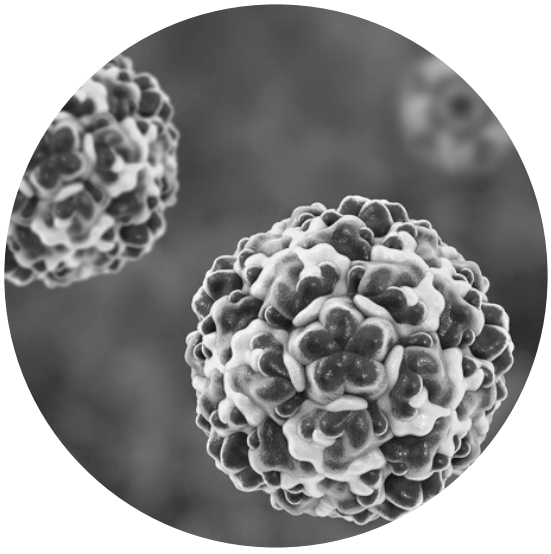
Rhinovirus human challenge study

How Virtus helped to investigate the efficacy, safety and pharmacodynamics of a new inhaled immunomodulator

The challenge

Pulmotect is developing a novel inhaled immunomodulator (PUL-042), which had shown efficacy in pre-clinical models against viral and bacterial infections and had completed two Phase I studies in healthy individuals.

Pulmotect wanted to generate a comprehensive dataset on the safety, pharmacodynamics and potential efficacy of PUL-042 to inform future trial design in COPD subjects, which was a potential target indication.



Approach

Most COPD exacerbations are caused by respiratory viral infections, such as human rhinovirus. Therefore Virtus designed a bespoke human virus challenge study, which was the most time and cost-effective way to generate COPD exacerbation relevant data.

This involved infecting GOLD 0 COPD subjects with rhinovirus (strain RV-A16). Study endpoints included multiple safety outcomes, cold and COPD specific symptom scores, lung and systemic markers of inflammation, and upper and lower airway virus load.

The double-blind study involved 10 subjects per arm, with 16 visits over 6 weeks performed in a specialised research facility in London.

Results

143 subjects were screened in total, 24 passed screening and were enrolled into the study. 20 subjects completed the study, and all 20 individuals were successfully infected with rhinovirus, as shown by positive virus load in nasal or sputum samples or seroconversion at day 42. The study generated over 30,000 unique data points from these 20 subjects and included data in all desired categories. PUL-042 was safe and well-tolerated, showing a safety profile similar to healthy subjects.

The study confirmed the safety profile of PUL-042 and also identified new systemic and local biomarkers suggesting a unique mechanism of action to better inform future trial designs.

- **100%** successful infection rate
- Demonstrated **safety** in target population
- Over **30,000** unique data points generated
- New biomarkers identified suggesting a **unique** mechanism of action

"This Phase 2a trial helped to further demonstrate the safety and characterize the activity of PUL-042. While exploratory, it provided key data to help shape future trials and potentially open up new indications for the platform technology of boosting immunity in the lungs.."

Colin Broom, MD, CEO
Pulmotect Inc

Outcomes & Impact

The study showed that PUL-042 was safe and well-tolerated in this subject population at the doses used and facilitated further studies in COPD subjects. PUL-042 was pharmacologically active, local and systemic effects including changes in the peripheral blood further underscore the fast and potent immunomodulatory activity of PUL-042 when given via the inhaled route. PUL-042 induced a defined set of biomarkers useful for further study.

The vast amount of safety, biomarker, microbiological and virological data demonstrate how valuable and cost-effective virus challenge models are when matched with diverse sampling techniques.

Find out more at :

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