Rapid Responses to Novel Lethal Viruses: The Potential of Recombinant Nanoparticle Vaccines Produced in a Baculovirus Insect Cell System

Gregory M. Glenn M.D.
SVP R&D
Novavax, Rockville, MD

EBOV/Makona GP Nanoparticle
Response to H7N9 and Ebola viruses: Case study on how the recombinant nanoparticle vaccine technology can be applied to challenges posed by novel lethal viruses

- H7N9 (2013) Influenza Vaccine Response
- Ebola Vaccine Response (2014-15)
  - Background
  - Novavax Ebola/Makona Glyoprotein Vaccine
  - Novavax saponin-based Matrix-M™ Adjuvant
  - Immunogenicity and animal challenge data
  - Plans forward
- Conclusions
Novavax Overview

- Novavax (Nasdaq: NVAX) is a clinical-stage vaccine company committed to delivering novel products to prevent a broad range of infectious diseases.
- Our recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for ground-breaking innovation that improves global health through safe and effective vaccines.

- HQ in Gaithersburg, MD with additional facilities in Rockville, MD and Uppsala, Sweden.
- Employ >300 individuals in Maryland
- Dedicated to developing novel vaccines to address infectious disease
  - 2 GMP manufacturing sites
  - Adjuvant manufacturing site
    - 4 Phase II programs
    - 2 Phase I programs
<table>
<thead>
<tr>
<th>Program</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Funding Support</th>
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<tbody>
<tr>
<td><strong>RSV</strong></td>
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<tr>
<td>Elderly</td>
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<tr>
<td>Infants (Maternal Immunization)</td>
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<td>Pediatrics (6 mos – 6 yrs)</td>
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<tr>
<td><strong>Influenza</strong></td>
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<td>Quadrivalent Seasonal</td>
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<tr>
<td>Pandemic (H7N9 + Matrix-M)</td>
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<td>BARDA</td>
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<td><strong>New Vaccines</strong></td>
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<td>Combination Respiratory</td>
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<td>Ebola + Matrix-M</td>
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<td>BARDA</td>
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Novavax Recombinant Vaccine Technology

Overview

- Select and engineer genetic sequences encoding vaccine antigens into baculovirus, infect insect cells
- Insect cell cellular machinery produces correctly modified and folded proteins
- Full-length antigens expressed in native conformation assemble into highly immunogenic nanoparticles during the purification process
- Present full length, properly folded antigens in a manner that stimulates effective immunity and avoids ‘decoy’ responses common in viruses
Recombinant Baculovirus-Sf9 Technology Enables a Rapid Vaccine Response to Novel Lethal Viruses

Viral Threats

- Process & assay development
- 1000L GMP production
- QC and QA for testing and release

Response

- Vaccine candidate development
- Preclinical study expertise
- Regulatory expertise

- Process & assay development
- 1000L GMP production
- QC and QA for testing and release

Clinical study expertise
3-month Response Time from Gene Sequence to GMP Batch Release for recombinant H7N9, Ebola Vaccines

<table>
<thead>
<tr>
<th>Key Activities</th>
<th>April</th>
<th>May</th>
<th>June</th>
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<tbody>
<tr>
<td>HA, NA gene synthesis</td>
<td></td>
<td>5/13</td>
<td></td>
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<tr>
<td>HA, NA gene cloning to P1 virus</td>
<td></td>
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<tr>
<td>Production – master virus seed (MVS)</td>
<td>4/25</td>
<td>5/25</td>
<td></td>
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<tr>
<td>Production – drug substance</td>
<td></td>
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<tr>
<td>Production – drug product</td>
<td></td>
<td></td>
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<tr>
<td>QC – MVS titer assay</td>
<td>5/11</td>
<td>5/27</td>
<td></td>
</tr>
<tr>
<td>QC – MVS release testing</td>
<td></td>
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<tr>
<td>QC – drug substance release testing</td>
<td>5/13</td>
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<tr>
<td>QC – SRID reagents qualified</td>
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<td></td>
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<tr>
<td>QA – batch and test data review</td>
<td>6/26</td>
<td></td>
<td></td>
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<tr>
<td>QA – GMP batch released</td>
<td></td>
<td>6/26</td>
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</tbody>
</table>

