hVIVO plc

2018 Interim Results

20 September 2018

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The Company reports under IFRS. Where foreign currency equivalents have been provided for convenience in this presentation, the exchange rates applied are those used in the relevant financial statements from which the figures have been extracted.

Today's Presenters

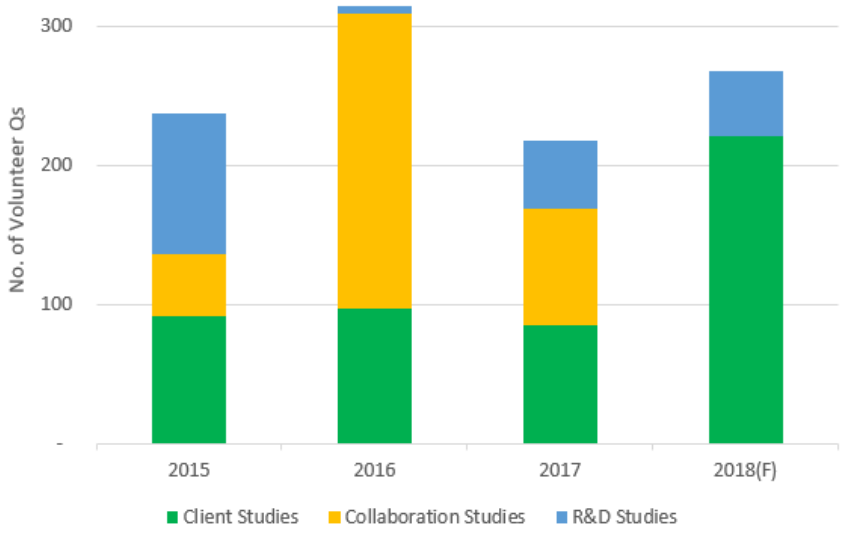
Dr Trevor Phillips
Executive Chairman
hVIVO

Graham Yeatman
Chief Financial & Business Officer
hVIVO

Executing on Our Strategy

1. Strong operational progress coupled with financial discipline
2. Seeing strongest potential sales pipeline for several years
3. Translation of sales pipeline into active contract negotiations, suggests improved outcome for H2 2018 and FY 2019 revenue
4. Impact of cost reduction initiatives and increased revenues will continue to improve bottom line

Financial Highlights H1 2018



	H1 2018	H1 2017	2017
Revenue	£4.9m	£3.9m	£10.9m
Gross profit	£1.2m	£1.0m	£3.6m
Gross margin	24.0%	25.6%	32.7%
Other income	£1.5m	£0.1m	£1.5m
R&D expense	£(2.8)m	£(2.8)m	£(6.1)m
Administrative expense	£(4.9)m	£(6.1)m	£(11.4)m
Loss on provision of services to JVs	£nil	£(0.7)m	£(0.8)m
Share of loss of associate & JV	£(0.4)m	£(0.6)m	£(1.6)m
Taxation – R&D tax credit refund	£0.9m	£1.4m	£1.9m
Loss for the period	£(4.4)m	£(7.7)m	£(12.9)m

Revenue

£4.9m

from client studies completing in H1'18

Gross Profit

£1.2m

lower utilisation in H1'18, but building from Q4'18

Other Income

£1.5m

£1.4m from DARPA cost share

Loss for period

£(4.4)m

Tightening cost base – turning point for becoming profitable

- Growing sales pipeline starting to convert - £11.9m contract signed post period end, commencing in Oct '18
- Driving operational efficiency and cost saving initiatives, focusing on the Company's core business
- Driving revenue growth and cash generation – exercising tight cost control & efficiency programmes to ensure we achieve profitability in 2019
- R&D expense – Prioritised spend completing a smaller no. of previously initiated projects – Includes £1.3m for flu contagiousness project, with cost share from DARPA

Balance Sheet: 30 June 2018

	30 June 2018	30 June 2017	31 Dec 2017
Non current assets	£17.5m	£19.6m	£18.0m
Current assets	£18.1m	£26.4m	£26.8m
Non-current liabilities	£(1.6)m	£(3.3)m	£(2.3)m
Current liabilities	£(4.6)m	£(4.3)m	£(9.2)m
Net assets	**£29.3m**	**£38.4m**	**£33.4m**
Cash at bank and on short term deposits	£10.7m	£15.4m	£20.3m
Contract assets (Accrued income)	£nominal	£nominal	£0.4m
Contract liabilities (Deferred income)	£(2.2)m	£(1.3)m	£(5.8)m

