vaxxinity

41st Annual J.P. Morgan Healthcare Conference

January 2023
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An expansively disruptive approach to chronic disease:

Efficiency of vaccines + Validation of mAbs in chronic disease = New class of therapeutics

Alzheimer’s  Parkinson’s  Migraine  Hypercholesterolemia  Others
VAXXINES are a potential new class of medicine for chronic diseases...

**Opportunity:** Any target accessible by a mAb is an opportunity for a VAXXINE to leapfrog to first line

- High probability of success
- Rapid R&D timelines
- Expansive market potential

Membrane-bound proteins

- E.g., SARS-CoV-2 RBD

Aggregated / Misfolded proteins

- E.g., Aβ, αSyn

Circulating proteins & peptides:
- Over-abundant proteins
- Peptides
- Hormones
...that aim to be more convenient, cost-effective, and scalable...

**More convenient dosing**

- Daily pill
- Bi-weekly infusion
- Quarterly IM

**Less than 1% of COGS compared to mAb**

Manufacturing efficiency advantage

Less material per dose

*Illustrative Example*
...with profound social and economic implications

mAbs are limited by:
- High prices
- Burdensome administration
- Complex manufacturing and challenges scaling production

Illustrative

Larger First-line Prevention

Smaller Later-line Treatment

mAb Market $163 billion (2019)

Developed World

Markets

Developing World
...with profound social and economic implications

Developing World Markets
Developed World

Larger First-line Prevention
Smaller Later-line Treatment
Indications

mAb Market $163 billion (2019)

Expanding The Addressable Market opportunity

Illustrative
VAXXINE platform achieved first commercial validation in animal health with millions of doses commercialized...

Anti-LHRH vaccine for immunocastration
...and has translated into a substantial portfolio of clinical data to date

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Count</th>
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<tbody>
<tr>
<td>4</td>
<td>Investigative VAXXINE medicines in clinical trials</td>
<td></td>
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<tr>
<td>8</td>
<td>Clinical trials conducted (ongoing and completed)</td>
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<tr>
<td>10</td>
<td>Repeat doses administered in patients over up to 3 years</td>
<td>&gt;4,250</td>
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<td></td>
<td>Participants dosed</td>
<td></td>
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Vaxxinity’s pipeline spans multiple therapeutic areas and validated targets

<table>
<thead>
<tr>
<th>Vaxxine Program (Target)</th>
<th>Indications</th>
<th>Preclinical</th>
<th>IND</th>
<th>Ph 1</th>
<th>Ph 2</th>
<th>Ph 3</th>
<th>Next Milestone</th>
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<tbody>
<tr>
<td>UB-311 (Aβ)</td>
<td>Alzheimer’s</td>
<td></td>
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<td></td>
<td>Begin pivotal study with partner</td>
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<td>UB-312 (aSyn)</td>
<td>Parkinson’s, Lewy body dementia</td>
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<td>Phase 1 Part B end-of-study readout 2023</td>
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<td>Anti-tau</td>
<td>Alzheimer’s, tauopathies</td>
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<td></td>
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<td>UB-313 (CGRP)</td>
<td>Migraine</td>
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<td>Interim Phase 1 data 1H23</td>
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<tr>
<td>VXX-401 (PCSK9)</td>
<td>Hypercholesterolemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Initiate FIH 1H23</td>
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<td>UB-612 (SARS-CoV-2)</td>
<td>Covid-19 prevention</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>Complete BLA submissions with MHRA and TGA 1H23</td>
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Synthetic Peptide VAXXINE Platform for Chronic Diseases
Vaccines for chronic diseases: the challenges

**Challenge:** overcome immune tolerance while avoiding T cell cytotoxicity and autoimmunity

**Response Rate**

**Challenge:** overcome immune tolerance across populations

**Immunogenicity**

**Challenge:** produce efficient antibodies at therapeutic levels

**Off-Target**

**Challenge:** induce only antibodies highly specific to the target

To avoid these challenges, the industry moved towards mAbs
Our synthetic peptide VAXXINE platform combines the power of mAbs with the convenience and accessibility of vaccines.

