Prepare™ Trial Topline Results

February 28, 2019

NOVAVAX | Creating Tomorrow's Vaccines Today

Safe harbor statement

Certain information, particularly information relating to future performance and other business matters, including expectations regarding clinical development, our planned use of the proceeds from the offering, market opportunities and anticipated milestones constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act.

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

Uncertainties include but are not limited to clinical trial results, dependence on third party contractors, competition for clinical resources and patient enrollment and risks that we may lack the financial resources to fund ongoing operations.

Additional information on Risk Factors are contained in Novavax’ filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2017, our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K, which are all available at http://www.sec.gov.

Forward-looking statements are based on current expectations and assumptions and currently available data and are neither predictions nor guarantees of future events or performance.

Current results may not be predictive of future results.

You should not place undue 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 information, future events, or otherwise, except as required by applicable law.

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“RSV is among the great threats to child health, causing illness and death by inflammatory disease of the lower respiratory tract.”

H. Cody Meissner, M.D,
Chief of the division of pediatric infectious diseases
Tufts Medical Center, Boston

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Principals and Practice of Pediatric Infections Diseases, 4th Edition, 2012, Etiologic Agents of Infectious Diseases

Respiratory syncytial virus

Largest unmet need for a vaccine-preventable disease

#1

Leading cause of hospitalizations in infants in the U.S., especially in the first 6 months of life[1]

#2

Leading cause of death in children under one year of age worldwide[2]

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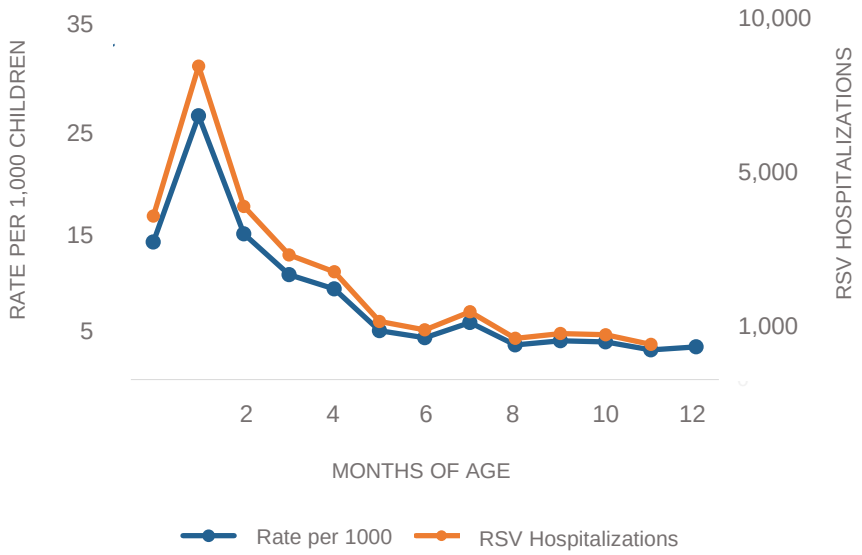
1. Leader S. J Pediatr. 2003;143:S127. 2. Losano R. Lancet. 2012/Dec15;380:2095

Timing of RSV hospitalizations in infants

Average Age and Number of RSV Hospitalizations
Children First Year of Life
2000-2005[1]



In the U.S.:

69%
of infants <1 year contract RSV

77%
of these RSV infections occur before 6 months of age

400,000
medical interventions

2-4% of infants < 6 months are admitted to the hospital

1. Ting S/Nair H. Lancet. 2017/Sep2;390:946

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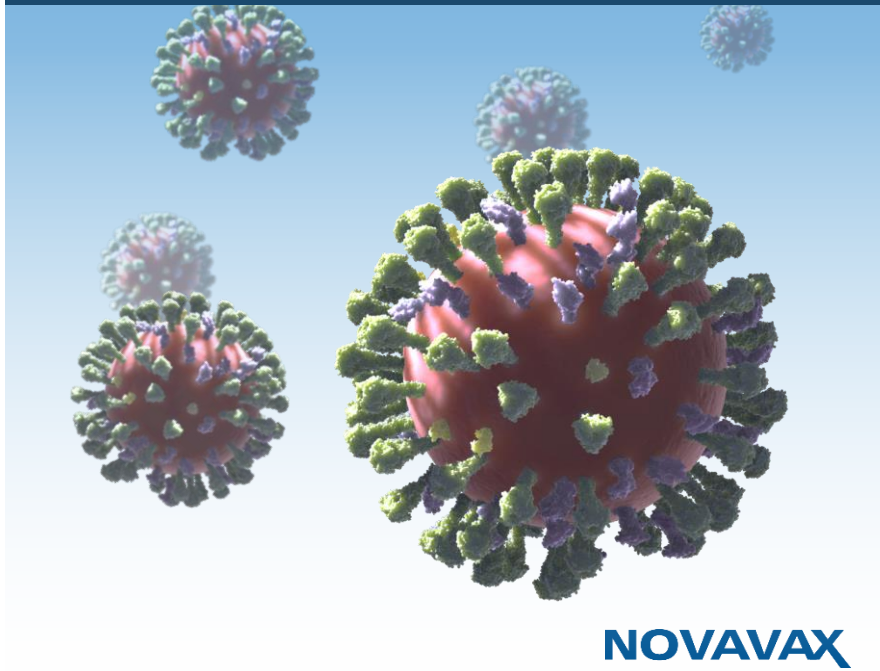
ResVax – RSV vaccine for infants via maternal immunization

- Prevention of severe RSV disease
- Protect infants as early as birth and during the first months of life when they are most at risk for hospitalization
- Ease of administration during routine OBGyn visit
- Maternal immunization a proven strategy to protect infants
- Importance of its safety profile – administered to >3,000 pregnant women in Prepare™ Phase 3 trial

ResVax is composed of recombinant RSV F nanoparticles adsorbed to aluminum phosphate. The F protein is essential to RSV infectivity and is the target of palivizumab.



Maternal vaccination has become a priority for expectant mothers, healthcare providers, and policy makers

> **Immunization during pregnancy has emerged as an important and successful public health intervention in both industrialized and developing countries.**
>
> –FDA[1]

Current vaccines recommended via maternal immunization include:

- Neonatal Tetanus[2]
- Whooping cough (Pertussis)[2]
- Influenza[2]

1. U.S. FDA. Vaccines for Use During Pregnancy to Protect Young Infants from Disease – FDA Update. Available at https://www.fda.gov/aboutfda/transparency/basics/ucm508553.htm.
2. CDC Guidelines during Pregnancy: https://www.cdc.gov/vaccines/pregnancy/downloads/immunizations-preg-chart.pdf

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THE Prepare™ TRIAL

Global footprint

Multi-year global trial

Enrollment occurred at 87 sites in 11 countries

Supported by Bill & Melinda Gates Foundation ($89 million grant)

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Goals and design

Primary objective

Determine the efficacy of maternal immunization with the RSV F vaccine against medically significant symptomatic RSV lower respiratory tract infection (LRTI) through 90, 120, 150 and 180 days of life in infants.

Design	Randomized, Observer-Blind, Placebo-Controlled	
	Number of Participants	• 4,636 third trimester pregnant women randomized 2:1 (vaccine:placebo)
	Length of Study Participation	• Maternal Participants: up to 9 months • Infant Participants: 1 year after delivery
	Dosing	• 1 intramuscular (IM) Injection of RSV F Vaccine or Placebo at 28-36 weeks Estimated Gestational Age (EGA)
	Safety Assessment	• Through 6 months post-partum in mothers • Through 1 year in infants

	Efficacy Assessment	• Active/passive surveillance in mothers and infants
		  • Confirmation of RSV infection by RT-PCR
		  • Medically significant tachypnea or pulse oximetry
		  • Confirmation of LRTI
		  • Data collected at clinical sites or from both site and hospitalization records

