done so already. You can add the prize email,

hello@singleshieldprize.com to your contacts to make sure that you don't miss anything important from us.

Finally, we encourage you to register for and attend our Proposers' Day on September 29th. If you scan this QR code, it will take you to the event page where you can view the details and register for the event.

Thank you all for joining us today. We're really excited to see the vaccine innovations that emerged through this process, and we look forward to reviewing your submissions.