

The Pill Against Pandemics A Disruptive Oral Vaccine Platform

Raymond James Virtual Human Health Innovations Conference

June 18, 2020

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Disruptive Oral Vaccine Platform



Convenient mode of administration

No needles, self administration (no appointments, no lines, social distancing)

Potential best-in-class efficacy against COVID-19 and other airborne viruses

Activates mucosal immunity, first line of defense, plus multiple immune system mechanisms

Environmentally friendly

No disposal of potentially billions of vials, syringes, needles, gloves, masks, cotton balls, etc.

Low cost distribution and storage

No refrigeration, room-temperature stable

Rapid Pandemic Response Platform

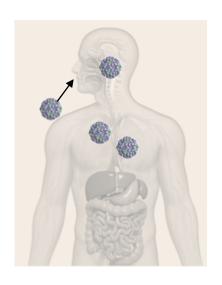
Plug-n-play platform, ready for future pandemics

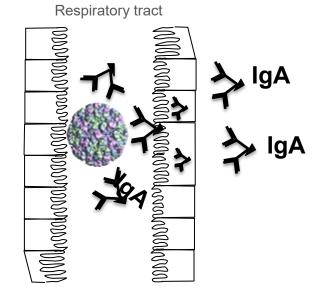


Protection by harnessing the multifunctionality of the mucosal immune system

Respiratory Viruses: The Vaxart platform gets the right molecule to the right place

Respiratory Viruses





Vaxart Generates Antigen
Specific IgA at Nasal and
Respiratory Sites

Evidence *suggesting* a Mucosal Correlate or Surrogate of Protection

- Influenza (IgA, α4β7 IgA ASC*)
- RSV (Nasal IgA, Memory IgA)

We believe this may be the case for COVID-19 as well

References:

Ambrose, et al., *Vaccine*, 2012 Gould, et al., *Frontiers in Microbio*, 2017 Habibi, et al., *Am J Resp and Crit Care Med*, 2015 Joyce, et al., *Vaccine* 2018 Kim, et al., *Sci Reports* 2016 Liebowitz et al., *Lancet Infectious Diseases*, Jan 2020



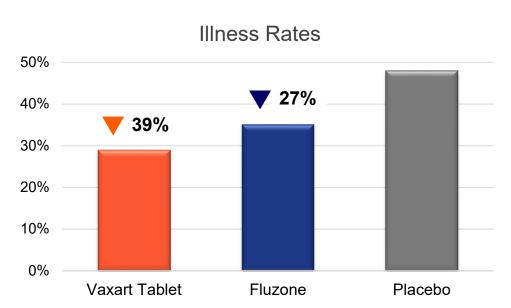
Proven Efficacy: Protection against a pandemic respiratory pathogen (2009 H1N1 influenza) after oral tablet delivery

H1N1 Pandemic vaccine made rapidly, tested in animals in a matter of weeks

Phase II human challenge study comparing Vaxart's oral tablet vaccine and Sanofi's Fluzone injectable flu vaccine



Reduction in Illness following challenge

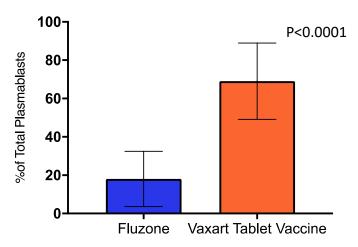


Liebowitz, et al, Lancet ID, 2020

Correlated With Mucosal Response In Humans

% of B cells that express the mucosal homing receptor

Vaxart Tablet Vaccine: Protection Highly



Safe, with Tolerability Comparable to Placebo

BARDA-funded flu study

| | Subjects with Solicited Symptom TEAEs | Pain at injection site | Tenderness at injection site | |
|----------|--|------------------------|------------------------------|------|
| Placebo | 42% | 2.8% | 2.8% | n=36 |
| VXA-A1.1 | 29% | 2.9% | 4.3% | n=70 |
| Fluzone | 36% | 13.9% | 26.4% | n=72 |
| | One of the reasons people don't like needles | | | |

Source: Liebowitz et al., Lancet Infectious Diseases, Jan 2020

460 patients in safety database, dosed across 3 viruses

- Flu: 245

- Influenza: 46

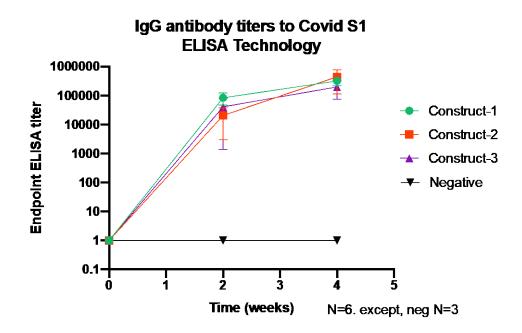
- Norovirus: 171

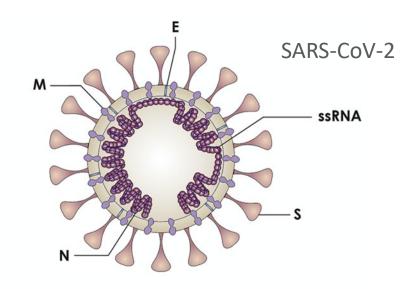


Oral COVID-19 Vaccine Development

Vaxart Program is Advancing Expeditiously

- Final vaccine candidate selected with the potential to generate broad responses
 - COVID-19 is a respiratory tract infection and this vaccine will promote mucosal and systemic immune responses







