Universal Influenza Vaccine
One ● For All

Company Presentation

April 2013

BiondVax Pharmaceuticals Ltd.

Forward Looking Statements

This presentation includes “forward-looking statements” within the meaning of applicable securities laws. These forward-looking statements involve risks and uncertainties, including those identified within the “Risk Factors” section of the Company's Shelf Prospectus dated January 17, 2012.

Although management of the Company believes the expectations reflected in such forward-looking statements are based on reasonable assumptions, the Company cannot assure investors that these expectations will prove correct, and the actual results that the Company achieves may differ materially from any forward-looking statements, due to such risks and uncertainties.

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BiondVax at a glance

BiondVax's Universal Flu Vaccine candidate M-001:

- In advanced Phase 2 clinical development
- Synergistic with current influenza vaccines
- Prepares for pandemics (incl. H5N1)

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A company that addresses a real market concern

BiondVax is in advanced clinical stages of developing a new kind of flu vaccine designed to protect long term against all flu strains, seasonal and pandemic

BiondVax in Focus

Dedicated to improving protection against flu

Publicly-traded on Tel Aviv Stock Exchange since June 2007 (TASE:BNDX)[1]

Comprehensive patent portfolio includes exclusive, worldwide license agreement with Weizmann Institute

Passed European QP GMP audit[2]

4 successful Phase I/II & II clinical trials involving 440 people

M-001 significantly improves efficacy of pandemic H5N1 vaccine (pre-clinical)

[1] http://www.tase.co.il/TASEEng/General/Company/companyDetails.htm?subDataType=0&companyId=001468&ShareId=01105204#SummaryLink

[2] Qualified Person (QP) Good Manufacturing Practices (GMP)

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One • For All - A Universal Flu Vaccine

More than 15 years of R&D at Weizmann Institute in lab of Prof Ruth Arnon

Weizmann Institute of Science

2005 — **BiondVax Operational**

2008 — Phase I/II

2010 — Phase II

BiondVax today

Phase III

FDA/EMA approval

2013 milestones:
- ☐ Submit USA IND (FDA)
- ☐ 3rd Phase II under IND

2012 milestones:
- ☐ Phase II in elderly completed
- ☐ European QP GMP audit passed

Pivotal Phase III clinical trials likely require strategic partner

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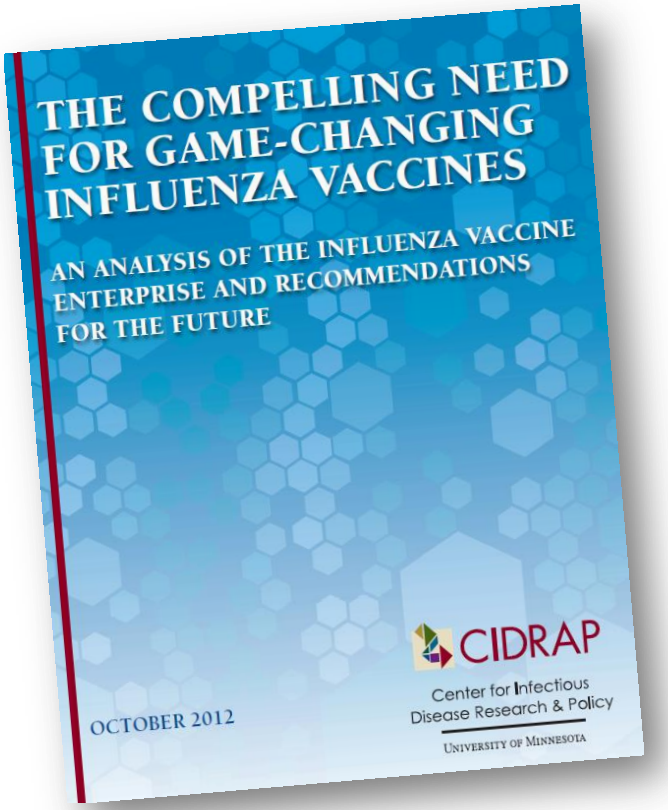
Compelling Market Need



Seasonal flu is the most common infectious disease causing ~500,000 deaths annually worldwide

Flu pandemics in the last century have killed more than 50 million people across the world

Influenza costs the US health care system ~$90 billion annually[1]

[1]Poland and Mulligan. The Imperative of Influenza Vaccines for Elderly Individuals. (2009) JID 200, 161-3