- Cash of £10.3m, prioritising spend and extending cash runway from building client clinical study pipeline, together with operational efficiencies and cost savings initiatives reducing cash burn and extending cash runway
  - £2.5m R&D tax refund received in July ‘18
  - Targeting cash flow positive in H2’18
- Non-current assets movement primarily relates to share of loss of PrEP Biopharm and Imutex
- Current assets reducing with cash
- Current liabilities movement primarily due to timing of new contract signatures and recognition of contract liabilities
- Non-current liabilities relate to unwinding of provisions against onerous leases and dilapidations

Financial Outlook

- Driving revenue growth and cash generation
- Targeting sustainable profitability – profitable in 2019
- R&D spend for 2019 will reduce significantly compared to 2018
  - Will only work on programmes designed to support/enhance service offerings
- Disciplined approach to capital allocation
- Multiple cost reduction initiatives enacted
  - Focus on efficient and effective operations to achieve operational excellence
  - Impact of changes will be fully realised in 2019

Operational Highlights H1 2018

- **Progress across contracted pipeline**
  - ***Human challenge studies:***
    - Conducted for multiple clients – range of challenge virus models
    - Initiation of novel cough model study – HRV
    - Encouraging level of pipeline contracts for Q4 2018 and beyond
    - Significant pipeline contract negotiations ongoing – expect to sign in 2018 & 2019
      - Will lead to very high level of unit occupancy in 2019
  - ***US Government agency collaboration:***
    - Good progress on flu contagiousness project, with cost-sharing grant with DARPA / Prometheus programme
      - Successfully concluded the clinical phase of the flu contagiousness challenge study - results to DARPA
      - Commenced data analytics work with DARPA to generate an algorithm to predict contagiousness
      - Project due to complete by end 2018

- **Driving operational excellence with cost efficiency**
  - Supporting drive to achieve sustainable profitability
    - Amend operating structure & processes
      - Streamlining processes and removing silos
    - Reduced cost base, significant process efficiencies
    - Focus on core business activity
      - Closing Welwyn
      - Ceasing research & discovery activities to focus only on activities designed to support/enhance service offerings

Operational Highlights H1 2018

- **Joint ventures – progress made**

  - ***Imutex***:

    1. **FLU-v** – strong FLU-v data package around a first-in-class 'universal', broad spectrum, standalone, flu vaccine candidate
    – Positive results from the Phase IIb Field (FLU-v 003) and Challenge studies (FLU-v- 004)
    – Management believe FLU-v is now able to advance into Phase III development
    – Further data analysis and full and final results of FLU-v 004 to be published by (NIAID), in due course
    – Publication of the FLU-v 003 full results by Universal Influenza Vaccines Secured Consortium (UNISEC) in due course

    2. **AGS-v** – universal mosquito-borne diseases vaccine candidate
    – Results of AGS-v Phase I first-in-man study conducted at NIAID expected by end 2018

  Exploring strategic alternatives with regards to both assets, including but not limited to a full sale, a licensing agreement or a non-dilutive funding

  - ***PrEP Biopharm:***

    1. **PrEP-001 –** novel pan-viral prophylactic
    – PrEP Bio management continue to plan for future development of PrEP-001

- **Board change**
  - Graham Yeatman, Chief Financial & Business Officer to step down from Board at end December 2018
  - Shelley Fraser FD, from immediate effect

Unique Market Opportunity

Human challenge studies

- Concept of human challenge studies not new:
  - hVIVO leading the way in the use of human challenge studies to establish early proof of concept
  - hVIVO expanding concept into product development for airways disease (asthma, COPD, cough) – ability to reduce cost, time and risk of achieving POC considerable – significant interest from big pharma
- Encouraging level of pipeline contract negotiations for Q4 2018 and beyond
  - Recent contract for £11.9m signed post period end

