EX-99.1 2 tm222428d1_ex99-1.htm EXHIBIT 99.1

Exhibit 99.1

SAFE HARBOR STATEMENT

Certain information, particularly information relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing NVX-CoV2373, COVID-NanoFlu™ combination vaccine, Omicron-specific vaccine, and other Novavax vaccine product candidates, the tim clinical trials, the potential for a booster dose of NVX-CoV2373 to provide protection against COVID-19 (including variants), the scope an regulatory filings and actions, anticipated manufacturing capacity, the global market opportunities for NVX-CoV2373, the readiness of chain and future availability of NVX-CoV2373 at a global scale and the commercialization and expected delivery of NVX-CoV2373, ar milestones constitute forward-looking statements.

Forward-looking statements may generally contain words such as "believe," "may," "could," "will," "possible," "can," "estimate," "cont "consider," "intend," "indicate," "plan," "project," "expect," "should," "would," or "assume" or variations of such words or other words with Novavax cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over tim actual results to differ materially from the results discussed in the forward-looking statements.

These risks and uncertainties include challenges satisfying, alone or together with partners, various safety, efficacy, and product requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; c scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax t regulatory pathways; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Opera Novavax' Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent Quarterly Reports on Form 10-Q, as filed with Exchange Commission, which are available at www.sec.gov and www.novavax.com.

Forward-looking statements are based on current expectations and assumptions and currently available data and are neither predictions future events or performance.

Current results may not be predictive of future results.

You should not place considerable reliance on forward-looking statements which speak only as of the date hereof.

The Company does not undertake to update or revise any forward-looking statements after they are made, whether as a result of new i events, or otherwise, except as required by applicable law.

Novavax™ (and all associated logos) and NanoFlu™ are trademarks of Novavax, Inc. Matrix-M™ is a trademark of Novavax AB.

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OUR SIGNIFICANT MOMENTUM

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NOVAVAX AT-A-GLANCE

HIGH EFFICACY FOR NVX-CoV2373
90% overall • 100% against moderate & severe disease

>6 BILLION LIVES IN MARK
REGULATORY AUTHORIZAT
Across 170+ countries around the globe

STRONG RESPONSE TO VARIANTS
93% against VoI/VoC • Cross-protection against Alpha, Beta • Robust responses against Delta, Omicron, others

~2 BILLION DOSES COMM
And >2 billion dose manufacturing capaci

$1.9 BILLION IN CASH*
Well-capitalized for commercial roll-out, pipeline expansion, and potential strategic M&A

ROBUST VACCINE PIPELIN
Addressing today's most serious infectious
COVID-19 (primary vaccination, boosting
• Influenza • Respiratory syncytial virus (RS

* Cash includes cash, cash equivalents and restricted cash as of 9/30/2021

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NVX-CoV2373 ADDRESSES THE EVOLVING PAN

NVX-CoV2373 VACCINE DESIGN

Vaccine nanoparticle

Matrix-M™ adjuvant
not to size

- Innovative vaccine nanoparticles based on recombinant protein technology
- Full-length SARS-CoV-2 Spike
- Formulated with unique Matrix-M™ adjuvant

Well-Tolerated with High Effi

Significant Global Capacity

Ease of Distribution & Admin

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MULTIPLE EMERGENCY USE AUTHORIZATIONS REC

Status of global regulatory filings

*Regulatory submissions in partnership with Serum Institute
**EUA request expected end of January 2022
***Regulatory submission of Biologics License Application (BLA) in partnership with SK bioscience
****Regulatory submission of New Drug Application in partnership with Takeda

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GLOBAL MARKET OPPORTUNITIES FOR NVX-CoV

PRIMARY VACCINATION

Addressing vaccine hesitancy through best-in-class efficacy based on well-understood technology

BOOSTER VACCINATION

Need for robust protection, inc against variants, driving contin demand for boosters