Influenza Vaccines is a $3B Market and Growing

Flu Vaccine Sales: Extensive and & Fast Growing

Seasonal

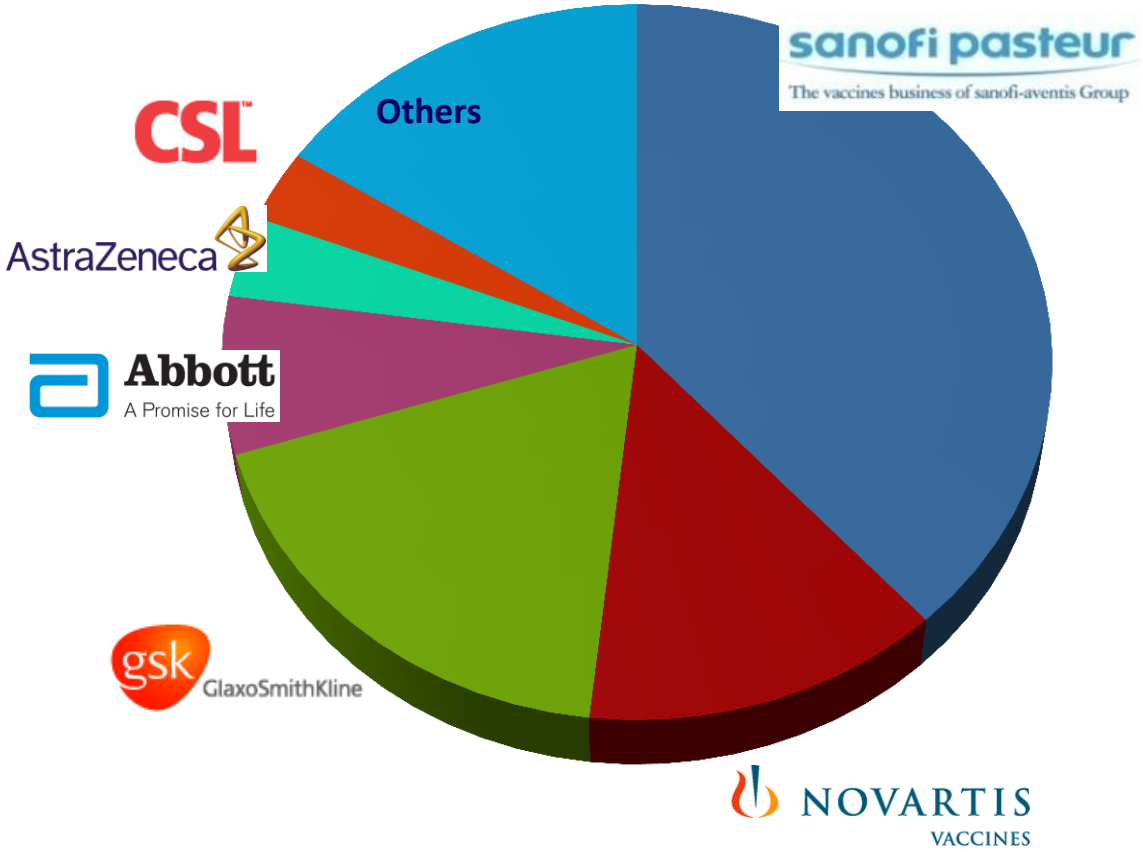
- **~500M doses** supplied[1]
- **~$3B** worldwide sales[1]
- **~$5B** worldwide sales (forecasted for 2021)[2]

Pandemic

- Swine flu (H1N1 2009) **~$3B** worldwide sales[3]

[1]http://www.sanofipasteur.com/sanofi-pasteur4/sp-media/SP_CORP/EN/222/1758/ENG_Factsheet%2520SP%2520world%2520manufacturer_2011_07_18.pdf
[2]http://www.prnewswire.com/news-releases/market-forecasts-seasonal-influenza-vaccines-170473196.html
[3]http://www.kaloramainformation.com/about/release.asp?id=1625

Market Share for Seasonal Flu Vaccines Today



Over $3B sales[1]

CAGR of 4%[2]

[1]http://www.sanofipasteur.com/sanofi-pasteur4/sp-media/SP_CORP/EN/222/1758/ENG_Factsheet%2520SP%2520world%2520manufacturer_2011_07_18.pdf

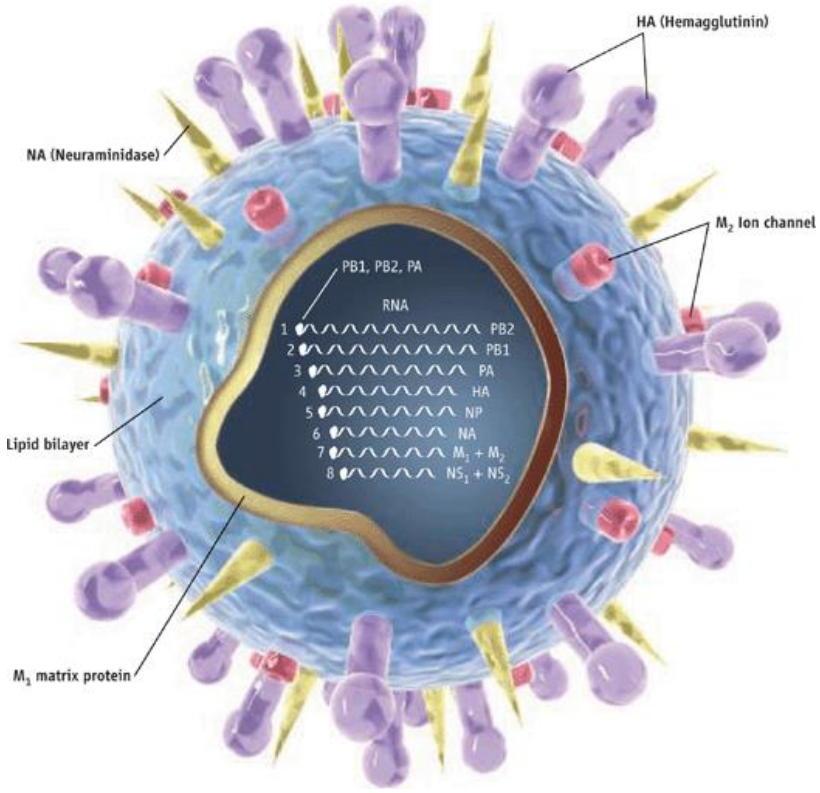
[2]http://www.gbiresearch.com/Report.aspx?ID=Seasonal-Influenza-Vaccines-Market-in-Top-Seven-Countries-to-2018&ReportType=Industry_Report&Title=Pharmaceuticals_and_Healthcare

