Using the power of our technology to create tomorrow's vaccines today.



## OUR APPROACH

Our scientists are committed to developing vaccine candidates for some of the world's toughest viral threats by utilizing our innovative recombinant nanoparticle vaccine platform.<sup>1</sup>

### **OUR SCIENCE**

Our vaccine technology combines genetic engineering with the immunogenicity-enhancing properties of our proprietary adjuvant to efficiently produce highly immunogenic particles targeting some of the most pressing viral infectious diseases.<sup>1</sup>



### **OUR PROPRIETARY TECHNOLOGY**

We are committed to delivering novel products that leverage our innovative proprietary recombinant nanoparticle vaccine technology to help prevent a broad range of infectious diseases.

Our proprietary adjuvant is used in some of our vaccines to help enhance the immune response.<sup>1</sup>



Vaccine <sup>2-39</sup>		Target Virus	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
NVX-CoV2373: prototype vaccine (≥18 years)	$\bigcirc$	SARS coronavirus-2		$\bigcirc$	$\bigcirc$	$\bigcirc$	
NVX-CoV2373: prototype vaccine (12-<18 years)	$\bigcirc$	SARS coronavirus-2				$\bigcirc$	
NVX-CoV2373/ Seasonal influenza vaccine (older adults 65+ years)	$\bigcirc$	SARS coronavirus-2/ seasonal influenza					
NanoFlu™: Seasonal influenza vaccine (older adults 65+ years)	$\bigcirc$	Seasonal influenza					
ResVax™: RSV F vaccine (maternal immunization 18-40 years)		Respiratory syncytial virus (RSV)				*	
<b>RSV F vaccine</b> (older adults 60+ years)	$\bigcirc$	Respiratory syncytial virus (RSV)				•*	
<b>RSV F vaccine</b> (pediatrics 2-6 years)		Respiratory syncytial virus (RSV)					
Combination seasonal influenza/ RSV F vaccine (older adults 60+ years)	$\bigcirc$	Seasonal influenza/ respiratory syncytial virus (RSV)					
Ebola GP vaccine	$\bigcirc$	Ebola virus					
Middle East Respiratory Syndrome (MERS) vaccine		MERS coronavirus					
Severe Acute Respiratory Syndrome (SARS) vaccine		SARS coronavirus	•				
Proprietary saponin-based adjuvant OActive,	not rec	ruiting ONot yet recruitir	ng 🖉 Recruitir	ng Com	pleted * D	id not meet pri	mary endpoint

As of July 30, 2021.

### NVX-CoV2373 prototype vaccine (NCT04368988, NCT04533399, NCT04583995, NCT04611802)<sup>214</sup>

- NVX-CoV2373 is a proprietary adjuvanted vaccine using recombinant nanoparticle technology to generate antigen derived from the coronavirus spike protein
- A pediatric expansion in adolescents (12-<18 years) of the phase 3 clinical trial involving NVX-CoV2373 is currently active<sup>9,13,14</sup>

### NVX-CoV2373/Seasonal influenza vaccine (NCT04961541)<sup>15-18</sup>

• Preclinical studies have been completed and phase 1 study has not yet begun recruiting

### NanoFlu™: Seasonal influenza vaccine (older adults 65+ years) (NCT04120194, NCT03658629, NCT03293498)<sup>19-23</sup>

• NanoFlu<sup>™</sup>, our proprietary adjuvanted vaccine, completed clinical trials to assess safety and immunogenicity compared with Fluzone® Quadrivalent.<sup>23</sup> The phase 3 trial met the primary immunogenicity endpoint

### ResVax<sup>™</sup>: Respiratory syncytial virus (RSV) F vaccine (infants via maternal immunization) (NCT02247726, NCT02624947)<sup>24-29</sup>

ResVax<sup>™</sup> - RSV F vaccine, an aluminum-adjuvanted RSV F vaccine, completed clinical trials to assess safety and tolerability in reducing hospitalizations in infants with RSV lower respiratory tract infection via maternal vaccination.<sup>26,28</sup> ResVax<sup>™</sup> - RSV F vaccine did not meet the primary endpoint in a phase 3 clinical trial<sup>27</sup>

