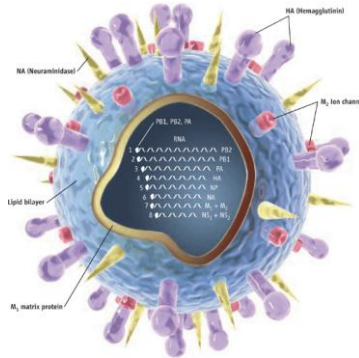


# BiondVax's Universal Flu Vaccine M-001: Leading the Way

## "BEST-IN-CLASS"

- Contains parts of 3 flu proteins (epitopes) **conserved** and **common** among A and B, **seasonal** and **pandemic**, flu strains
- Selected T and B-Cell epitopes activate both arms of immune system – **humoral** and **cellular**
- The flu epitopes are arranged in a single **recombinant protein** of ~50 kDa
- Recombinant protein **easily** produced by fermentation in bacteria **year-round**
- **Robust** manufacturing process generating **product in only 6-8 weeks**



Activates antibody & cellular immunity

Conserved & common parts of flu proteins



Single recombinant protein

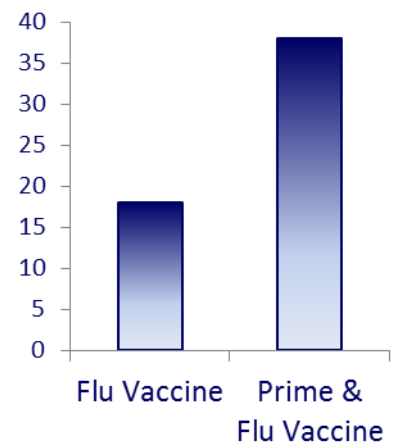
Produced in *E.coli* year-round



## "QUICK-TO-MARKET"

- Proof of concept already demonstrated in **4 successful clinical trials** involving **440 participants**
- Two Phase I/II as well as **two Phase II clinical trials completed**, in young adults (aged 18-49), older adults (aged 55-75) and elderly (65+)
- **Good safety profile, well-tolerated** and **immunogenic**
- M-001 can serve as **universal flu vaccine** and **universal primer** for strain-specific flu vaccines
- When given to **elderly** as **prime** before standard seasonal flu vaccines results in more elderly attaining sufficient immune responses (HAI)
- **Priming indication** allows evaluation of immunogenicity using the **standard surrogate marker for flu protection (HAI)** accepted by FDA and EMA regulatory authorities
- **Priming indication** provides **short and clear regulatory pathway to licensing**

% Responders to Swine Flu Strain in Flu Vaccine



# M-001 : Universal Flu Vaccine & Universal Primer for Standard Flu Vaccines

## Universal Primer: Unmet Need



### For Elderly and Seasonal Flu Vaccine:

- 70% (in US) of elderly (65+) receive standard flu vaccines but only small proportion respond sufficiently (HAI)
- Elderly more likely to experience ‘slippery slope’ whereby complications of flu lead to hospitalization and death; 90% of flu-related deaths are elderly
- Flu disease has high associated economic burden; estimated at \$90 billion in US
- Growing elderly population; predicted 1 in 4 will be 65+ in OECD countries by 2050

### For General Public in Event of Pandemic Flu:

- Adults respond poorly to existing avian pandemic H5N1 flu vaccines
- Avian pandemic H5N1 flu vaccine must be given at least twice in high doses, will be difficult for supply to meet demand in time (takes 6-8 months to produce)

## Universal Primer: Value Proposition

Difference in Medicare payments for high dose vs. standard seasonal flu vaccine is ~\$15; therefore, M-001 primer can be priced at \$5 – \$15 per dose

### Yearly Seasonal OECD Sales Potential:

\$315 - \$1,900m

### Pre-pandemic OECD Sales Potential:

\$1,500 - \$13,500m

Peak Sales (\$ m)		Uptake in Elderly		Peak Sales (\$ m)		Uptake in General Public	
		35%	70%			25%	75%
Price per Dose (\$)	5.00	\$315	\$650	Price per Dose (\$)	5.00	\$1,500	\$4,500
	10.00	\$650	\$1,250		10.00	\$3,000	\$9,000
	15.00	\$950	\$1,900		15.00	\$4,500	\$13,500

#### Assumptions for Peak Sales:

- Uptake is proportion of people that receive M-001 as well as strain-specific flu vaccine
- Current population in OECD is 1.2bn , of which 15% are elderly (OECD Factbooks 2009 and 2011)