Current flu vaccines have limitations

Flu vaccines today only target known strains and not emerging ones

Current Vaccines Do Not Target Common Regions

Components of the influenza virus contain two kinds of region: **common** and **variable**



The Influenza Virus

Common Regions

e.g., in Matrix (M_1) protein

Rarely changes between strains.

Current vaccines do not target these regions as requires measuring cellular immunity.

Variable Regions

e.g., in Hemagglutinin(HA) protein

Changes between strains.

This is the target of current vaccines and triggers antibody immunity.

Complexity of production (takes 6-8 months) means each vaccine only targets 3 or 4 strains.

BiondVax's approach

Developing a universal vaccine to protect against **ALL flu strains**

BiondVax's Universal Flu Vaccine M-001

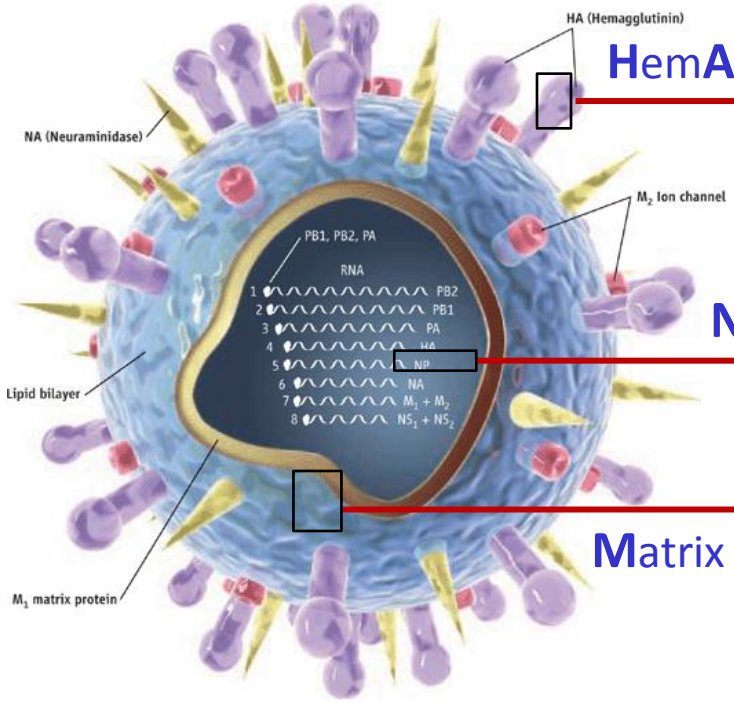
Design: Targets Common Regions

Nine common regions are connected to make one recombinant protein called M-001

Production: Quick and Robust

Produced easily and quickly all year-round within 6-8 weeks via fermentation in *E.coli*

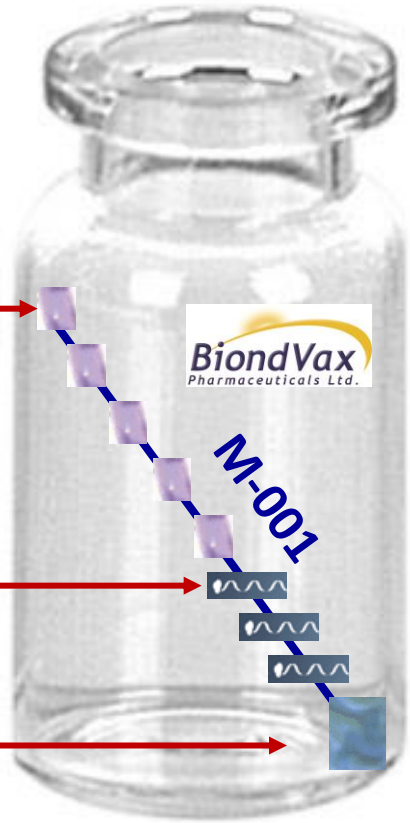
The Influenza Virus



Hem**A**gglutinin (HA)

