

Advancing Single-Administration Vaccines Against Pandemic Influenza A(H5N1): The Single Shield Prize

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Background

The novel influenza viruses remain among the most serious pandemic threats facing global public health, combining the potential for rapid person-to-person spread with little background immunity to protect the population from infection. All licensed vaccines currently rely on a two-dose prime-boost regimen to elicit the neutralizing antibody responses necessary for seroprotection and to achieve strong, durable immunity. This reliance presents a significant challenge during a pandemic, when resources are limited and speed is critical.

Objective

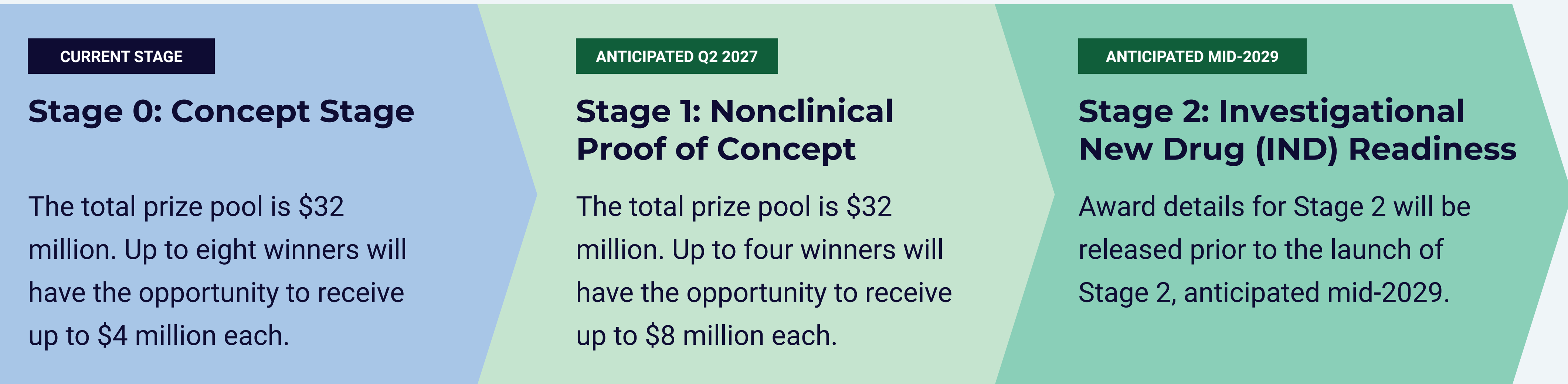
The Single Shield Prize aims to accelerate development of single-administration vaccine platforms for pandemic influenza. The prize calls for innovations in recombinant hemagglutinin (rHA) protein or inactivated virus vaccines (e.g. novel vaccine formulations, antigen presentation, controlled release technologies, and vaccine delivery methods). By focusing on vaccine platforms used in established influenza vaccines, the prize targets innovations with the best chance of success within the competition’s development timeline.

Public Health Rationale

Single-administration vaccines can improve public health and safety by: (1) enabling greater immunization capacity with finite manufacturing resources; (2) reducing the resource burden on health care systems; (3) removing barriers to completing vaccination while enabling protection on a shorter timeline.

Approach

The Single Shield Prize employs an open innovation challenge model to attract novel approaches, de-risk early-stage development, and address market failures, offering financial incentives calibrated to accelerate progress toward a defined goal. The model encourages participation from both established and emerging innovators and encourages entrants to collaborate on creative solutions that may not be achieved independently. To evaluate vaccine candidates, the prize will use a set of Desired Product Attributes that target nonclinical metrics aligned with approved two-dose pandemic influenza vaccines. These metrics span biological performance, formulation and delivery, and manufacturability.



Conclusion

The Single Shield Prize establishes a technically rigorous, outcomes-driven framework to catalyze innovation in single-administration A(H5N1) virus vaccine science. By defining clear success criteria and incentivizing a range of potential innovators, this open innovation competition is structured to generate promising pandemic countermeasure candidates, advancing the two strongest candidates toward Phase 1 clinical trials, while also supporting platform-level innovations with potential applicability across other indications.

Concept stage evaluation criteria	
Innovative product design and scientific rationale	The degree to which the submission presents an innovative yet feasible single-administration vaccine approach aligned with the Desired Product Attributes and clearly describes how the proposed formulation, adjuvant, and delivery approach is expected to enhance the magnitude, quality, and durability of the immune response to the target antigen(s) following a single administration.
Nonclinical development plan	The degree to which the submission presents an achievable nonclinical development strategy aligned with the Desired Product Attributes, including formulation optimization, relevant in vitro characterization, and appropriately designed animal studies to evaluate immunogenicity, durability, and protective efficacy. The proposed studies should include clearly defined success criteria and demonstrate how the formulation will be evaluated throughout development.
Regulatory engagement and manufacturing strategy	The degree to which the submission demonstrates a credible regulatory and manufacturing strategy that supports future clinical translation and is aligned with FDA expectations for IND-enabling development, scalable manufacturing, quality, and CMC development. Prior regulatory experience, where applicable, and a realistic plan for regulatory engagement should be described.
Operational readiness and risk mitigation	The degree to which the submission demonstrates that the Primary Entrant and any included partners possess and/or have access to the scientific, technical, manufacturing, and operational expertise required to successfully execute the proposed work. The submission should identify key technical and development risks and practical mitigation plans/strategies to address them across the product lifecycle.



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