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Trial highlights

THE Prepare™ TRIAL

Trial execution and immunogenicity data as expected

Safety appears benign in mothers and infants

Efficacy endpoints

- Primary endpoint (Day 90 site data) did not succeed (39.4%, 97.5%CI, -1.0% to 63.7%)
- ResVax demonstrated efficacy in preventing RSV-hospitalization (44.4%, 95%CI, 19.6% to 61.5%)
- Pre-specified exploratory endpoints severe hypoxemia and hospitalization using both site and hospitalization data are clinically meaningful and statistically significant
- Gestational age at the time of vaccination greatly affects efficacy
- U.S. efficacy was low compared to ROW by most measures and seems to be related to timing of immunization that influenced both immunity and exposure to RSV

Prevention of hospitalization and RSV illness with severe hypoxemia is a key finding

- Effects were very clear and robust enough to be manifested as a 25.3% (95%CI, 5.4% to 41.0%) reduction of **all** respiratory hospitalizations and a 39.1% (95%CI, 14.6% to 56.6%) reduction of all-cause severe hypoxemia in infants of immunized mothers through 180 days of life.

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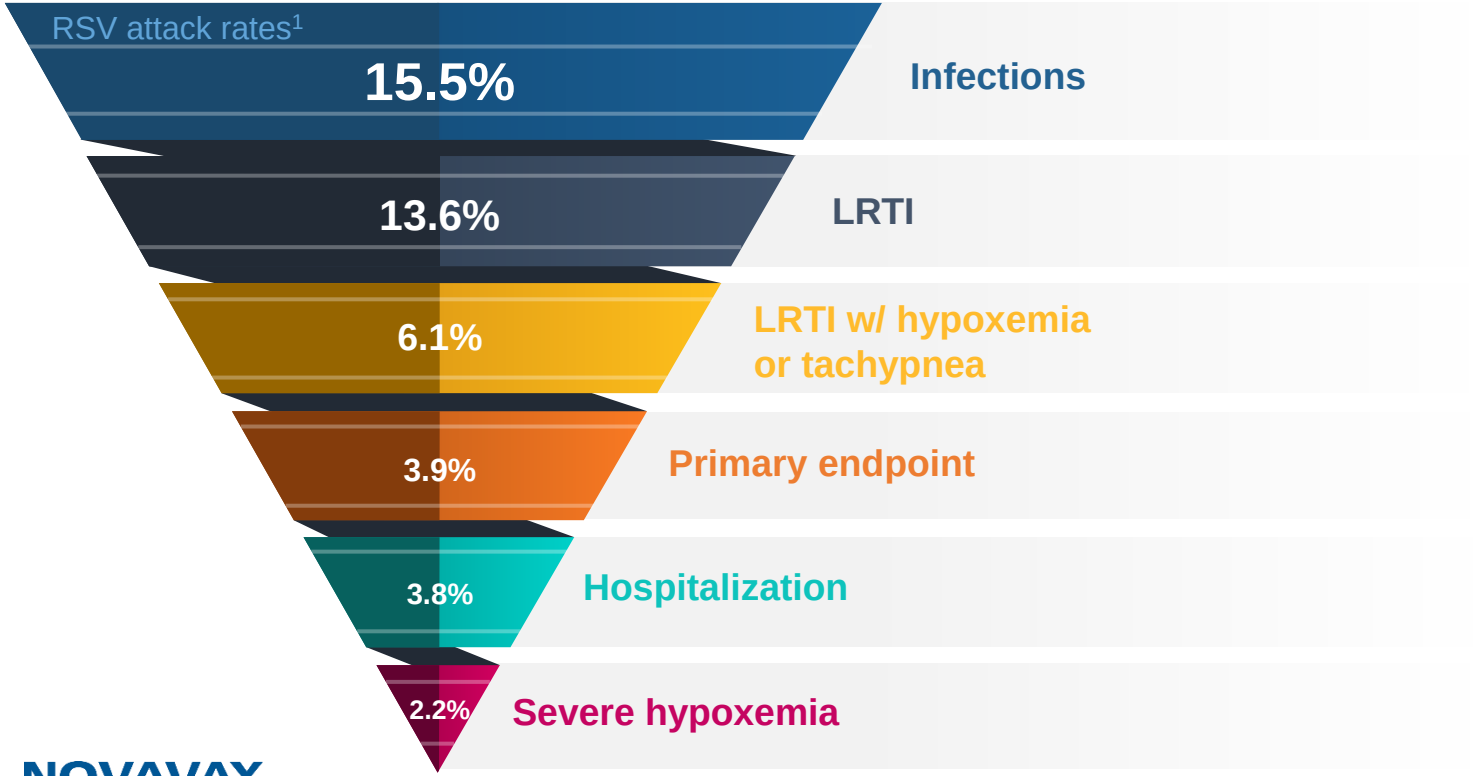
We observed the expected hierarchy of attack rates by severity