Advantages of our COVID-19 vs others

| | Technology | Limitations | Likely Immune | Needles | | |
|-----------------|----------------------|---------------------|----------------|---------|--|--|
| Vector-based | | | | | | |
| CanSinoBio | rAd5 injected | | | Yes | | |
| AZ/ Oxford | Chimp rAd | Antivector Immunity | nAb, T cells | | | |
| Janssen | rAd26 injected | | | | | |
| DNA/RNA | | | | | | |
| Moderna | Stabilized RNA | Now technology | nAb | Yes | | |
| Pfizer/BioNTech | RNA | New technology | IIAD | | | |
| Protein | | | | | | |
| Novavax | lace of cell culture | ADE automatica Ala | A I. | Yes | | |
| Sanofi/PS | Insect cell culture | ADE, only makes Ab | Ab | | | |
| Oral Vaccine | | | | | | |
| Vaxart | rAd5 oral tablet | Smaller company | IgA, Mucosal T | No | | |



Oral COVID-19 Vaccine - Phase 1 Ready

Clinical/Regulatory Activities

- IND submission in June
- Clinical Study FPI Summer 2020
 - Phase 1 open label, dose ranging

CDMO Partners

- Tech Transfers Complete
- GMP Bulk Vaccine in Progress







Environmentally friendly vaccination campaigns

Even in large scale

- A COVID-19 vaccination campaign would include ...
 - 200+ million in the US
 - 2-3+ billion globally



x 3 Billion =





Prophylactic & Therapeutic Oral Vaccine Candidates

| | | Trials Conducted to Date or in Progress | | | | |
|---------------------------------|---------------------------------------|---|---------|---------|---------------|--|
| | | Preclinical | Phase 1 | Phase 2 | Phase 3 | Marketed |
| PROPHYLACT | TIC VACCINES | | | | | |
| Norovirus ¹ | Bivalent | | | | | |
| Seasonal Influenza ² | Monovalent | | | | | |
| | Quadrivalent | | | | | |
| Influenza | Universal ³ | | | | Janssen 🔰 🥉 | armaceutical companies of common of the companies of the common of the c |
| COVID-19 | | | | | | |
| RSV ⁴ | | | | | | |
| THERAPEUT | IC VACCINES | | | | | |
| HPV ⁵ | HPV, cervical dysplasia and/or cancer | | | | | |

- 1) Bivalent Phase 1 demonstrated IgA ASC response rates of 90 93% for GII.4 and 78 86% for GI.1
- 2) Monovalent H1 flu vaccine completed phase 2 Proof of Concept efficacy study.
- 3) Janssen collaboration with an option to negotiate an exclusive license.
- 4) RSV program to be partnered with new antigen partner.
- 5) HPV therapeutic pre-IND feedback received.



Norovirus Vaccine \$3B+ U.S. Market

Government Policy will Drive Demand

| | Age | 0-4 | 5 – 64 | 65+ |
|---------------------------------|-----|--------------------|-------------------|-------------------|
| Population US | | 20M | 260M | 50M |
| Price Target | | \$100 ¹ | \$50 ¹ | \$50 ¹ |
| Prospect of ACIP recommendation | | High | Low | High |
| Percent vaccinated ² | | 70%³ | 4% | 65% 4 |
| Market potential | | \$1.4B+ | \$0.5B | \$1.6B+ |



Development / Competitive Status

- Vaxart vaccine Phase 1 complete
- Phase 2 Ready
 - Challenge study
 - Safety and Immunogenicity study
- Partnering discussions ongoing





Management Team with Deep Experience in Vaccines



ANDREI FLOROIU, MBA Chief Executive Officer

Strategy, Corporate Finance, Biopharma Investing, Vaccines





agenus



SEAN TUCKER, PHD Founder and Chief Scientific Officer

Mucosal Immunology Gene Delivery









SHAILY JAINI GARG

SVP, Clinical Development and **Project Management**

Global Clinical Development, Regulatory Affairs and Project Management













BRANT BIEHN

SVP, Commercial Operations

Global Market Development, Sales and Business Development







MARGARET ECHERD, CPA MBA

Vice President, Corporate Controller

Tech & Devices, Multiple Financings











Highlights

- Disruptive Oral vaccine platform
 - Validated approach: BARDA-funded flu challenge study
 - Could emerge as the ideal solution for COVID-19
 - o Potentially best in class efficacy: mucosal & systemic immunity
 - Appeal of oral administration, low cost across supply chain, environmentally friendly
 - Advantages apply to other airborne & mucosal viruses e.g., flu, norovirus, etc.
- Covid-19 program advancing rapidly
 - Phase 1 to start in Summer 2020
 - Manufacturing in place
- Norovirus program phase 2 ready
- Rapid response pandemic platform: plug-n-play, ready for future pandemics
- Strong balance sheet: ~\$30M cash on hand per March 31





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