### H7N9 A/Anhui VLP
- Highly lethal virus
- Novel
- Pandemic potential
- Became endemic

### Ebola GP Particle
- Highly lethal virus
- Novel
- Pandemic potential
- Became endemic

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**Key Activities**

<table>
<thead>
<tr>
<th>Key Activities</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
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<td>Publication of Gire <em>et al.</em> in Science</td>
<td>9/12</td>
<td>9/24</td>
<td>10/21</td>
<td>11/26</td>
</tr>
<tr>
<td>EBOV GP gene plasmid construction</td>
<td>9/16</td>
<td>10/17</td>
<td>11/14</td>
<td>12/19</td>
</tr>
<tr>
<td>EBOV GP gene cloning to P1 virus</td>
<td>9/16</td>
<td>10/17</td>
<td>11/14</td>
<td>12/19</td>
</tr>
<tr>
<td>Production – master virus seed (MVS)</td>
<td>10/10</td>
<td>11/10</td>
<td>12/2</td>
<td>12/19</td>
</tr>
<tr>
<td>Production – drug substance, upstream</td>
<td>10/30</td>
<td>11/11</td>
<td>12/9</td>
<td></td>
</tr>
<tr>
<td>Production – drug substance, downstream</td>
<td>11/11</td>
<td>12/4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production – drug product</td>
<td>11/12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development – purification process</td>
<td>11/14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development – EBOV GP ELISA</td>
<td>11/4</td>
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<tr>
<td>QC – MVS release testing</td>
<td>11/26</td>
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<tr>
<td>QC – drug substance release testing</td>
<td>12/2</td>
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<td></td>
</tr>
<tr>
<td>QC – drug product release testing</td>
<td>12/9</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>QA – batch and QC record review</td>
<td>12/19</td>
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<tr>
<td>QA – GMP batch release</td>
<td>12/19</td>
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</tbody>
</table>
A lethal A/Anhui wild type virus mouse challenge model was rapidly developed.

Mice were immunized with VLP vaccines w/wo saponin adjuvant.

Both H7N9 vaccines protected the mice from death, even without adjuvant, H7 VLP vaccines were cross-protective against distantly-related strains.

H5N1 and controls were not protected.

Development of influenza H7N9 virus like particle (VLP) vaccine: Homologous A/Anhui/1/2013 (H7N9) protection and heterologous A/chicken/Jalisco/CPA1/2012 (H7N3) cross-protection in vaccinated mice challenged with H7N9 virus.

Gale E. Smith*, David C. Flyer, Ramadevi Raghunandan, Ye Liu, Ziping Wei, Yingyun Wu, Eloi Kpamegan, Denise Courbron, Louis F. Fries III, Gregory M. Glenn

Novavax, Inc., 9520 Belward Campus Drive, Rockville, MD 20850, United States
Clinical Immunogenicity: A/Anhui/1/2013 HAI Response to H7N9/saponin adjuvanted vaccine at d 28 in 225 subjects vaccinated at d 0 and 21

Day 35 A/Anhui/1/2013 HAI Titer Distributions

Low Dose Adjuvant Vaccine
Novavax Avian Influenza H7N9 Results and Outcomes

H7N9 VLP alone or with Saponin Adjuvant (2013)
- 225 subjects vaccinated 91 days post publication of gene sequence
- Achieved dose-sparing goals with 5 μg dose
- Seroconversion and seroprotection rates: 81% HAI, 97% NAI
- Achieved within 45 days of immunization

H7N9 VLP alone or with Matrix-M (Novavax Saponin Adjuvant) (2014)
- Achieved dose-sparing goals with 3.75 μg dose
- H7N9 with Matrix-M demonstrated strong HA and NA antibody responses

Received FDA Fast Track Designation in October 2014

Rapidity to a GMP product release and clinical data in P1 trial unprecedented
Timeliness of Vaccine Production Provides the Greatest Impact in a Pandemic

Estimating the potential effects of a vaccine program against an emerging influenza pandemic-United States.

Biggerstaff M¹, Reed C¹, Swerdlow DL², Gambhir M³, Graitcer S⁴, Finelli L¹, Borse RH⁵, Rasmussen SA⁶, Meltzer Ml⁵, Bridges CB⁴.

Abstract

BACKGROUND: Human illness from influenza A(H7N9) was identified in March 2013, and candidate vaccine viruses were soon developed. To understand factors that may impact influenza vaccination programs, we developed a model to evaluate hospitalizations and deaths averted considering various scenarios.

METHODS: We utilized a model incorporating epidemic curves with clinical attack rates of 20% or 30% in a single wave of illness, case hospitalization ratios of 0.5% or 4.2%, and case fatality ratios of 0.08% or 0.53%. We considered scenarios that achieved 80% vaccination coverage, various starts of vaccination programs (16 or 8 weeks before, the same week of, or 8 or 16 weeks after start of pandemic), an administration rate of 10 or 30 million doses per week (the latter rate is an untested assumption), and 2 levels of vaccine effectiveness (2 doses of vaccine required; either 62% or 80% effective for persons aged <60 years, and either 43% or 60% effective for persons aged ≥60 years).