Human challenge model - clinical development -

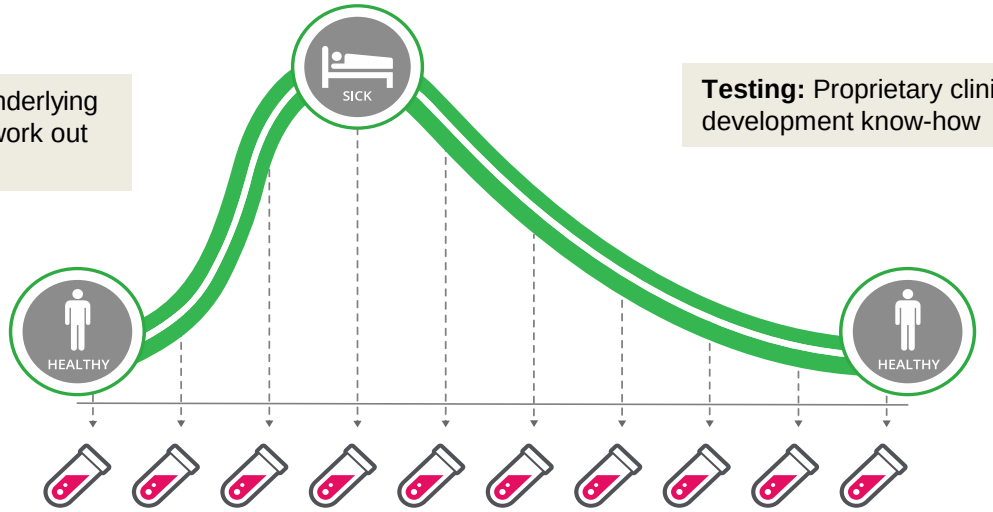
- Provide early proof of concept efficacy data for candidate selection
- Enable accelerated development of pipeline compounds, through early identification of endpoints
- Effectively translate animal data to human endpoints and to relate healthy volunteer data to field outcome
- Require relatively small numbers of subjects, hence lower time and cost, to achieve clinical proof-of-concept
- Lower the subsequent risk of negative outcomes when performing large field-based Phase II and III studies, given that the early detection of efficacy and identification of endpoints can strengthen protocol design and patient selection in the later phase studies

hVIVO's Established Human 'Disease in Motion' Approach

Rich source of data from proprietary clinical platform enables early profiling and targeting of drug candidates in airways disease

Biological Insight

Discovery: Reveals the underlying biology. Takes the guess work out of targeting therapeutics



Testing: Proprietary clinical development know-how

Clinical Trials

See disease in motion

- Uncovers biological activity usually hidden from view
- Illuminates the healthy to sick journey
- Captures acute onset

Tackles uniquely human diseases

- Ineffective animal models linked to high unmet medical need
- Flu, RSV and Cold viruses used to generate and exacerbate disease state

Industry leading clinical development know-how and pioneer in conducting viral and allergen challenge studies in humans

Strategic Priorities

Driving revenue growth with cash generation

- Strong pipeline of sales negotiations expected to be realised as contracted studies in 2019-2020
- Driving revenue growth and cash generation in turn leading to sustained profitability
- Operational excellence - driving operational efficiency and cost containment as we continue to focus on the core business
- Progress strategic discussions with regards to FLU-v to maximise the strategic options available to the Company and Imutex
- Fund further progression of own/part-owned programmes only through partnering / out-licensing / non-dilutive sources – HVO-001, Imutex, PReP

The FLU-v Story

Broad Spectrum Stand-alone Influenza Vaccine

1 Compelling Market Opportunity – FLU-v

- Opportunity to redefine the influenza market with a blockbuster global sales potential

2 Supportive Regulatory and Academic Environment

- Key parties are pushing for a universal solution

3 Unique Solution with Compelling Competitive Advantage

- Only product to demonstrate efficacy to date; Broad spectrum (A, B and Pandemic Strains), true stand-alone

4 Excellent Clinical Profile

- Highly robust Phase II-b field and challenge study results supporting readiness for Phase III

5 Robust Patent Portfolio in Place

- Wide-ranging multi-national patents and market exclusivities covering both vaccine components and their homologies

6 Simple, Cost-effective and Scalable Manufacturing Process

- Classic synthetic manufacturing process provides significant advantages to biological systems

7 Innovative Platform for Significant Applications Beyond Influenza

- Compelling platform for capabilities in the broader antiviral space

Exploring strategic alternatives with regards to both assets, including but not limited to a full sale, a licensing agreement or a non-dilutive funding