**Components**

- B cell epitopes
- Th peptide carriers
- Proprietary linker and formulation

**Advantages**

- Overcomes immune tolerance with high response rate and titers
- Target-specific antibodies
- Durable response
- Synthetic, low-cost, scalable
- Plug & Play, modular

**The VAXXINE Platform**

Activate CD4+ cells and stimulate B-cells

**Components**

- B cell epitope
- Th peptide carrier
- Linker
UB-311 consistently elicits high quantities of potent antibodies that bind to the toxic Aβ aggregates

1. mAbs have **validated Aβ** as a target for Alzheimer’s

2. In Ph1 and Ph2a trial, elicits **high quantities of antibodies** that **cross the BBB** and bind to **toxic Aβ oligomers**

3. Generally **safe and well tolerated** with no ARIA-E in Ph2a main study

4. Trends of ~**50% slowing of cognitive decline** across key measures

5. **Pivotal-study-ready** with FDA alignment on protocol, population and endpoint
A more convenient and accessible Aβ vaccine has the potential to go earlier into prevention and significantly expand the addressable market.
UB-312 consistently elicits antibodies that penetrate the BBB against the toxic species of αSyn

UB-312 elicits high levels of anti-αSyn antibodies

...that penetrate the BBB, detectable in CSF at ~0.2%

And preferentially target αSyn and avoid monomers

Guinea pig sera in vitro (Ron Melki’s lab; Nimmo et al. 2020)
UB-312 preclinical data shows impact on pathology in both CNS and gut and improvement in motor symptoms

**UB-312 significantly reduces pathology in gut in transgenic mice**

![Red = αSyn immunoreactivity; Blue = DAPI (nuclei)](image)

And αSyn pathology in CNS with improvement on behavior

**UB-312 reduces αSyn brain pathology...**

**...and improves motor symptoms**

![Transgenic mice in vivo (Nimmo et al. 2022)](image)
UB-313 aims to be first choice for migraine sufferers to reclaim their lives

**UB-313 Summary**

- VAXXINE against CGRP ligand
- Target convenient 2-4X annual dosing
- Low COGS

**Data through Preclinical POC**

- High antibody titers across species
- Binding potency comparable to mAbs
- Inhibits CGRP-induced cAMP in human cells dose-dependently
- Activity in translatable animal model (dermal blood flow) comparable to mAbs

**UB-313 animal proof-of-concept study**

Rats (n = 6-8 / group) were immunized with the “rat version” of UB-313 and challenged with Capsaicin. Local dermal blood flow (DBF) was measured by Laser Doppler Imaging. *p < 0.05; **p < 0.01


**Status: Ph1 fully enrolled, topline data 1H23**
UB-313 Phase 1 Trial to Assess Safety, Tolerability, Immunogenicity, and Capsaicin-Induced Dermal Blood Flow in Healthy Volunteers

N=40

Cohort 1: 100/100/100μg
Cohort 2: 300/100/100μg
Cohort 3: 300/300/300μg
Cohort 4: 600/100/100μg

Abbreviations: C = capsaicin challenge; PBO = placebo; SCR = Screening Period
Migraine remains a widespread debilitating disease with large unmet need, despite effective new CGRP treatments.

- Accessible
- Convenient
- Well-tolerated

UB-313

CGRP drugs mAbs and -gepants

Payer hurdles:
step edits, prior authorizations, high copays

New class of CGRP drugs are well-tolerated and effective, but large unmet need remains:
- Accessibility without payer hurdles
- More convenient dosing schedule
- Better tolerability of first-line drugs

How could a CGRP vaccine address unmet need?

Prevention of migraine with CGRP therapies

OTC
Leapfrogging CGRP mAbs and orals to become a first-line therapy presents a blockbuster commercial opportunity

**Indications**

Today's CGRP market
- Second and third line
  ~1-1.5M patients

First line prevention market
- Chronic and episodic (US)
  ~15 M patients

Worldwide prevention market
- Chronic and episodic (global)
  > 400 M patients

25% of TAM
@ $500/year
= $50 billion

Market size estimates based on internal analyses and third-party research reports.
VXX-401 aims to vaccinate the world against heart disease

VXX-401 Summary

- VAXXINE against PCSK9
- Target convenient 2-4X annual dosing
- Low COGS enables accessibility as earlier line and on worldwide basis

Data through Preclinical POC

- High antibody titers and response rate
- Decreases LDL cholesterol by up to 54% in non-human primates vs. placebo

Status: Begin Ph1 in 1H23

VXX-401 Reduces LDL-c Comparable to Single Dose of Approved MAb

Placebo and VXX-401 groups received IM injections at weeks 0, 3, 6, 13, 16, 19. Evolocumab group received one 3 mg/kg SC injection at week 19.
N = 3 NHPs in VXX-401 group, 6 NHPs across 2 control groups
This was a non-optimized vaccine formulation using the same peptide immunogen as VXX-401.
VXX-401 Phase 1 Trial to Assess Safety, Tolerability, Immunogenicity and Pharmacodynamics in Subjects with Elevated LDL-C