Nucleo**P**rotein (NP)

Matrix protein (M_1)



M-001 Already Tested in Advanced Human Trials

Good Safety Profile

In Phase I/II & Phase II human clinical trials (440 people)

Anti-Influenza Activity

Triggers antibody and cellular immune responses

Utility

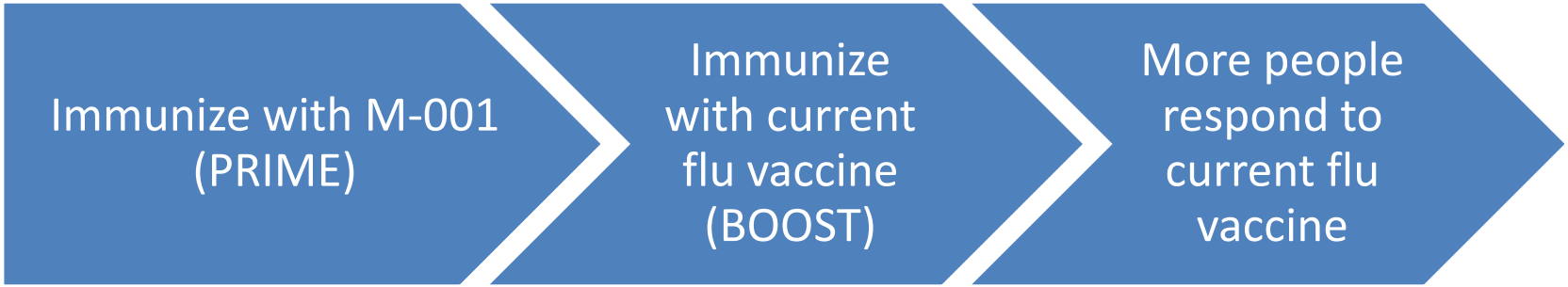
Unchanging formulation manufactured in only 6-8 weeks

Universality

Anti-influenza responses to multiple strains

Additional Use for M-001

M-001 synergizes with current flu vaccines



Clinically important:

- **reduces vulnerability of elderly:** who need improved vaccines urgently
- **enables pandemic preparedness:** people could be vaccinated ('primed') while the pandemic strain-specific vaccine is manufactured

Commercially important:

- **serves as an alternative regulatory pathway**: could prove shorter & cheaper
- **facilitates commercialization of M-001 as universal flu vaccine**

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M-001: Three Products, Large Market Potential

Seasonal Primer for Elderly	Pandemic Primer	Universal Flu Vaccine
Given to elderly each year before boosting with seasonal flu vaccine	Given to entire population upon pandemic alert while pandemic strain-specific vaccine is manufactured	Given to entire population every 3-5 years to protect against seasonal & pandemic flu strains
Potential price/dose: ~$10 Assuming given yearly to 70% of OECD elderly: **~$1.3B[1]**	Potential price/dose: ~$10 Assuming given to half of OECD population : **~$6B[2]**	Potential price/dose: ~$50 Assuming 500M yearly vaccine doses: **~$5B[3]**

[1]Population in OECD is 1.2B. ~15% are elderly. (OECD Factbook 2011) Calculation: 1.2x15%x70%x$10

[2]Population in OECD is 1.2B. (OECD Factbook 2011) Calculation: 1.2x50%x$10

[3]500M doses supplied worldwide in 2010 (see slide 9). M-001 given once every 5 years.
Potential price taken from: Vaccines for the 21st Century (Institute of Medicine). Calculation: 500x20%x$50

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Seasonal Primer for Elderly

A growing population at risk for flu complications

1 in 4 people in OECD countries predicted to be over 65 in 2050[1].
However US data show that current vaccines are not good enough:

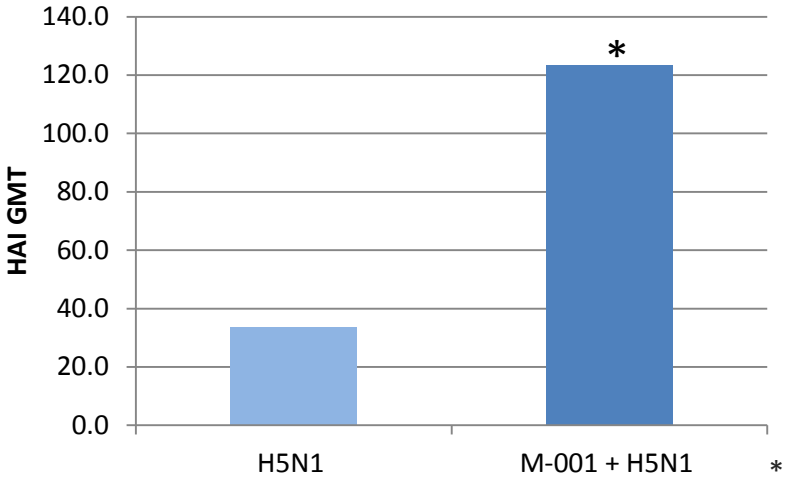
~70% of the US elderly receive influenza vaccines[2], yet