Compelling Market Opportunity

Flu is a Global Issue

Seasonal Flu[1]

	**3,000,000** hospitalisations	**290,000-650,000** deaths	**$260bn** economic burden
	**200,000** hospitalisations	**12,000-56,000** deaths	**$87bn** economic burden
	**19,000** hospitalisations	**8,000** deaths	**£55-72bn** economic burden

Pandemic Flu[2]

- Pandemic strain: new to human
- We can't predict when or where the next epidemic or pandemic will begin
- Many challenges exist worldwide that increase the risk that outbreaks will occur and spread rapidly, including:
  - Increased risk of infectious pathogens "spilling over" from animals to humans
  - Development of antimicrobial resistance
  - Spread of infectious diseases through global travel and trade
  - Acts of bioterrorism
  - Weak public health infrastructures

A severe pandemic can result in millions of deaths, and even the most conservative estimates suggest that pandemics reduce global GDP by up to 1%

[1]http://www.endfluenza.com [2]CDC, WHO

Outlook and 2018 Newsflow

- Committed to a strategy of driving revenue growth and cash generation and in turn leading to sustainable profitability
- Ongoing cost control and efficiency programmes
- Disciplined approach to capital allocation, supporting/enhancing service offerings
- Successfully convert growing number of sales leads into contracted work
- Strategic alternatives for further development of Imutex assets
- Board expectations remain unchanged for the full year – higher level of sales for H2 vs H1
- Full impact of actions to be realised in 2019

NEWSFLOW		
Programme/work	**Partner/collaborator**	**Event**
AGS-v Phase Ib study mosquito-borne illness vaccine platform	Imutex / NIAID	Results expected by end 2018
FLU-v 004 - Phase IIb field study	Imutex / UNISEC	Full and final results published by NIAID – expected Q4 2018
FLU-v 003 - Phase IIb challenge study	Imutex / NIAID	Full results published by UNISEC – expected Q4 2018

To become the partner of choice for companies developing products in airways disease

Appendices

hVIVO – Uniquely Positioned Clinical Development Services Business in Airways Disease

Company Profile

- Listed in UK on AIM (HVO)
  - Established in 1989 - spin out from Queen Mary University, London
- Headquarters, London
  - Quarantine unit opened 2011
  - c. 130 employees
- Blue chip institutional investor base

FYE 31-Dec-2017 & HYE 30-Jun-2018 Financials

- Revenue: £10.9m (£4.9m)
- Gross profit: £3.6m (£1.2m)
- Short term deposits, cash & cash equivalents: £20.3m (£10.7m)
  - Committed to driving revenue growth and cash generation leading to sustained profitability
  - Ongoing tight cost control and efficiency programmes
  - Disciplined approach to capital allocation

Significant Know-how and Proprietary Models

- Industry leading clinical development services business
- Pioneer of human disease models based upon viral and allergen challenge
- Industry leading human-based clinical trial platform to accelerate drug and vaccine development in respiratory and infectious diseases

Established Global Customers and Collaborations

Significant Shareholders

As at 30 August 2018, hVIVO plc is aware of the following interests in more than 3% of its shares:

	No.	%
Woodford Investment Management	22,138,760	27.95%
Invesco Perpetual	21,249,382	26.83%
IP Group	13,063,883	16.49%
Lansdowne Partners	4,734,271	5.98%
Sand Aire	3,076,031	3.88%

FLU-v

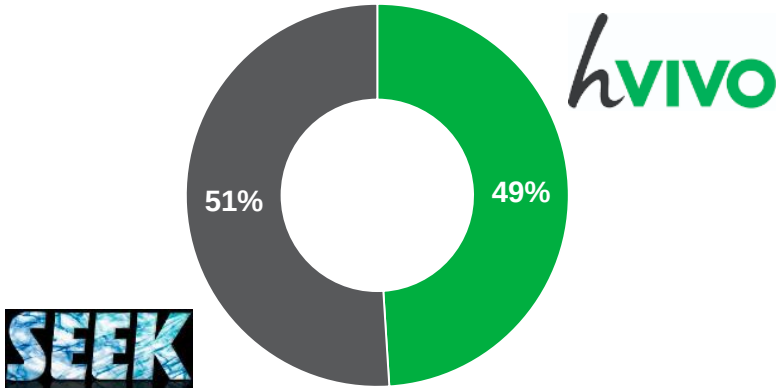
Imutex Limited

Imutex – Exciting Key Asset has the Opportunity to Redefine the Global Flu Vaccine Market