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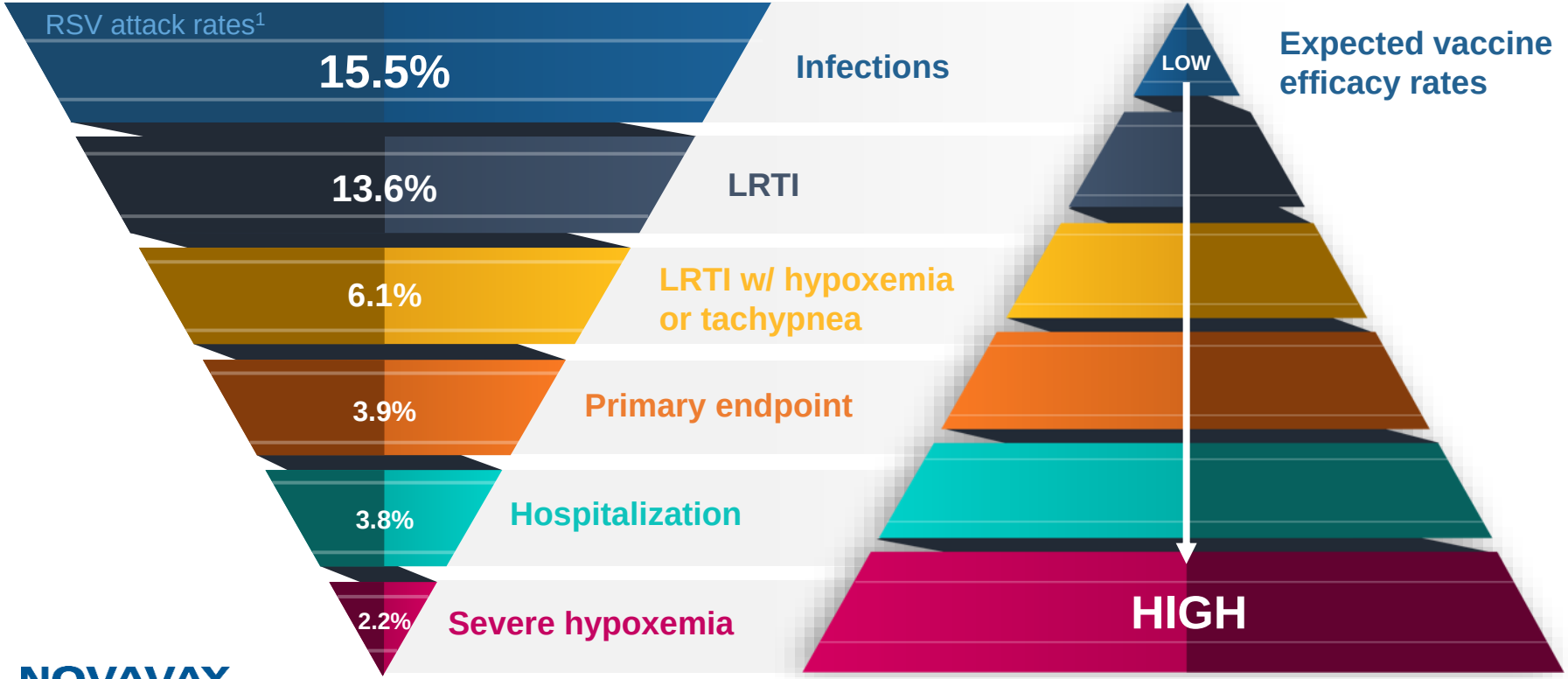