- Only a small % respond sufficiently[3] and....
- The elderly account for 90% of influenza–related deaths[4]

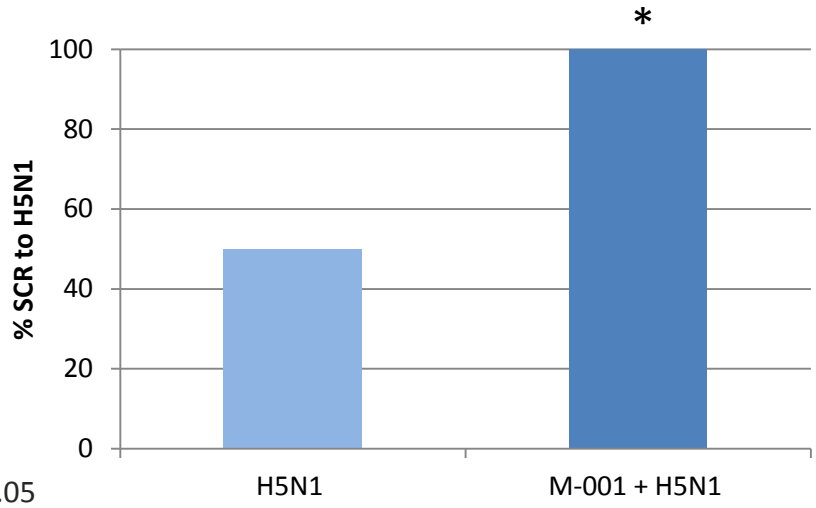
[1]OECD Factbook 2009 Economic, Environmental and Social Statistics
[2]http://stats.oecd.org/Index.aspx?DataSetCode=HEALTH PROC
[3]Minimum seroconversion required for vaccine approval for elderly is 30%
[4]Poland and Mulligan. (2009) JID 200, 161-3

Pandemic Primer: M-001 and H5N1 Synergy

Higher Levels of HAI Antibodies[1]



More Mice Seroconverted[2]

