hVIVO

Infectious diseases

RSV vaccines and treatments

THE CHALLENGE

Respiratory syncytial virus (RSV) is the single most important cause of lower respiratory tract infection (LRTI) in infants and young children worldwide and can cause LRTI in elderly and immunocompromised patients; it is associated with significant morbidity and mortality in these populations. However, RSV is recognised as a significant cause of respiratory illness in all age groups and there are no effective licensed therapies generally available. Novel correlates of protection are being explored and developing vaccine correlates can assist to bridging other populations. Healthy volunteer human challenge models will play a major role in the development process.

VALIDATED RSV MODEL

Created a novel RSV challenge model now validated across multiple studies

Conducted a number of human RSV challenge studies for a range of customers:

- Currently, the only validated RSV challenge model commercially available
- Validated across multiple studies with vaccines and antivirals directed towards RSV

VACCINES

CONCEPTUAL CHALLENGES

- Testing proof of concept in the target population (pediatrics or elderly)
- No clear product development pathway
- Correlates of infection are poorly understood
- Lack of fully translatable immunogenicity animal models

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

- Healthy adult model enables fast efficient proof of concept demonstration and safety in disease model before moving to at risk populations in field trials
- Elderly (60+) model, enables demonstration of proof of concept in target population with weakened immunity
- For vaccines, both options facilitate efficient investigation of known and novel correlates of vaccine protective effect

ANTIVIRALS / TREATMENTS

CONCEPTUAL CHALLENGES

- Testing proof of concept in the target population (pediatrics or elderly)
- No clear product development pathway
- Correlates of infection are poorly understood
- Lack of fully translatable immunogenicity animal models

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

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
- Efficient resistance monitoring

IMMUNOMODULATORS

CONCEPTUAL CHALLENGES

- Limited RSV immunomodulators in development
- Limited focus on adult/elderly populations

hVIVO HUMAN CHALLENGE MODELS: TOWARDS A DEEPER UNDERSTANDING

- 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)*