# RSV F vaccine (older adults 60+ years) (NCT03026348, NCT02266628, NCT02608502)<sup>24,30-33</sup>

• RSV F vaccine for older adults completed clinical trials to assess immunogenicity and safety with and without aluminum phosphate or proprietary adjuvants.<sup>31</sup> RSV F vaccine in older adults 60+ years did not meet the primary endpoint in a phase 3 clinical trial

### RSV F vaccine (pediatrics 2-6 years) (NCT02296463)<sup>24,34</sup>

• RSV F vaccine completed a phase 1 trial to assess safety and immunogenicity in children between 2 and 6 years of age

# Combination seasonal influenza/RSV F vaccine (older adults 60+ years) (NCT01709019)<sup>24,35</sup>

 Combination seasonal influenza/RSV F vaccine completed a phase 1 trial to evaluate safety and immunogenicity against both seasonal influenza and RSV

### Ebola glycoprotein (GP) vaccine (NCT02370589)<sup>36,37</sup>

• Ebola GP adjuvanted vaccine, which utilizes core recombinant baculovirus technology, completed a phase 1 trial to assess immunogenicity and tolerability in humans

#### Middle East Respiratory Syndrome (MERS) vaccine<sup>38</sup>

• MERS vaccine candidate was developed from the major surface spike protein of the circulating MERS strain and blocks infection in laboratory studies

### Severe Acute Respiratory Syndrome (SARS) vaccine<sup>39</sup>

• SARS vaccine candidate was developed from the major spike protein and blocks infection in laboratory studies



#### **References:**

I. Novavax.com. Science and technology. Accessed July 8, 2021. https://www.novavax.com/science-and-technology-overview

2. Tian J-H, Patel N, Haupt R, et al. SARS-CoV-2 spike glycoprotein vaccine candidate NVX-CoV2373 immunogenicity in baboons and protection in mice. Nat Commun. 2021;12(1):372. doi: 10.1038/s41467-020-20653-8

3. Alter G, Gorman M, Patel N, et al. Collaboration between the Fab and Fc contribute to maximal protection against SARS-CoV-2 following NVX-CoV2373 subunit vaccine with Matrix-M<sup>™</sup> vaccination. Preprint. *Res Sq.* 2021;rs.3.rs-200342. Published 2021 Feb 15. doi:10.21203/rs.3.rs-200342/v1

4. Guebre-Xabier M, Patel N, Tian JH, et al. NVX-CoV2373 vaccine protects cynomolgus macaque upper and lower airways against SARS-CoV-2 challenge. *Vaccine*. 2020;38(50):7892-7896.

5. Bangaru S, Ozorowski G, Turner HL, et al. Structural analysis of full-length SARS-CoV-2 spike protein from an advanced vaccine candidate. *Science*. 2020;370(6520):1089-1094.

6. Keech C, Albert G, Cho I, et al. Phase 1-2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. N Engl J Med. 2020;383(24):2320-2332.

7. Shinde V, Bhikha S, Hoosain Z, et al. Efficacy of NVX-CoV2373 Covid-19 vaccine against the B.1.351 variant. N Engl J Med. 2021;384(20):1899-1909.

8. Heath PT, Galiza EP, Baxter DN, et al. Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine [published online ahead of print, 2021 Jun 30]. N Engl J Med. 2021;NEJMoa2107659. doi:10.1056/NEJMoa2107659

**9.** A study to evaluate the efficacy, immune response, and safety of a COVID-19 vaccine in adults  $\geq$  18 years with a pediatric expansion in adolescents (12-17 years) at risk for SARS-CoV-2. ClinicalTrials.gov identifier: NCT04611802. Updated May 6, 2021. Accessed July 8, 2021. https://clinicaltrials.gov/ct2/show/NCT04611802

10. Evaluation of the safety and immunogenicity of a SARS-CoV-2 rS nanoparticle vaccine with/without Matrix-M adjuvant. ClinicalTrials.gov identifier: NCT04368988. Updated October 9, 2020. Accessed July 8, 2021. <a href="https://www.clinicaltrials.gov/ct2/show/NCT04368988">https://www.clinicaltrials.gov/ct2/show/NCT04368988</a>