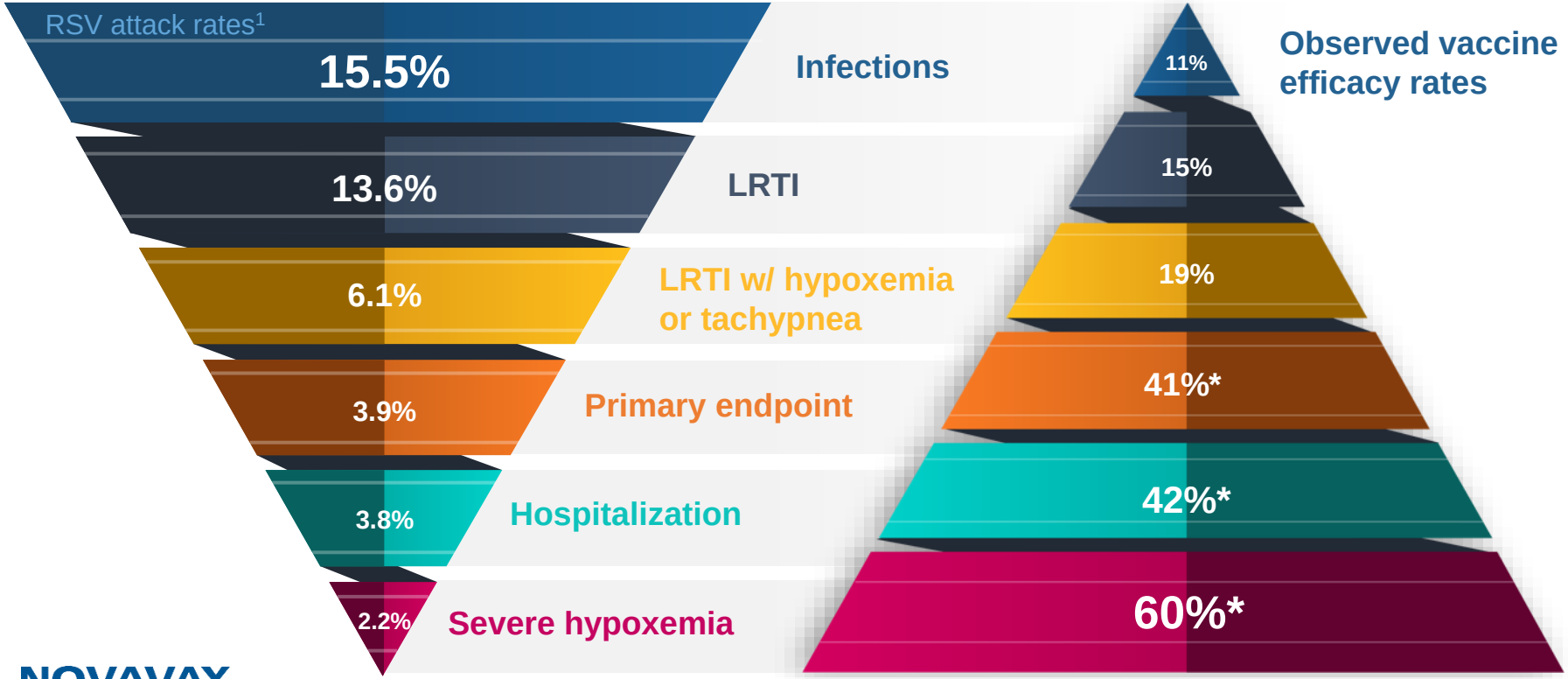
1. Expanded data from sites and hospitalizations, through 90 days, * LB 95%CI >0