RESULTS: The start date of vaccination campaigns most influenced impact; 141 000-2 200 000 hospitalizations and 11 000-281 000 deaths were averted when campaigns started before a pandemic, and <100-1 300 000 hospitalizations and 0-165 000 deaths were averted for programs beginning the same time as or after the introduction of the pandemic virus. The rate of vaccine administration and vaccine effectiveness did not influence campaign impact as much as timing of the start of campaign.

CONCLUSIONS: Our findings suggest that efforts to improve the timeliness of vaccine production will provide the greatest impacts for future pandemic vaccination programs.
Ebola: Epidemic Status and History

• New cases continue to appear in Guinea and Sierra Leone
• 20+ known Filovirus outbreaks since 1976
• Three studies published in 1986 documented Ebola antibody prevalence rates of 10.6, 13.4 and 14 percent in northwestern Liberia
• In Sierra Leone May 2014 at funeral in Guinea attendees were infected with cluster 1, 2 viruses leading to cluster 3 Ebola and sustained human-to-human transmission in West Africa.
Strategy for Development of a Recombinant Viral Vaccine: EBOV

**Recombinant GP**
- Full length EBOV/Makona Gene
- Recombinant GP from insect cells
- Purified GP trimers form nanoparticles

**EBOV mAb(s)**
- Protective in NHPs
- Similar activity produced by the vaccine?
- Multiple mAbs=multiple targets on the GP protein
- Avoid decoy immunity

**Key Insight**
- High affinity binding to vaccine by protective mAbs = epitopes intact, displayed
- Predictive of protection in active immunization setting

**Immunization Results**
- Nanoparticle vaccine induces high levels of anti-GP IgG antibodies
- Durable and neutralizing antibody responses
- Polyclonal antibodies with overlapping specificities to effective mAbs induced at similar levels and activity compared to protective mAbs
- EBOV/Makona GP vaccine induces active protection in mice and macaques
- Antibodies protective in passive immunization
In Sierra Leone May 2014 at funeral in Guinea attendees were infected with cluster 1, 2 viruses leading to cluster 3 Ebola and sustained human-to-human transmission in West Africa.
Sept 12, 2014 Novavax begin development of recombinant EBOV/Makona GP subunit vaccine

Recombinant EBOV/Makona Glycoprotein (GP)
- GenBank #AIG96283
- EBOV [H.sapiens -wt/SLE/2014/Makona-G3798]; cluster 3
- Full length, unmodified GP gene
- Synthetic, codon optimized
- Cloned into a baculovirus vector rBV-GP

CLONING
Baculovirus vector rBV-GP

EXPRESSION
rBV-GP infected Sf9 cells

PURIFICATION
EBOV GP nanoparticles

Glycosylated GP Nanoparticles
EBOV/Makona GP nanoparticle TEM negative stain image and 2D class averaging

- Central core region with GP2/hydrophobic domains (blue)
- Six visible chalice-like GP1/mucin domain trimers extending concentrically from a central core (pink)
Matrix M Adjuvant: Enhances Magnitude and Quality of Immune Responses

Saponin-based adjuvant

- Adjuvant nano-particulate formulation (approx 40 nm particles, cage-like)
- EBOV GP is stable in co-formulation with Matrix-M1 at 2-8°C

Clinical Experience

- 7 GLP-compliant toxicity studies, benign results
- Clinical trials in US, Hungary, and Norway w/Matrix and antigen
  - Antigens include (H5N1, H7N9, rabies, HSV-2, seasonal influenza)
- Developing in partnership with BARDA for pandemic influenza vaccine
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### Binding kinetics purified recombinant EBOV/Mak GP to functional EBOV mAb: High Affinity Binding

<table>
<thead>
<tr>
<th>mAb</th>
<th>EBOV GP Epitope</th>
<th>SPR $K_D$ (nM)</th>
</tr>
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<tbody>
<tr>
<td><strong>KZ52</strong></td>
<td>aa 42-43, 513, 550-553, 556 GP1/GP2</td>
<td>Conformational Pre-fusion GP2</td>
</tr>
<tr>
<td><strong>13C6</strong></td>
<td>aa 1-295 GP1</td>
<td>Conformational In ZMapp</td>
</tr>
<tr>
<td><strong>6D8</strong></td>
<td>aa 389-405 GP1 HNTPVYKLDISEATQVE</td>
<td>Linear</td>
</tr>
<tr>
<td><strong>13F6</strong></td>
<td>aa 401-417 GP1 ATQVEQHHHRRTDNSDATQA $^{1}$</td>
<td>Linear Neutralizing</td>
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</table>