PEDIATRIC VACCINATION

Efficacy and safety profile enabling desirability for pediatric populations

EQUITABLE ACCESS

Delivering on global need thro commitment to equitable distrib

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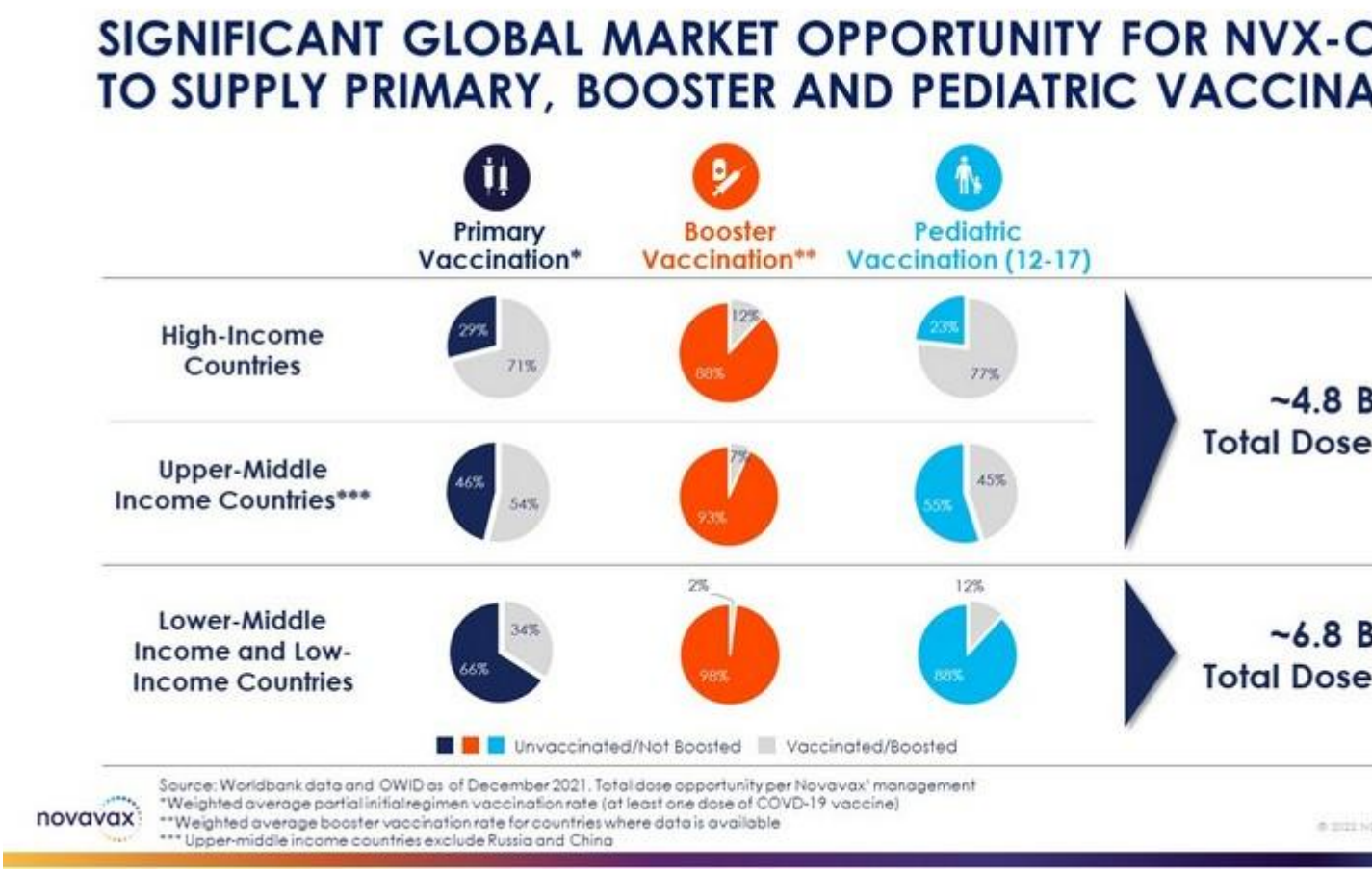
SIGNIFICANT GLOBAL MARKET OPPORTUNITY FOR NVX-C
TO SUPPLY PRIMARY, BOOSTER AND PEDIATRIC VACCINA
Primary Vaccination*
Booster Vaccination**
Pediatric Vaccination (12-17)
High-Income Countries
29%
71%
12%
88%
23%
77%
~4.8 B
Total Dose
Upper-Middle Income Countries***
46%
54%
7%
93%
55%
45%
Lower-Middle Income and Low-Income Countries
34%
66%
2%
98%
12%
88%
~6.8 B
Total Dose
Unvaccinated/Not Boosted
Vaccinated/Boosted
Source: Worldbank data and OWID as of December 2021. Total dose opportunity per Novavax' management
*Weighted average partial initial regimen vaccination rate (at least one dose of COVD-19 vaccine)
**Weighted average booster vaccination rate for countries where data is available
*** Upper-middle income countries exclude Russia and China
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~2 BILLION DOSES OF NVX-CoV2373 COMMITTED GL