What was our expectation for relative efficacy against the RSV infections/endpoints?



1. Expanded data from sites and hospitalizations, through 90 days, * LB 95%CI >0

A hierarchy of efficacy by severity of disease



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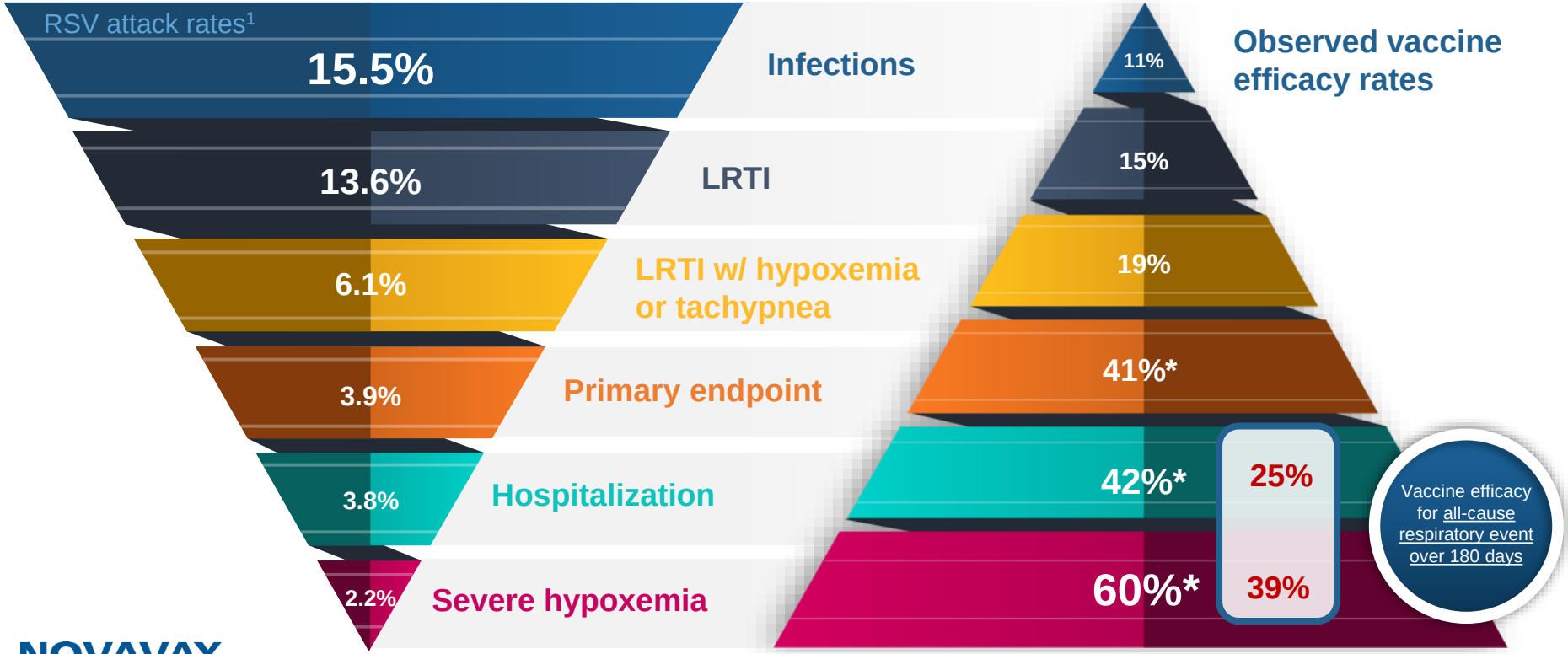
Vaccine impact on all-cause respiratory disease