Key protective epitopes are present and intact
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### Baboon Immunogenicity Study: anti-EBOV/Makona GP ELISA and Competition ELISA with 13C6 mAb

<table>
<thead>
<tr>
<th>Group</th>
<th>Vaccine</th>
<th>Day 0</th>
<th>Day 21 1 dose regimen</th>
<th>Day 31 2 dose regimen</th>
<th>13C6 µg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60µg EBOV GP</td>
<td>&lt;100</td>
<td>631</td>
<td>1,517</td>
<td>&lt;4</td>
</tr>
<tr>
<td>2</td>
<td>60µg EBOV GP 800µg AlPO4</td>
<td>&lt;100</td>
<td>19,227</td>
<td>285,206</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>60µg EBOV GP 50µg Matrix</td>
<td>&lt;100</td>
<td>13,115</td>
<td>6,870,339</td>
<td>159</td>
</tr>
<tr>
<td>4</td>
<td>5µg EBOV GP 50µg Matrix</td>
<td>&lt;100</td>
<td>3,242</td>
<td>11,302,798</td>
<td>129</td>
</tr>
</tbody>
</table>

13C6 mAb conformational, neutralizing, protective in NHPs, component of Zmapp Palivizumab (RSV) protective at 30 ug/ml

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**EBOV/Makona anti-GP responses to cAd3-Ebo vaccine**

- $2 \times 10^{11}$ cAd3-EBO vaccine (EC90 = 623)
- $2 \times 10^{10}$ cAd3-EBO vaccine (EC90 = 177)

Baboons – Durability anti-EBOV GP IgG response

Anti-Makona GP IgG ELISA - EC$_{90}$

Day 150 GMT

<table>
<thead>
<tr>
<th>Group</th>
<th>ELISA EC$_{90}$</th>
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<tbody>
<tr>
<td>5ug GP + Matrix</td>
<td>46,651</td>
</tr>
<tr>
<td>60ug GP + Matrix</td>
<td>38,694</td>
</tr>
<tr>
<td>60ug GP + AlPO4</td>
<td>5,907</td>
</tr>
<tr>
<td>60ug GP</td>
<td>3,380</td>
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EBOV/Mak GP vaccine IFNγ-Elispot response in baboons day 31

<table>
<thead>
<tr>
<th></th>
<th>60 ug GP NHP4711</th>
<th>60ug GP/AIPO4 NHP 7311</th>
<th>60ug GP/Matrix M NHP 4411</th>
<th>5ug GP/Matrix M NHP 5910</th>
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<tbody>
<tr>
<td>Medium</td>
<td></td>
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<tr>
<td>Ebola peptide pool 1 (aa1-171)</td>
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<tr>
<td>Ebola peptide Pool 2 (aa 172-335)</td>
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<tr>
<td>Ebola peptide Pool 3 (336-495)</td>
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<td>Ebola peptide Pool 4 (496-676)</td>
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<td>Ebola-GP</td>
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Robust IFNγ-Elispot responses to 5ug EBOV GP + Matrix-M vaccine
Ebola-GP/Matrix-M induced multifunctional T cell response in baboons

**Cytokines: interferon-γ, TNF-α and IL-2**
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RSV
CONFIDENTIAL
EBOV/Makona vaccine anti-EBOV/Makona GP Antibody Responses and Challenge Results

Immunogenicity

Challenge Study: Ricardo Carrion, Jr, Rob Davey, Manu Anantpadama, Gabriela Worwa, Texas Biomedical Research Institute San Antonio, TX
DMID/NIAID: EBOV/Makona vaccine anti-EBOV/Makona GP IgG ELISA (EC50) and 100% Protection

Group G (n=2)
5µg GP + Matrix-M
0wk                    3wk
Ebola/Kikwit
wk9; 100 pfu

Group F (n=2)
5µg GP + Matrix-M
0wk                    6wk
Ebola/Kikwit
wk12; 100 pfu

Challenge Results:
Survival
• 5µg EBOV/GP 100% (4/4)
• Saline control 0% (0/2)
Guinea EBOV GP vaccine EC90 IgG and neutralizing antibody responses in mice (day 28)

2014 Guinea EBOV GP IgG ELISA (EC90)

1976 Mayinga EBOLA (PsVNA50)

Group (n=10)
- Control
- 5µg EBOV GP
- 5µg EBOV GP + AlPO₄
- 5µg EBOV GP + Matrix M