Ensuring fair and equitable global access

GAVI / COVAX FACILITY

~1.1 Billion Doses

- APA with Gavi
- NVAX to provide 350 million doses
- Serum Institute to provide 750 million doses
- **Fair and equitable access** of NVX-CoV2373 around the world

COMMITMENT TO US GOVERN

110 Million Doses

Doses committed to US g
part of funding commitm

ADVANCE PURCHASE AGREEMENTS

Up to 430 Million Doses

- European Commission
- UK
- Canada
- Australia
- New Zealand
- Switzerland
- United Arab Emirates
- Singapore

LICENSING AGREEMENTS

Up to 400 Million Doses

- SK bioscience granted
in Republic of Korea ar
license in Thailand and
- Serum Institute granted
in India and non-exclus
UMICs and LMICs
- Takeda granted exclus
Japan

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MANUFACTURING INFRASTRUCTURE SUPPORTS GLOBA DEMAND FOR NVX-CoV2373

Antigen Production

- ✓ Significant bioreactor capacity at multiple sites
- ✓ Additional sites to be added to harmonized regulatory file

Sites: Novavax CZ • Serum Institute • SK bioscience • Takeda • Biofabri • Biologics Manufacturing Centre • FujiFilm •

Matrix-M Adjuvant Production

- ✓ Raw material secured
- ✓ Large-scale production at Novavax AB and contract manufacturing sites

Sites: Novavax AB • AGC Biologics • PolyPeptide Group

Partnership with Serum Institute

- ✓ World's largest vaccine manufacturer by volume, used in ~170 countries
- ✓ Provides significant capacity to support global manufacturing scale-up

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CLINICAL & REGULATORY OVERVIEW

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EXPANDING LABEL AND POLICY INDICATIONS

Additional clinical data being developed to support expanded recommendations for

	Strategic Approach
 **Primary Vaccination**	• Receive regulatory authorizations in additional markets • Distribute doses to ensure broad, equitable access • Collect additional data against emerging variants
 **Booster Vaccination**	• Initiate additional boosting studies • Utilize all data generated for heterologous / mix-and-match boosting • Pursue label indications and policy recommendations
 **Pediatric Vaccination**	• Complete regulatory filing for pediatric indication (12 – 17 years) • Initiate studies in younger age groups

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CONSISTENT EFFICACY ACROSS PHASE 3 STUDIES

	UK Phase 3 N=15,203	PREVENT-19 N=29,960
Overall Efficacy	**89.7%**	**90.4%**
"Matched" / Prototype Efficacy	**96.4%** Prototype	**100%** (Non-VoI/VoC)
Efficacy Against Variants	**86.3%** Alpha (B.1.1.7)	**93.6%** Alpha (B.1.1.7) **92.6%** All VoI/VoC
Efficacy Against Severe Disease	**NS** (all 5 severe cases in placebo group)	**100%**
"High Risk" Populations	**90.9%**	**91.0%**

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ROBUST DATA TO SUPPORT NVX-CoV2373 AS A BOOSTER

Additional data expected from ongoing studies in 2022

Homologous

Phase 2 U.S. & Australia

- Functional inhibition increased 6x (prototype) to 19.9x (Omicron) compared to peak responses following 2-dose primary series
- Increase in neutralization, with Delta and Omicron titers comparable to levels associated with protection in Phase 3 studies

Heterologous

COV-BOOST (UK)*

- Substantial increase in functional antibody titers following mRNA and viral vector vaccines