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<th>Week</th>
<th>SCR</th>
<th>0</th>
<th>1</th>
<th>4</th>
<th>5</th>
<th>8</th>
<th>9</th>
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</table>

Dosing:
- **Cohorts 1, 3**: 100/100/100μg
- **Cohorts 2, 4**: 100/100/100/100μg

Randomization (9 active: 3 PBO):
- **Cohort 1**: 100/100/100μg
- **Cohort 2**: 100/100/100/100μg
- **Cohort 3**: 300/300/300μg
- **Cohort 4**: 300/300/300/300μg
Cardiovascular disease remains the number one killer in the world, despite effective treatments to lower LDL cholesterol.

New class of PCSK9 drugs are well-tolerated and effective, but large unmet need remains:

- Accessibility without payer hurdles
- Better compliance of first-line drugs through more convenient dosing schedule and better tolerability

How could a PCSK9 vaccine address unmet need?

Simplified primary prevention guidelines

Lifestyle changes

Statins

Combination with PCSK9 drugs

VXX-401

- Accessible
- Convenient
- Well-tolerated

Payer hurdles:
step edits, prior authorizations, high copays
VXX-401 has large commercial opportunity in meeting major global public health need

- **Total potential addressable market**
  - ~2 billion people at risk
  - 20% of TAM @ $300/year = $120 billion

- **Existing high cholesterol market**
  - ~500 M patients

- **Today’s PCSK9 market**
  - Second and third line
  - <1% qualified patients

- **LLT market**
  - Statin and other LLTs
  - ~200 M patients

- **Market size estimates based on internal analyses and third-party research reports.**
UB-612: Positive readout in Ph3 pivotal trial
UB-612 is next-generation COVID-19 booster against S1-RBD designed for broader and more durable protection

UB-612 is a protein/peptide vaccine targeting S1-RBD site and other epitopes on S, N and M proteins

- Neutralizing activity across many SARS-CoV-2 variants including Omicron BA.5, Delta, Alpha, Beta*
- Antibody half-life ~6 months* (competing platforms 1-3 months)
- Standard 2-8°C cold chain
- Capacity to manufacture and price at market with strong margins

*Guirakhoo et al., Journal of Infectious Diseases (2022)
Phase 3 global study shows UB-612 boosts antibodies comparable to Pfizer-BioNTech and multi-fold superior to AZ and Sinopharm vaccines

Neutralizing Antibodies: Omicron BA.5

Seroconversion Rates: Omicron BA.5

Ph3 topline results from live SARS-CoV-2 virus neutralization assay 28 days post-injection

*Statistically non-inferior, defined as lower bound of 95% CI for UB-612 SCR – comparator SCR > -10%; statistically superior to ChAdOx1-S and BIBP

Lower bound GMR CI UB-612 vs. Pfizer against Omicron = 0.94
Framing the COVID-19 booster market

- 2.6 billion booster doses sold to date, and climbing
- 2% of market @ $12 / dose = $600 M

Persons primed with COVID-19 vaccines by platform

- mRNA: 1.2 B
- Adenovirus: 1.6 B
- Inactivated: 2.2 B
- Total: 5.0 B

Market size estimates based on internal analyses and third-party research reports.
Vaxxinity 2023 milestones supported by strong financial position

<table>
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<tr>
<th>Program</th>
<th>1H</th>
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<td>Ph1 Part B Read-out</td>
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<td>(αSyn)</td>
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<td>Ph1 Topline</td>
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<td>(CGRP)</td>
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<td>VXX-401</td>
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<tr>
<td>(PCSK9)</td>
<td>Ph1 Start</td>
<td>Ph1 Topline</td>
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<tr>
<td>UB-612</td>
<td>MAA Submission</td>
<td>Approval</td>
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<tr>
<td>(SARS-CoV-2)</td>
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**$102.2M**

Cash + liquid assets as of 9/30/2022

**$10M**

Grants from CEPI & MJPP

**126.04M**

Common Shares Outstanding as of 9/30/2022

*Includes $18.9M in cash & cash equivalents; $80.2M in short-term investments; $3.1M restricted cash
DEMOCRATIZE HEALTH.

Our vision is to provide cheaper, safer, more convenient, and effective medicines for chronic disease to all.