11. A study looking at the effectiveness and safety of a COVID-19 vaccine in South African adults. ClinicalTrials.gov identifier: NCT04533399. Updated November 2, 2020. Accessed July 8, 2021. <a href="https://clinicaltrials.gov/ct2/show/NCT04533399">https://clinicaltrials.gov/ct2/show/NCT04533399</a>

12. A study looking at the effectiveness, immune response, and safety of a COVID-19 vaccine in adults in the United Kingdom. ClinicalTrials.gov identifier: NCT04583995. Updated November 17, 2020. Accessed July 14, 2021. <u>https://clinicaltrials.gov/ct2/show/NCT04583995</u>

13. Kunzmann K. Novavax initiates pediatric, adolescent COVID-19 vaccine study. Accessed July 8, 2021. <u>https://www.contagionlive.com/view/novavax-initiates-pediatric-adolescent-covid-19-vaccine-study</u>

14. Novavax.com. PREVENT-19 phase 3 trial data factsheet. Accessed July 15, 2021. <u>https://www.novavax.com/sites/default/files/2021-01/Novavax-PREVENT-19-Factsheet.pdf</u>

15. Massare MJ, Patel N, Zhou B, et al. Combination respiratory vaccine containing recombinant SARS-CoV-2 spike and quadrivalent seasonal influenza hemagglutinin nanoparticles with Matrix-M adjuvant. *bioRxiv*. https://doi.org/10.1101/2021.05.05.442782

16. Phase 1/2 study of the safety and immunogenicity of influenza and COVID-19 combination vaccine. ClinicalTrials.gov identifier: NCT04961541. Updated July 14, 2021. Accessed July 14, 2021. https://clinicaltrials.gov/ct2/show/NCT04961541

17. Toback S, Galiza E, Cosgrove C, et al, on behalf of the 2019 nCoV-302 Study Group. Safety, immunogenicity, and efficacy of a COVID-19 vaccine (NVX-CoV2373) co-administered with seasonal influenza vaccines. *Lancet*. In press.

18. Novavax announces positive results from first study of influenza vaccine and COVID-19 vaccine candidate administered simultaneously. Press release. PRNewswire; June 14, 2021.

19. Smith G, Liu Y, Flyer D, et al. Novel hemagglutinin nanoparticle influenza vaccine with Matrix-M<sup>™</sup> adjuvant induces hemagglutination inhibition, neutralizing, and protective responses in ferrets against homologous and drifted A(H3N2) subtypes. *Vaccine*. 2017;35(40):5366-5372. doi: 10.1016/j. vaccine.2017.08.021

20. Shinde V, Cai R, Plested J, et al. Induction of cross-reactive hemagglutination inhibiting antibody and polyfunctional CD4+ T-cell responses by a recombinant Matrix-M-adjuvanted hemagglutinin nanoparticle influenza vaccine [published online ahead of print, 2020 Nov 4]. *Clin Infect Dis.* 2020;ciaa1673. doi:10.1093/cid/ciaa1673

**21.** Evaluation of the safety and immunogenicity of a recombinant trivalent nanoparticle influenza vaccine with Matrix M-1 adjuvant (NanoFlu). ClinicalTrials.gov identifier: NCT03293498. Updated October 17, 2019. Accessed July 8, 2021. <u>https://clinicaltrials.gov/ct2/show/NCT03293498</u>

22. Phase 2 dose and formulation confirmation of Quad-NIV in older adults. ClinicalTrials.gov identifier: NCT03658629. Updated April 28, 2020. Accessed July 29, 2021. https://clinicaltrials.gov/ct2/show/NCT03658629

23. Phase 3 pivotal trial of NanoFlu™ in older adults. ClinicalTrials.gov identifier: NCT04120194. Updated April 17, 2020. Accessed July 8, 2021. <u>https://</u> clinicaltrials.gov/ct2/show/NCT04120194

24. Raghunandan R, Lu H, Zhou B, et al. An insect cell derived respiratory syncytial virus (RSV) F nanoparticle vaccine induces antigenic site II antibodies and protects against RSV challenge in cotton rats by active and passive immunization. *Vaccine*. 2014;32(48):6485-6492. doi: 10.1016/j.vaccine.2014.09.030
25. Glenn GM, Smith G, Fries L, et al. Safety and immunogenicity of a Sf9 insect cell-derived respiratory syncytial virus fusion protein nanoparticle vaccine. *Vaccine*. 2013;31(3):524-532. doi: 10.1016/j.vaccine.2012.11.009

