hVIVO

Infectious diseases

Flu vaccines & treatments

THE CHALLENGE

Seasonal influenza ("flu") causes significant morbidity and mortality each year and the threat of a pandemic influenza continues to pose a global issue to health. Government health agencies and organisations and a large number of academic, public and private organisations, encourage development of universal / broad spectrum flu vaccines. Novel correlates of protection are being explored and the role of cellular immunity has come to the forefront of vaccine research. Healthy volunteer human challenge models of wild-type influenza will play a major role in this development process.

PROVEN FLU DISEASE MODELS

hVIVO has been studying influenza for over 20 years and been conducting influenza human challenge studies with our flu disease models for more than 15 years.

We have conducted numerous flu challenge studies for a range of industry, governmental and academic clients, making our models the most well-used commercial flu disease models available on the market.

FLU VACCINES

CONCEPTUAL CHALLENGES

Demonstrating efficacy of novel vaccines in the field is time-consuming, costly and associated with risk

- Initial exposure to virus unknown
- Variation in circulating strains
- Large study size and duration
- Difficult to power for clinical efficacy
- Seasonality limitations
- Biomarker identification difficult

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

- Effective exploration of vaccine efficacy & correlates of protection
- Match study design to product mechanism of action
- Immunological Assays
- Host Response Analysis
- Time-dependent measurements of biomarkers

Primary Endpoints:

- Reduction in incidence of symptomatic infection
- Reduction in disease severity

ANTIVIRALS AND TREATMENTS

CONCEPTUAL CHALLENGES

Establishing efficacy of anitvirals in early clinical trials in influenza is challenging

- Initial exposure to virus unknown
- Dose ranging and timing difficult
- Comorbitities and other confounders

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

Clinical proof-of concept and dosing finding delivered in a controlled setting

- Study design matched to investigational product mechanism of actions
- Optimisation of treatment timing
- Time-dependent measurements of biomarkers
- Triggered-dosing options (time or virological)
- Controlled strain exposure
- Consistent placebo response
- Flu season independent
- Efficient resistance monitoring

IMMUNOMODULATORS

CONCEPTUAL CHALLENGES

Demonstrating clinical efficacy in early stage field trials is challenging

- Baseline prior to infection unachievable, difficult to establish host response
- Effect with/without standard of care treatment difficult to establish
- Large study size and duration
- Seasonality limitations
- Circulating strain variation
- Biomarker identification difficult
- Initial exposure to virus unknown

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

Clinical proof-of-concept and host-virus interaction in a controlled setting

Well controlled quarantine environments

- Baseline well established prior to infection
- Appropriate for both prophylaxis and treatment
- Flexible dosing and timing
- Establish safety & efficacy to impact infected subjects host response
- Investigate and demonstrate target engagement
- Controlled combination-treatment with drug and standard of care or antivirals

INDUSTRY LEADING PROVIDER OF VIRAL CHALLENGE STUDIES

CHALLENGE STUDIES

Provide early human proof-of-concept efficacy data to support drug and vaccine candidate selection

Support accelerated development of pipeline compounds, through early identification of the appropriate endpoints, dose response and timing and biomarkers for incorporation in later clinical studies

Reduced costs as the model requires a relatively small number of subjects investigated over a shorter period of time to deliver an efficacy outcome

OUR CHALLENGE MODELS

INFECTIOUS DISEASES
- FLU
- HRV
- RSV

RESPIRATORY
- ASTHMA
- COUGH
- COPD

LAB SERVICES

LABORATORY OFFERING
- Virology
- Immunology
- Biomarkers

HVIVO HUMAN CHALLENGE FULL-SERVICE SOLUTION

Unparalleled experience in the design, conduct and analysis of human models of disease

- Study design & protocol development
- Recruitment
- Monitoring
- Ethics & regulatory submission
- Pharmacy
- Data management and biostatistics
- Laboratory support
- Biomarker development
- Clinical Study report
- Clinical Trial: Inpatient or outpatient

STANDARDISED STUDY PROCESS

'Commited to delivering study excellence'

Protocol design
- Study management process
- Services deliver quality results
- Meeting client needs and timelines
- Trials conducted using controlled settings and processes

Screening & recruitment
- Recruitment of volunteers in the UK using the 'FluCamp' brand

Quarantine
- Bespoke quarantine unit in Whitechapel, London for conducting challenge studies: 24 en-suite rooms

Viral challenge
- Well characterised challenge
- Exact exposure time to virus

Intensive sample collections
- Virology
- Immunology
- Biomarkers

Quarantine discharge and follow up
- Immunugenicity
- Seroconversion
- Standard 28 days can be up to 1 year

ABOUT HVIVO

Established in 1989 as a spin out from Queen Mary University, London, hVIVO is a trusted partner and industry leading clinical development services business pioneering human disease models based upon viral challenge. Using human challenge studies to establish early proof of concept, hVIVO's clinical trial platform can accelerate drug and vaccine development in respiratory and infectious diseases specifically leveraging hVIVO's established human disease challenge models in influenza 'flu', respiratory syncytial virus 'RSV' and human rhinovirus 'HRV' and more recently the expansion and development of these models in other respiratory indications for asthma, chronic obstructive pulmonary disease "COPD", cough and related new therapies and in special populations.

For more information contact: BD@hvivo.com

** human rhinovirus (HRV) and respiratory syncytial virus (RSV)*