Infectious Diseases

RSV vaccines and treatments

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 MODELS

RSV challenge model now validated across multiple studies

New older adults model available

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
- New RSV challenge model available in older adults (60-75) - targets population associated with significant unmet need in RSV

RSV 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

Primary & Secondary Endpoints:

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

Antiviral/Treatments

Conceptual Challenges

Establishing efficacy of antivirals in early clinical trials is challenging Initial exposure to virus unknown

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

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

Immunomodulator

Conceptual Challenges

Demonstrating clinical efficacy in early stage field trials is challenging Initial exposure to virus unknown

- 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
- Circulating strain variation
- Biomarker identification difficult

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