1. Expanded data from sites and hospitalizations, through 90 days, * LB 95%CI >0

Primary, secondary, and exploratory efficacy endpoints

Primary endpoint: medically-significant RSV LRTI

- RSV detected by RT-PCR and
- At least one manifestation of LRTI, and
- At least one of the following:
  - SpO2 <95% at sea level or <92% at >1800m
  - Respiratory rate ≥70 bpm in infants 0 to 59 days of age or ≥60 bpm in infants ≥60 days of age

Secondary endpoints

- RSV LRTI with hospitalization
- RSV LRTI with severe hypoxemia

Exploratory efficacy endpoints

- Same as primary and secondary with data from sites and hospitalizations (expanded data)

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Evaluation of Day 90 efficacy endpoints

All countries, per-protocol population

Day 90 Vac. Efficacy (%) (97.52%CI and 95%CI for MS RSV LRTI primary endpoint, all others 95%CI) Placebo, Vaccine cases	**RSV MS LRTI**	**RSV hospitalizations**	**RSV LRTI w/ severe hypoxemia**
Primary and secondary: Site data	**39.4** (-1, 63.7) (5.3, 61.2) 35/1430, 41/2765	**44.4** (19.6, 61.5) 53/1430, 57/2765	**48.3** (-8.2, 75.3) 14/1430, 14/2765

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Pre-specified exploratory: Expanded data	**40.9** (15.9, 58.5) 56/1430, 64/2765	**41.7** (16.7, 59.2) 55/1430, 62/2765	**59.6** (32.1, 76.0) 32/1430, 25/2765

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Post hoc: Vaccination <33 weeks GA	**41.4** (4.1, 64.2) 29/848, 33/1646	**53.5** (23.0, 71.9) 31/848, 28/1646	**70.2** (37.6, 85.7) 19/848, 11/1646

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Geographic imbalance in efficacy

Pre-specified exploratory: expanded data, per protocol population

Day 90 Vac. Efficacy (%) (95%CI) Placebo, Vaccine cases	**All**	**U.S.**	**S. Africa**	**ROW***
MS RSV LRTI	**40.9** (15.9, 58.5) 56/1430, 64/2765	**-32.7** (-238.9, 48.1) 6/346, 15/652	**57.0** (32.7, 72.5) 40/732, 34/1447	**20.7** (-74.6, 64.0) 10/352, 15/666

U.S. efficacy was low compared to ROW by most measures and appears to be related to timing of immunization, including the negative effects of late gestational age immunization and short intervals to birth, conditions which were more common in U.S. subjects.

* ROW = All countries except U.S. and South Africa

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Effect of gestational age at immunization <33 weeks

Pre-specified exploratory endpoints: expanded data, per protocol population

Day 90 Vac. Efficacy (%) (95%CI) Placebo, Vaccine cases	All		U.S.		S. Africa	
	< 33 weeks	≥ 33 weeks	< 33 weeks	≥ 33 weeks	< 33 weeks	≥ 33 weeks
RSV MS-LRTI	**41.4** (4.1, 64.2) 29/848 33/1646	**40.3** (0.9, 64.0) 27/582 31/1119	**-9.7** (-259.2, 66.5) 4/175 8/319	**-79.7** (-755.8, 62.3) 2/171 7/333	**55.4** (19.5, 75.3) 23/528 20/1029	**59.8** (20.1, 79.8) 17/204 14/418
RSV hospitalization	**53.5** (23.0, 71.9) 31/848 28/1646	**26.3** (-23.1, 55.9) 24/582 34/1119	**26.9** (-223.1, 83.4) 3/175 4/319	**--** 0/171 7/333	**61.0** (29.8, 78.3) 25/528 19/1029	**57.7** (12.8, 79.5) 15/204 13/418
RSV LRTI w/ severe hypoxemia	**70.2** (37.6, 85.7) 19/848 11/1646	**44.0** (-18.4, 73.5) 13/582 14/1119	**45.1** (-286.1, 92.2) 2/175 2/319	**--** 0/171 3/333	**80.8** (51.1, 92.4) 16/528 6/1029	**67.5** (9.8, 89.2) 9/204 6/418