Overview

- In April 2016, hVIVO plc ("hVIVO") formed **Imutex Limited** ("Imutex") with the SEEK Group ("SEEK") to develop vaccines against influenza (FLU-v) and universal mosquito-borne diseases (AGS-v)
- Imutex's most advanced asset **FLU-v** is a robust and differentiated advanced-stage influenza vaccine candidate
  - Significant potential as a long-lasting broad spectrum stand-alone vaccine
  - Highly supportive positive Phase II-b results and currently close to readiness for Phase III
  - Broad impact for a burden on global public health in an estimated market worth between $10-20bn

Supportive and Experienced Shareholders



Current Pipeline

Candidate	Phase: Pre-Clinical	I	II	III	Status
FLU-v *Influenza*	➔	➔	➔	➔	• Endpoints and efficacy met in Phase II-b field study and challenge study in collaboration with NIAID/NIH in the U.S. and UNISEC consortium in the EU • Ready for Phase III in Europe and U.S.
AGS-v *Mosquito-borne Diseases*	➔	➔			• Phase I-b results expected by end 2018

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[1]http://www.endfluenza.com [2]CDC, WHO

2 Supportive Regulatory and Academic Environment

Parties Pushing for a Universal Influenza Solution

- **FDA and EMA are both supportive for development of a universal flu vaccine; Imutex will now work with both the FDA and the EMA to progress pathway**
- **Large number of academic, public and private organisations, which Imutex is working with (such as, WHO, BARDA, NIH), encourage development of a universal flu vaccine – Imutex working with these organisations**

WHO

Global Vaccine Plan which calls for at least one licensed universal influenza vaccine by 2020

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Prefer a standalone vaccine over a booster to the annual vaccine

NIH
National Institutes of Health

Strategic Plan for developing a universal influenza vaccine

BARDA
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Prioritise support for vaccines that induce broad immunity so as to prime the population against newly emerging influenza viruses or other respiratory viruses of pandemic potential

USAMRIID
United States Army Medical Research Institute of Infectious Diseases
Biodefense solutions to protect our nation

Medicines & Healthcare products Regulatory Agency

Supportive of development of universal flu vaccine at various stages, from pre-clinical evaluation to clinical trials

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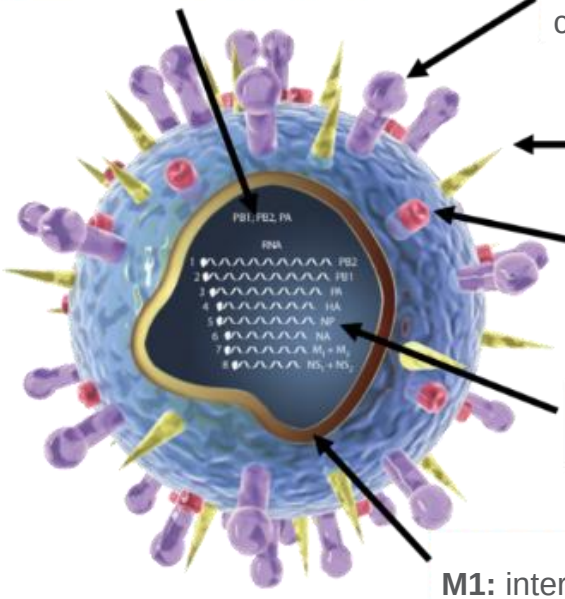
3 Differentiated Approach in the Influenza Vaccination Space

FLU-v – Broad Spectrum Stand-alone Flu Vaccine Candidate | A, B and pandemic strains

An equimolar combination of four individual synthetic polypeptides (20 to 32 aa long) covering conserved immunogenic regions in M1, M2 and NP-A and NP-B