Jay Hooper, USAMRIID
Methods. Mice were immunized on day 0, 14 and 28 and on Day 42 mice were challenged by intraperitoneal inoculation of 1,000 pfu of mouse adapted ebolavirus (1976 Mayinga). Ricardo Carrion, Texas Biomed.
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Purified fully human anti-rGP (Guinea, 2014) polyclonal antibody: passive protection

- Tc bovine (Human IgG) were immunized with recombinant Guinea Ebola GP vaccine
- Fully human anti-GP polyclonal antibodies were purified from plasma
- Polyclonal Anti-GP IgG given i.p. at 24 or 48 hrs post challenge

Mice (10 per group) were challenged IP with 100pfu of Mouse-adapted Zaire Ebola virus (ma-EBOV) generated by Mike Bray at USAMRIID. Mice were then treated at 1 day post or two days post infection with 100mg/kg of human hyperimmune sera antibody via the IP route. The control mice received the control sera at 1 day post exposure.

John Dye/USAMRIID
Clinical Study: Novavax EBOV-H-101

- Phase 1, blinded, controlled in 230 adults 18 to <50 y.o.
- Dose ranging, 1 and 2 dose regimens w/wo Matrix-M adjuvant
- Immune responses thru 1 year
  - GP EC50 ELISA, PRNT, PsVNA, anti-13C6, and T-cell responses
Summary

- Novavax: is a mid-size recombinant vaccine company that is uniquely capable of responding to novel lethal viral threats
- Recombinant tools/adjuvants allow NVAX scientists to solve difficult vaccine puzzles
- Demonstrated in the context of H7N9 Vaccine and Ebola Vaccines
- Path forward, regulatory approval and business models for these efforts are being assessed
- In light of the robust biological responses to the vaccines, there is a compelling case to attempt to develop and make available recombinant nanoparticle vaccines and saponin adjuvants when novel lethal viruses arise and show signs of persistence
Acknowledgement – Novavax Ebola vaccine SWOT Team

Our foundation for success is rooted in the expertise and dedication of the people who performed the necessary activities. We appreciate and recognize the dedicated employees who contributed to this project:

**Adjuvant Production (Sweden):**

**Analytical Development:**
Ali Abosaiedi, Casper Alabanza, Elena Bogatcheva, Liming Fan, Yali Lu, Bruce McNair, Alan Ng, Sonyun Rizzo, Yanhong Wei, Zhiwen Yang, Emnet Yitbarek

**Contracts:**
John Herrmann, Jesse Oropesa

**Discovery:**
Chineye Emeche, David Flyer, Desheng Jiang, Raffa Khatoon, Hanxin Lu, Mike Massare, Haiyan Mu, Jim Norton, Haifeng Song, Jing-Hui Tian, Luis Verona, Kyle Williston, Małgorzata Wisniewska, Yingyun Wu

**Environmental, Health, and Safety:**
Jean Williams

**Engineering:**
Jeff Blake, Matt DePola, Jenny Mott, Jim White

**Executive Assistants:**
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**Information Technology:**
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**Manufacturing:**

**Materials Management:**
Jim Adams, Lamar Higdon, Michael Kelly, Mike Money, David Praisner, Matthew Price, Michael Price, Christine Thompson, Brian Webber, Andrew Wright

**Process Development:**
Patrick Allen, Ankita Balsaraf, Daniel Baskind, John Burd, Doug Clark, Wanda Franklin, Darlyce Franks-Washington, Amit Gangar, Mikhail Goldfarb, Jeanie Kim, Mark Koehler, Abhita Malayiva, Jingya Zhu

**Quality Assurance:**
Marinela Alvero, Ahmed Bakare, Charline Bermudez, Adrienne Caddell, Michelle Chaikin, Tonia Cheung, Frances Cox, Ashley Flood, Gwen Hines, Sobia Khan, Sandra Klaiber, Denise Krohn, Yian Yen Lee, Denise Lou too, Jodie Marti, Kimberly Mullan, Fred Shemer, Vanessa Smiley, Lamonua Thorne, John Togba, Tracy Whitehair, Kathleen Williams, Lynae Wright

**Quality Control:**
Khalid Ahmad, Nota Aigbogun, Sabrina Cusick, Khalia Davis, Kirsha Forte, Thomas Gantt, Brian Howie, Tony Kallarackal, Tina Keeney, Janiece Lartman, Emily Miller, Cheryl Mowen, Nohea Nichols, Oluyemisi Ojifinni, Vidhi Pankh, Raza Zaidi

**Regulatory:**
Susan Hensley, Tim Wan

**Validation:**
Joan Abrams, Dana Johnston