Mothers immunized <33 weeks of gestational age had higher vaccine efficacy across all endpoints

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Regulatory path forward

Discuss data and licensure path forward with the FDA and European regulatory authorities

Basis for discussion:

- Vaccine is safe
- Immune responses, transfer, and antibody half-lives are similar across countries
- Immunization can be focused on 26 to <33 weeks gestational age to optimize efficacy
- Prevention of hospitalization/severe hypoxemia is a key finding
    - Effects were very clear and robust enough to be manifested at the all-cause level, globally

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Critical efficacy findings

Day 90 Vac. Efficacy (%) (95%CI) Placebo, Vaccine cases	**RSV MS LRTI**	**RSV hospitalizations**	**RSV LRTI w/ severe hypoxemia**
Primary and secondary: Site data through 90 days	**39.4** (5.3, 61.2) 35/1430, 41/2765	**44.4** (19.6, 61.5) 53/1430, 57/2765	**48.3** (-8.2, 75.3) 14/1430, 14/2765
Pre-specified exploratory: Expanded data through 90 days	**40.9** (15.9, 58.5) 56/1430, 64/2765	**41.7** (16.7, 59.2) 55/1430, 62/2765	**59.6** (32.1, 76.0) 32/1430, 25/2765
All-cause LRTI: data through 180 days		**25.3*** (5.6, 41.0) 117/1430, 169/2765	**39.1*** (14.6, 56.6) 62/1430, 73/2765

*All-cause LRTI w/ severe hypoxemia pre-specified, exploratory. All-cause LRTI hospitalization post hoc.

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“All-cause” findings

All hospitalizations with LRTI signs or symptoms that includes but doesn’t require RSV detection

The effect of the pneumococcal vaccine against all-cause LRTI hospitalization was 7-9%[1], or against all-cause ‘clinical pneumonia’ was 4-7%[2,3]

25% reduction in all hospitalizations with LRTI signs or symptoms is a major effect

Similarly, 39% reduction of severe hypoxemia would lower the risk of death and therefore has significant public health ramifications

- Hypoxemia: 4-5x increased risk of death with severe hypoxemia[4,5,6]

1. Madhi et al. Clin Infect Dis. 2005 May 15;40(10):1511-8; 2. Cutts et al. Lancet. 2005 Mar 26-Apr 1;365(9465):1139-46.; 3. Black et al. Pediatr Infect Dis J. 2002 Sep;21(9):810-5.; 4. Usen et al. BMJ. 1999 Jan 9;318(7176):86-91.; 5. Onyango et al, BMJ. 1993 Mar 6;306(6878):612-5.; 6. Subhi et al, Lancet Infect Dis. 2009 Apr;9(4):219-27.

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Conclusions

- Vaccine appears to be safe in mothers and infants.
- First RSV vaccine to demonstrate efficacy against RSV-hospitalization in a Phase 3 trial.
- Prevention of RSV LRTI hospitalization and RSV LRTI with severe hypoxemia are key findings.
- Reduction in all-cause hospitalization and respiratory illness with severe hypoxemia has major public health implications globally.
- Novavax will present the data to regulatory authorities to seek advice on path forward.

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“We are very encouraged that the Novavax maternal RSV vaccine reduced severe RSV hypoxemia by 60% in the first months of life and believe this vaccine has great potential for reducing RSV-associated deaths in young babies.”

Keith Klugman, M.D., Ph.D.
Director of the Bill & Melinda Gates Foundation’s Pneumonia Program

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The power of collaboration through our partners

BILL & MELINDA GATES foundation

$89 Million in grants

PATH

$7 Million in grants

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