Non-structural proteins. Conserved
Potential targets for T cell immunity



HA: surface, highly variable immunodominant head conserved stem

NA: surface, variable, slower drift

M2: surface, fairly conserved. Possible Ab-medicated protection

NP: internal highly conserved. Induces CMI

M1: internal highly conserved. Induces CMI

3 Differentiated Approach in the Influenza Vaccination Space

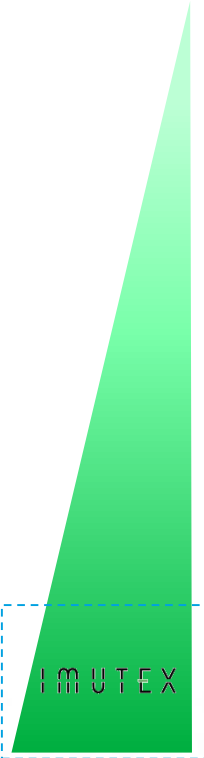
Clear Advantage in Terms of Vaccination Frequency and Strain Coverage

Imutex has a unique solution with compelling competitive advantage over both vaccination frequency (no more than once every 5 years) and strain coverage (annual, pandemic and A & B in both humans and animals)

Proposed Solutions

	Advantages	Considerations
Booster to Annual	• Vaccine given alongside the annual that boosts the immune response and provides cross protection against strains if the guess is wrong or if they drift slightly during the season	• Doses limited by annual manufacturing cap • No supporting evidence that a boosted immune system can provide broad strain protection • Relies on findings from swine flu pandemic
Standalone	• Vaccines given alone, no need for annual • HA head/stem or stalk only targets certain groups of flu strains; peptide approach can target A, B or all strains	• Needs to be updated regularly and people re-vaccinated regularly, or may still need to receive the annual vaccine if the strain circulating is different • Will not cover a pandemic strain • **If standalone covers all strains then none of the above issues arise**

NIH[1] Schematic of Solutions



Vaccine	Coverage
Strain-specific	Current circulating strains
Subtype-specific	All strains within a single HA subtype (e.g., H1)
Multi-subtype	Multi HA subtype within single group (e.g., H1/H5/H9)
Pan-group	Covering all group 1 and 2
Universal influenza vaccine	**All influenza (+/-influenza B)**

Imutex approach has full-spectrum strain coverage

- Source: Company information
- [1] National Institutes of Health.

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4 Excellent Profile

FLU-v Overview

- **FLU-v was effective against all human A and B strains and animal strains (which become pandemic strains)**
- **Most robust and consistent data package in the market for statistically significant reductions in both infection rate and symptom severity for confirmed influenza**

High Confidence with Two Phase II-b Study Results	•Flu-v 003 study showed statistical significance in key immune indicators, an 83% reduction in severe influenza and better than placebo in all other efficacy endpoints •Flu-v 004 study showed statistical significant results in reduction in number of confirmed influenza cases
Universal	•Tested across multiple A&B strains anticipate full coverage of all human strains •Covers all animal strains – pandemic protection •Both immune arms activated – T&B cells
Vaccination	•Single injection •Stand-alone vaccine, not linked to or limited by annual vaccine •Long lasting protection •Can vaccinate all year round, not limited to annual production
Manufacturing	•Synthetic process, low cost and efficient •Freeze dried, no need for cold-chain storage & transport
Evidence	•Immune response and clinical efficacy from two phase II studies •Real world and viral challenge studies •Phase III ready, breakthrough designation potential

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4 Excellent Profile

FLU-v 004 Phase II-b Challenge Study | Results Summary

✓ **Statistically significant results in reduction in number of confirmed influenza cases**

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4 Excellent Profile

FLU-v 003 Phase II-b Field Study | Design

A randomised, double-blind, placebo-controlled, real world study in 176 volunteers to evaluate safety, immunogenicity and efficacy of different formulations and dosing regimens S/C in collaboration with UNISEC[1]

Aims		
Confirm the safety and tolerability of different regimens and formulations of FLU-v	Determine the immunogenicity response (T&B cells mediated) to FLU-v vaccination	Determine the efficacy of FLU-v in a Real World setting

Vaccination – 4 groups: Day 0 and 21

Two regimes were tested:
Single dose adjuvanted FLU-v (500ug in emulsified adjuvant)

Two doses, given 21 days apart, of non-adjuvanted FLU-v (500ug in saline vehicle)