26. RSV F vaccine maternal immunization study in healthy third-trimester pregnant women. ClinicalTrials.gov identifier: NCT02247726. Updated June 6, 2017. Accessed July 8, 2021. https://clinicaltrials.gov/ct2/show/NCT02247726

27. Madhi SA, Polack FP, Piedra PA, et al, for the Prepare Study Group. Respiratory syncytial virus vaccination during pregnancy and effects in infants. N Engl J Med. 2020;383(5):426-439. doi: 10.1056/NEJMoa1908380

28. Novavax announces topline results from phase 3 Prepare<sup>™</sup> trial of ResVax<sup>™</sup> for prevention of RSV disease in infants via maternal immunization. Press release. Nasdaq; February 28, 2019.

29. A study to determine the safety and efficacy of the RSV F vaccine to protect infants via maternal immunization. ClinicalTrials.gov identifier: NCT02624947. Updated April 14, 2020. Accessed July 8, 2021. https://www.clinicaltrials.gov/ct2/show/NCT02624947

30. Fries L, Shinde V, Stoddard JJ, et al. Immunogenicity and safety of a respiratory syncytial virus fusion protein (RSV F) nanoparticle vaccine in older adults. *Immun Ageing.* 2017;14:8. doi: 10.1186/s12979-017-0090-7

31. Placebo-controlled study to evaluate the safety and immunogenicity of the RSV-F vaccine in elderly adults. ClinicalTrials.gov identifier: NCT02266628. Updated June 6, 2017. Accessed July 8, 2021. https://clinicaltrials.gov/ct2/show/NCT02266628

32. Safety and immunogenicity study to evaluate single- or two-dose regimens of RSV F vaccine with and without aluminum phosphate or Matrix-MI<sup>™</sup> adjuvants in clinically-stable older adults. ClinicalTrials.gov identifier: NCT03026348. Updated August 31, 2018. Accessed July 8, 2021. <u>https://clinicaltrials.gov/ct2/show/NCT03026348</u>

33. A study to evaluate the efficacy of an RSV F vaccine in older adults. ClinicalTrials.gov identifier: NCT02608502. Updated September 19, 2017. Accessed July 8, 2021. <u>https://clinicaltrials.gov/ct2/show/NCT02608502</u>

34. A phase I randomized, observer-blinded, dose-ranging study in healthy subjects 24 to <72 months of age. ClinicalTrials.gov identifier: NCT02296463. Updated April 28, 2016. Accessed July 8, 2021. https://clinicaltrials.gov/ct2/show/NCT02296463

35. RSV-F vaccine and influenza vaccine co-administration study in the elderly. ClinicalTrials.gov identifier: NCT01709019. Updated March 5, 2014. Accessed July 8, 2021. https://clinicaltrials.gov/ct2/show/NCT01709019

36. Bengtsson KL, Song H, Stertman L, et al. Matrix-M adjuvant enhances antibody, cellular and protective immune responses of a Zaire Ebola/Makona virus glycoprotein (GP) nanoparticle vaccine in mice. Vaccine. 2016;34(16):1927-1935. doi: 10.1016/j.vaccine.2016.02.033

37. Study to evaluate the immunogenicity and safety of an Ebola virus (EBOV) glycoprotein (CP) vaccine in healthy adults. ClinicalTrials.gov identifier: NCT02370589. Updated September 22, 2016. Accessed July 8, 2021. <u>https://clinicaltrials.gov/ct2/show/NCT02370589</u>

38. Coleman CM, Venkataraman T, Liu YV, et al. MERS-CoV spike nanoparticles protect mice from MERS-CoV infection. *Vaccine*. 2017;35(12):1586-1589. doi: 10.1016/j.vaccine.2017.02.012

39. Coleman CM, Liu YV, Mu H, et al. Purified coronavirus spike protein nanoparticles induce coronavirus neutralizing antibodies in mice. *Vaccine*. 2014;32(26):3169-3174. doi: 10.1016/j.vaccine.2014.04.016