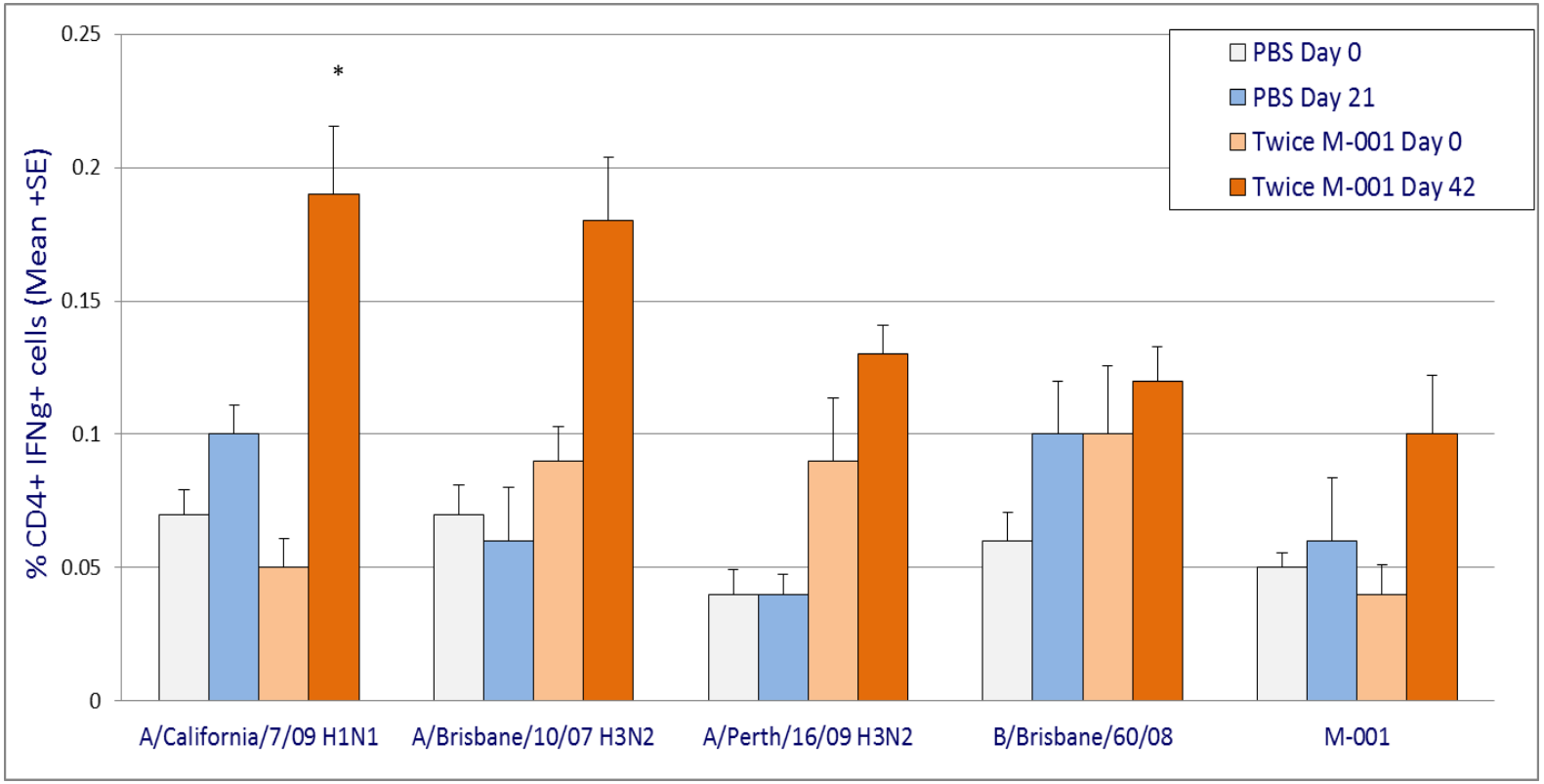


1. HAI GMT– hemagglutinin inhibition geometric mean titer is the serial dilution of serum that after incubation with a fixed amount of a certain influenza strain is no longer capable of preventing agglutination of erythrocytes; regulatory authorities consider the dilution 1:40 indicative of protective immunity
2. Seroconversion - % of mice with mean fold increase in HAI GMT ≥4x and HAI GMT≥ 1:40 post-immunization

M-001 priming potentially enables one instead of two doses H5N1 vaccine per person

Universal Flu vaccine: CMI to Multiple Flu Strains

M-001 Activates Cell Mediated Immunity (CMI) to Various Flu Antigens



BVX-005: 500 mcg M-001 administered twice with interval of 21 days; Placebo (PBS) once

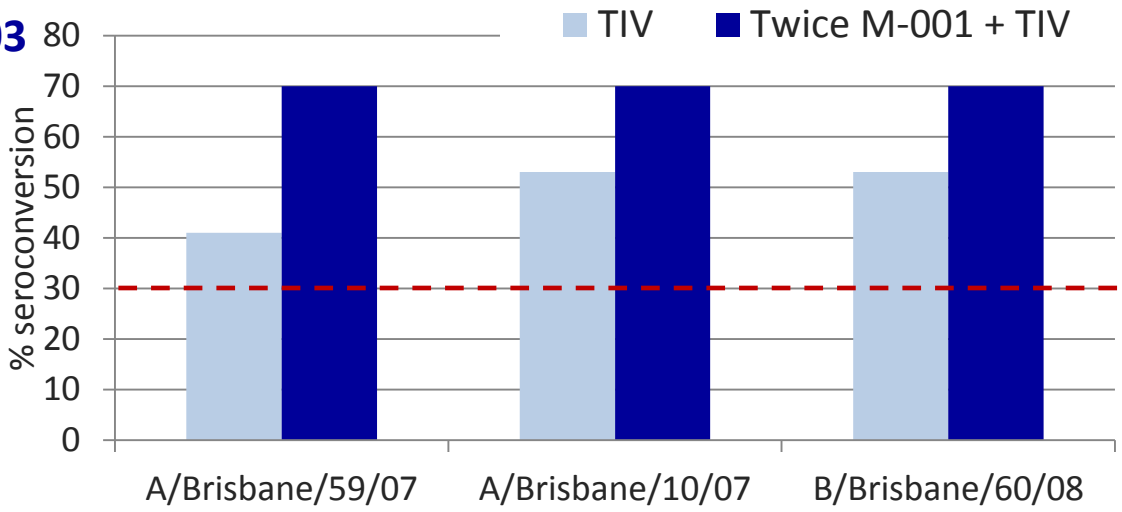
Mechanism of Action: M-001 results in expanded population of IFN-gamma-secreting CD4+ T Helper cells reactive to HA proteins

Universal Flu Vaccine: Synergy with Every TIV(HAI)

More people seroconverted to all tested TIV viruses

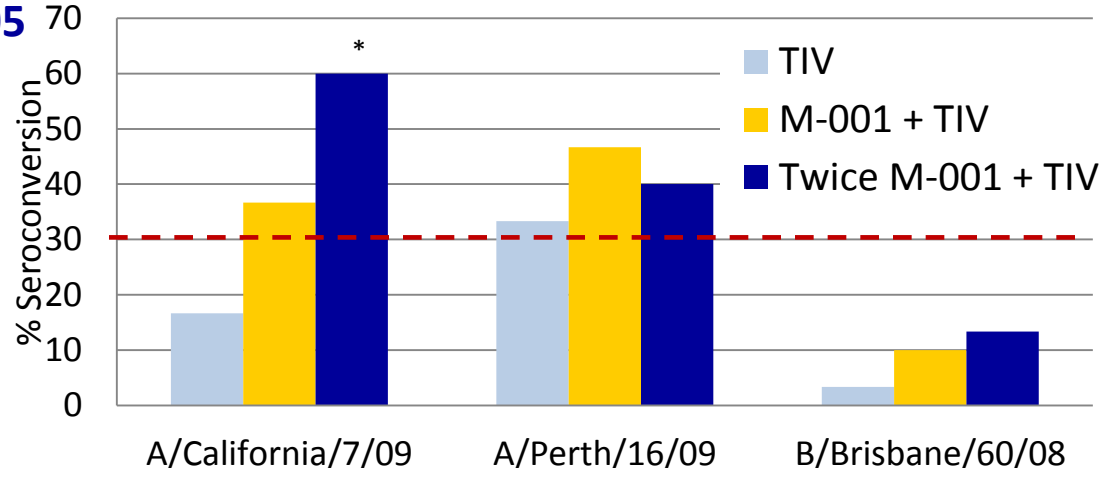
M-001's **UNIVERSAL IMMUNOGENICITY** supported by M-001 priming of different TIV boosts