Both regimes had matching placebo

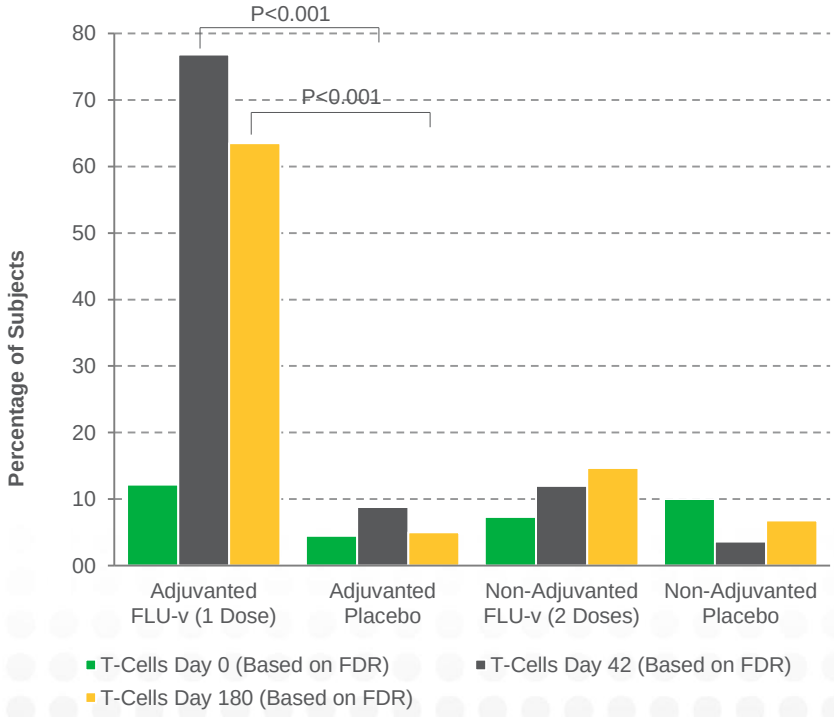
[1] Universal Influenza Vaccines Secured

4 Excellent Profile

FLU-v 003 Phase II-b Field Study | Primary and Secondary Endpoints Results Met

Primary Endpoint – T-Cell Mediated Immune Response

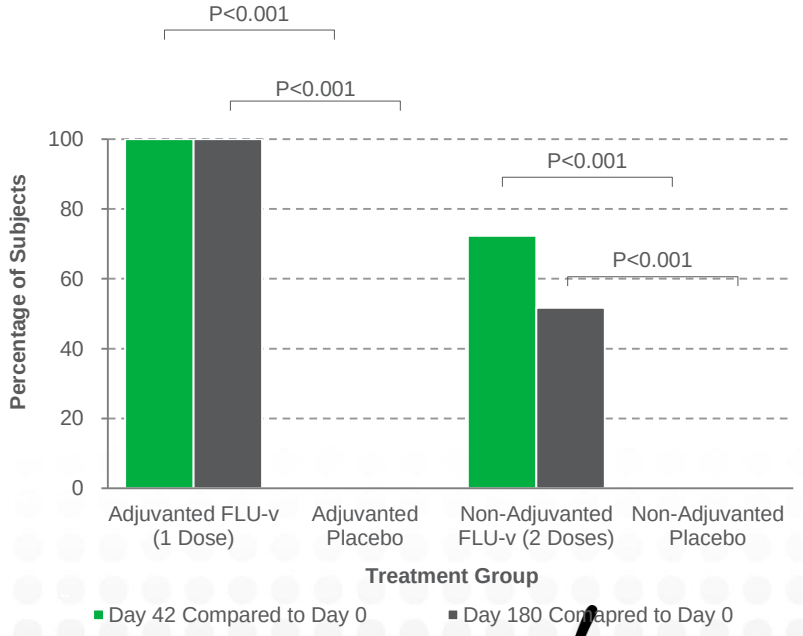
- Primary endpoint of enhancing T-cell responses was met demonstrating a statistically significant enhancement of the number of responders positive for interferon gamma (IFNg) producing T-cells (p<0.001), at both 42 days and 180 days after single vaccination
- IFNg is one of the most important markers of T-cell and immunoglobulin of B-cell mediated immunity effective against influenza infection
- Similar results obtained with TNFa and IL-2 responders