Ongoing Stu

PREVENT-

Phase 2b South

Phase 2 U.S. & A

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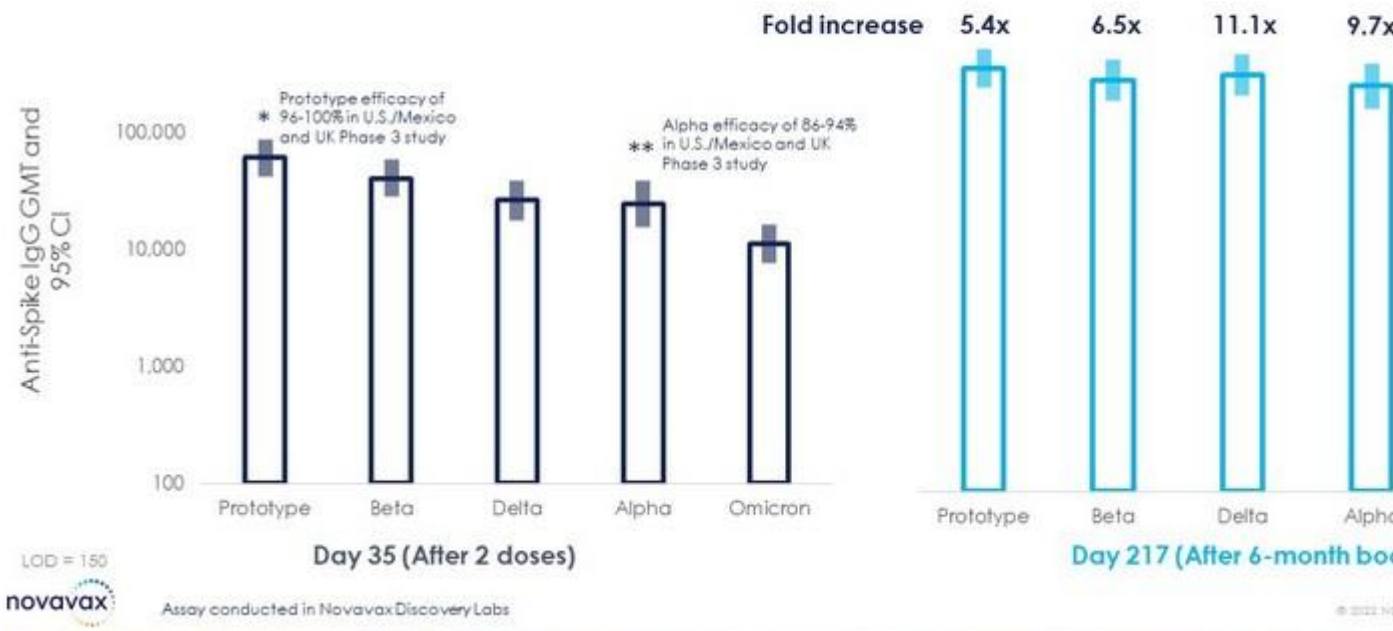
*Study led by University Hospital Southampton NHS Foundation Trust and other NIHR sites; Supported by UK government Vaccines Taskforce (VTF) and Department of Health and Social Care

VARIANT-SPECIFIC RESPONSES INDUCED, WITH SIGNIFICANT IgG INCREASE AFTER 6-MONTH BOOST

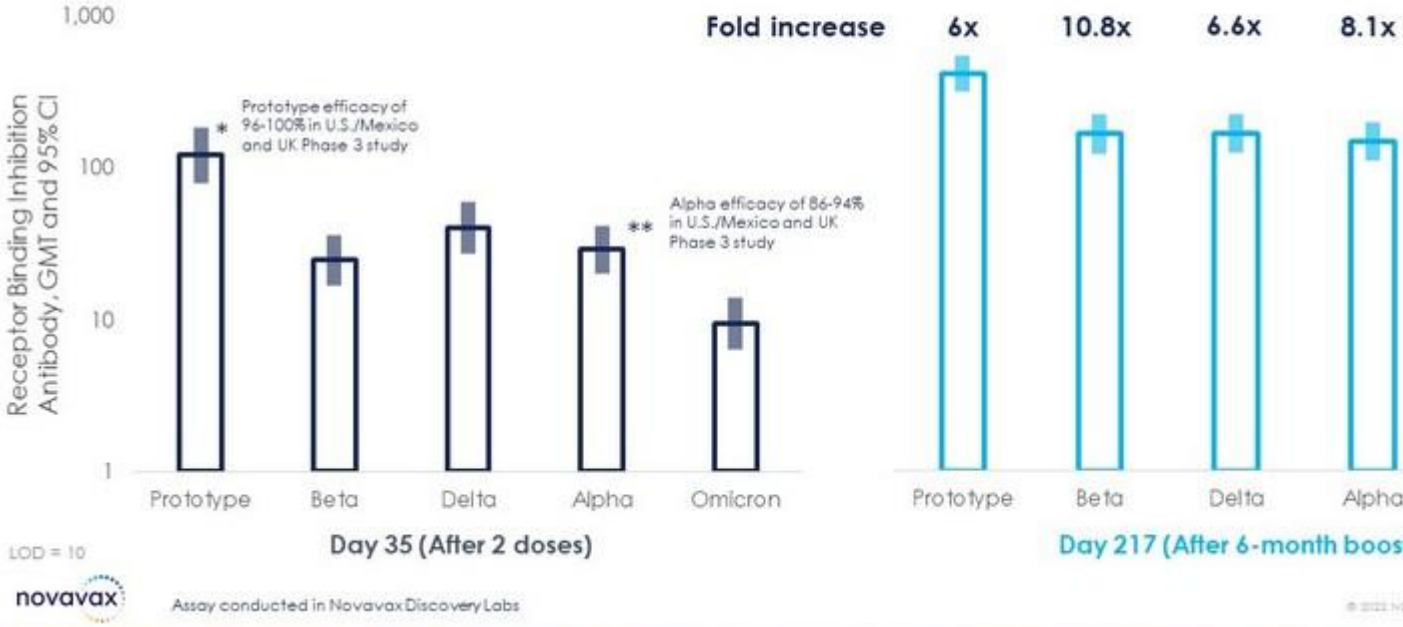
100% seroconversion after 2 doses against all tested variants