BVX-003



Minimum required for regulatory approval

BVX-005



1. **Seroconversion**: % of individuals with mean fold increase in HAI ≥4x and HAI ≥ 1:40 post-immunization
2. **In BVX-003**: 500 mcg M-001, TIV (Vaxigrip 2009) and Placebo (either PBS or adjuvanted PBS)
3. **In BVX-005:** 500 mcg M-001, TIV (Vaxigrip 2011) and Placebo (PBS).

* = P<0.05

The Road Ahead

Competitive Advantages of BiondVax's M-001

- **SAFETY**: Demonstrated good safety profile in advanced clinical trials with 440 people
- **ACTIVITY**: Triggers anti-influenza immune responses in younger and older adults and elderly without any added adjuvant
- **MULTIPLE PRODUCTS**: Universal influenza vaccine and primer for current influenza vaccines
- **PRACTICAL**: Quick and easy, year-round production and stockpiling

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Multiple Products, Multiple Pathways

Seasonal Primer for Elderly

- Phase II and III: M-001 priming current seasonal flu vaccine vs seasonal flu vaccine alone
- Endpoints: efficacy plus current antibody immune marker (HAI)

Pandemic Primer

- Phase II and III: M-001 priming pandemic flu vaccine vs pandemic flu vaccine alone
- Endpoint: current antibody immune marker (HAI)

Universal Flu Vaccine

- Phase II: M-001 vs placebo
- Phase III: M-001 vs current seasonal flu vaccine
- Endpoints: protection plus new cellular immune marker

Pivotal Phase III clinical trials likely require strategic partner

BiondVax's Partners

Weizmann Institute of Science, Israel
Worldwide exclusive license agreement

Hadassah University Medical Center, Israel
Clinical Research Center

MonoSol Rx, USA
Collaboration to develop oral delivery for M-001

Tel Aviv Sourasky Medical Center, Israel
Clinical Research Center

Kimron Veterinary Institute, Israel
Avian influenza studies in animal model

Scientific Package

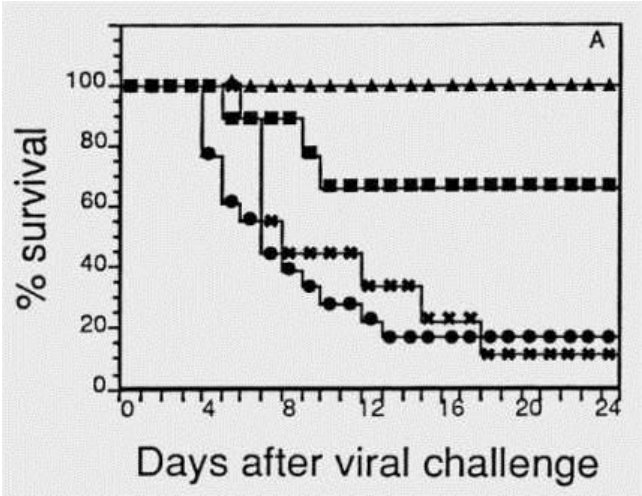
M-001 has demonstrated safety and triggered anti-influenza responses in animal studies and human clinical trials

Pre-Clinical Studies

M-001 Protects Against Lethal Flu Infection

Peptide-based Influenza Vaccine

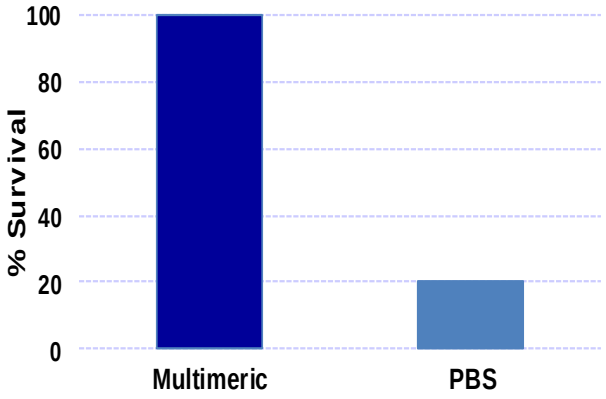
Animal studies at the Weizmann Institute showed that a mixture of B-cell + T-helper + CTL peptides provides optimal protection against influenza infection:



(●) Untreated control
(**x**) B-cell epitope
(■) B-cell epitope & CTL epitope
(▲) B-cell & CTL & T helper epitope
Vaccine, Vol. 14 (1) pp. 85-92, 1996

Multimeric Recombinant Vaccine

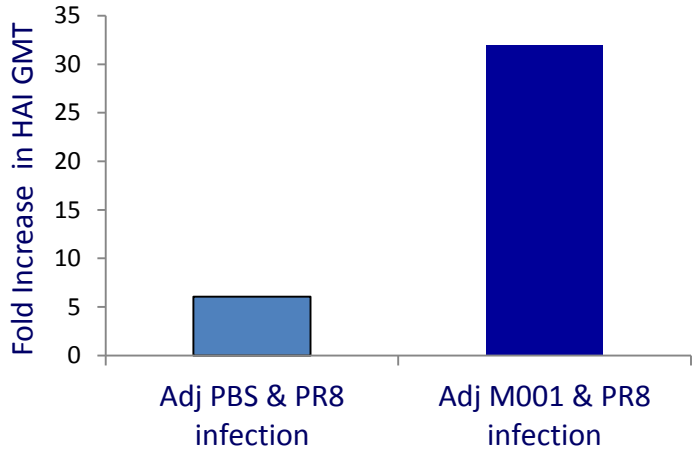
Animal studies at BiondVax showed that a single recombinant protein comprising select peptides **conserved** & **common** among type A and B influenza strains activates **cellular and humoral immunity** and affords protection against lethal influenza challenge:



HLA A*0201 transgenic mice immunized IM x3 with adjuvanted M-001 vaccine were infected with highly lethal (30LD50) dose of H3N2

M-001 Enhances Immunity to Natural Infection

Higher Levels of HAI Antibodies[1]



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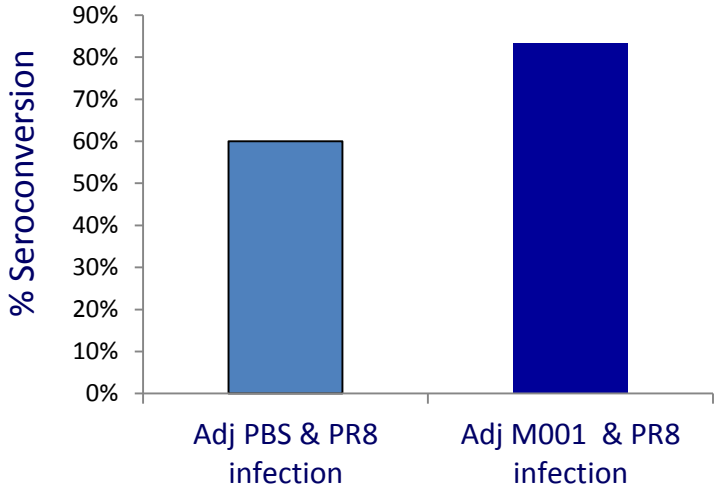

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2. **Seroconversion** - % of mice with mean fold increase in HAI GMT ≥4x and HAI GMT≥ 1:40 post-immunization
3. **Adj** - Freund's adjuvant

M-001 immunization results in elevated HAI immune responses to sub lethal intranasal infection with PR/8/34

Human Trials

2 Phase I/II and 2 Phase II clinical trials with 440 older and younger adults and elderly

4 Successful Clinical Trials – 440 Participants

♀♂ Population		Younger Adults		Older Adults / Elderly	
Clinical Trial		BVX-002	BVX-004	BVX-003	BVX-005
Phase		I/II	II	I/II	II
Safety		✓	✓	✓	✓
Immune Responses		✓	✓	✓	✓
Humoral (antibodies)	HAI	N/A	(partial TIV)	✓ (full TIV)	✓ (full TIV)
Cellular	IFN-g	✓	✓	✓	✓
	IL-2	✓	N/D	✓	N/D
	FACS	N/D	✓	N/D	✓

Design:

- Randomized
- Blinded: single BVX-002, -003 and double BVX-004, -005

Endpoints:

- Primary endpoint: safety
- Secondary (exploratory) endpoint: immune responses

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M-001: Good Safety Profile & Well-Tolerated

No significant differences between treatment and control groups

No treatment-related Severe Adverse Events

Most adverse events were **mild**[1]

All adverse events observed were **transient**

Trial	Year	Population (age)	N (M-001)	N (Placebo)	Total N
BVX-002	2009	Younger Adults (18-49)	43	20	63
BVX-003	2010	Older Adults (55-75)	40	20	60
BVX-004	2011	Younger Adults (18-49)	112	88	200
BVX-005	2012	Elderly (65+)	90	30	120
			285	158	443

[1]Mild Side Effects:

- Local reactions: injection site pain, erythema (skin redness), swelling
- Systemic reactions: myalgia (muscle ache), malaise (general discomfort), fever

A Game Changer for Influenza Vaccines

Thank You!

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