Secondary Endpoint – B-Cell Mediated Immune Response

- Secondary immunogenicity related endpoint was to assess the FLU-v specific antibody, immunoglobulin (IgG) responses at both 42 and 180 days after single vaccination compared to placebo
- The secondary endpoint achieved a statistically significant increase in antibody titers of 100% of vaccinated subjects (p<0.001)

Frequency of IgG Responders



4 Excellent Profile

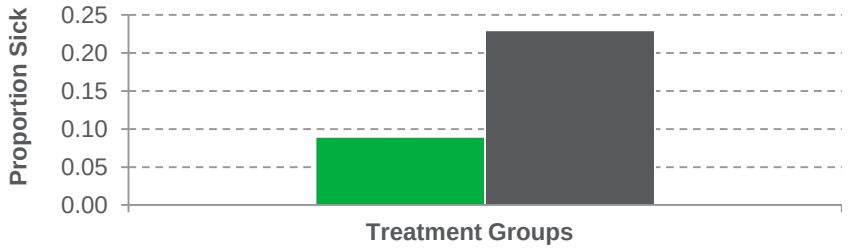
FLU-v 003 Phase II-b Field Study | Symptom / Severity Score and Safety

- **The reduction in the number and severity of symptoms observed in this study was consistent with the top-line FLU-v 004 challenge study results**
- **In this study a single dose of FLU-v was shown to induce the strongest immunological response rates and this group also experienced a 60% reduction in influenza confirmed infections and an 83% reduction in the number of influenza confirmed cases with severe symptoms compared to placebo**

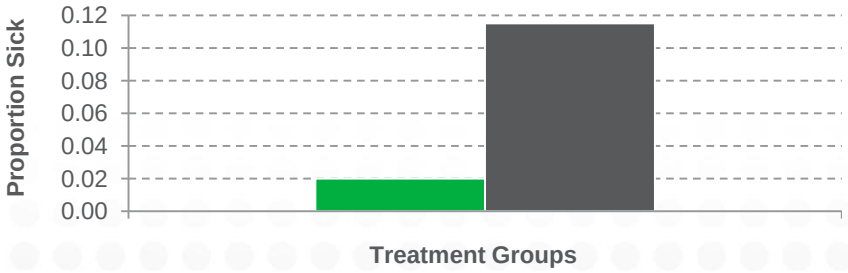
Symptom / Severity Score

Consistent Trend in Reduction of Infections and Influenza Symptoms (Number, Severity & Duration) Following Single Dose of FLU-v

Positive Influenza (FAS)



Positive Influenza Severe Symptoms (FAS)



■ Adjuvanted FLU-v (1 dose) (N=51) ■ Adjuvanted Placebo (N= 26)

- **NB: Study not powered for efficacy**

Safety

Safe & Well Tolerated

Main AE's mild/moderate, some severe at site of injection only

As expected, adjuvant formulation increases number of transient injection site reactions

5 Robust Patent Portfolio in Place

Wide-ranging multi-national patents and market exclusivities covering both polypeptides and polypeptide-inclusive compositions, as well as their homologies

- Robust patent portfolio filed in 34 countries
- PCT Application filed in 2007
- 21 patents granted (in US, EU, Eurasia, China and many other countries)
- 13 pending patents (also in US, EU and many other countries)
- Up to 10 year market exclusivity on grant of market authorisation in certain major countries

6 Simple, Cost-effective and Scalable Manufacturing Process

No constraint on manufacturing capacity as synthetic process and not biological system allowing all year round manufacturing

- Stable at 5° Celsius for 2 years, no preservatives added
- Finished product mixed with Adjuvant and water for injection
- Freeze drying minimises cold-chain during storage and transport
- Low cost and scalable manufacturing up to kg levels and can be undertaken in multiple plants around the world

7 Innovative Platform for Significant Applications Beyond Influenza

Imutex's exciting pipeline and platform capabilities provide significant long-term strategic benefits reaching beyond the field of vaccines

- ✓ **Access to innovative universal influenza treatment recognised by the NIH as a potential game-changer**
- ✓ **Proven symptom reduction capabilities**
- ✓ **Opportunity to explore supplemental strategic alternatives thanks to massive data collection capabilities associated with global reach of FLU-v**
- ✓ **Platform for additional attractive indications**