FUNCTIONAL INHIBITION OF hACE2 AGAINST VARIANTS INCREASED AFTER 6-MONTH BOOST

Magnitude of immune responses for all variants was greater than the peak observed a

100% seroconversion against all variants after 6-month boost



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Assay conducted in Novavax Discovery Labs

PREVENT-19

PEDIATRIC EXPANSION TO SUPPORT REGULATORY SUBMISSION IN 1Q 2022

April 2021
First dose

June 2021
Completed enrollment

October 2021
Completed blinded crossover

Expected 1
Complete regul
for pediatric in
(12 – 17 ye

Study Design

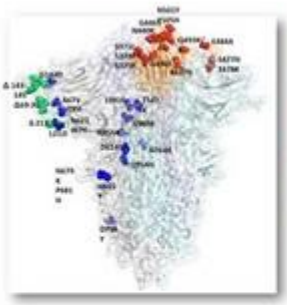
- 2,248 adolescents (12-17 years)
- Randomized 2:1

Initial Findings

After 2 doses: functional
responses **2.4-4x higher** tho
including against **Delta** an

OMICRON VACCINE DEVELOPMENT UNDERWAY

Approach demonstrates ability to rapidly develop and scale strain change



December 2021

- Initiated development of Omicron-s vaccine
- Demonstrated cross-reactive immun against Omicron variant from two-d regimen of NVX-CoV2373
- Initiated GMP manufacturing for On specific vaccine

Expected 1Q 2022

- Initiate clinical studies of Omicron-sp vaccine

LEADER IN COVID, NANOFLU™ AND COMBINATION VACCINE DEVELOPMENT

A transformative innovation to fight both illnesses

September 2021
- Initiated Phase 1/2 clinical trial of combin
- Safety, immunogenicity, and dose finding

October 2021
- Completed enrollment of Phase 1/2 clinic
- ~640 adults 50 – 70 years of age

Expected 2022
- Announce data from Phase 1/2 clinical t
- Initiate Phase 2 clinical trial for COVID-No combination vaccine and NanoFlu stand

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NEAR-TERM VACCINE PIPELINE

Significant opportunities for future development

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*Authorized in select geographies under trade names Covovax™ and Nuvaxovid™

KEY UPCOMING MILESTONES

1H 2022

NVX-CoV2373

Primary Vaccination

- Receive regulatory authorizations in additional markets
- Distribute doses in authorized geographies
- File for EUA with the U.S. FDA

Boosting Vaccination

- Initiate additional boosting studies
- Pursue boosting label indications and policy recommendations

Pediatric Vaccination

- Complete regulatory filing for pediatric indication (12 – 17 years)
- Initiate clinical studies in younger age groups

Omicron Variant Vaccine

- Initiate clinical studies

COVID-NanoFlu Combination Vaccine

- Announce data from COVID-NanoFlu combination vaccine Phase 1/2 trial

2H 2022+

- Supply vaccine for COVID-19 boosters and seasonal revaccination
- Initiate Phase 2 clinical trial for COVID-NanoFlu combination vaccine and NanoFlu standalone
- Development of additional standalone and combination respiratory vaccines

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Creating tomorrow's
vaccines today.
Q&A