Respiratory syncytial virus (RSV) is recognized as a significant problem in both pediatric and adult immunocompromised hosts and is associated with significant morbidity and mortality. The severity of clinical manifestations and the incidence of mortality depends on the magnitude of the immune suppression. The group at highest risk for severe RSV infection is bone marrow transplant recipients. We have previously demonstrated that our product, RI-002 which is an IVIG containing standardized, high levels of neutralizing anti-RSV antibody titers prevents pulmonary infection in a cotton rat model of RSV, an animal model regarded as the ideal surrogate for RSV infection in humans. RI-002 is nearing completion of its phase three clinical trial designed to prevent serious infections in patients with primary immune deficiency disease (PIDD).

The studies described were designed to determine whether RI-002: 1. Could prevent systemic dissemination of the virus 2. Could treat normal and immune suppressed RSV infected animals 3. Could prevent systemic dissemination of the virus

Methods

Animal studies: cotton rats chronically suppressed with Cytoxa showed a 90% reduction of lymphocytes and circulating immunoglobulin. Animals were infected with 10^5 PFU RSV A/Long and injected intraperitoneally on day 1 (normal animals) and days 1, 4 and 7 (immune suppressed animals) with RI-002 and sacrificed on days 4 and 10 post-infection. Standard ELISA tests were performed for quantitation of antibodies to other non RSV respiratory viruses.

Conclusion

RSV respiratory viruses.

Standard ELISA tests were performed for quantitation of antibodies to other non RSV respiratory viruses.

Immune Suppressed Cotton Rats

Comparison of RI-002 to Standard IVIG for Other Respiratory Viruses

Reduction of Viral Load in the Lungs of Normal Cotton Rats Treated with RI-002 (Log_{10} PFU*)

*High dose = 1,500mg/kg; Low Dose = 750 mg/kg

Conclusions

IVIG containing standardized, high levels of neutralizing RSV antibody titers also contains elevated levels of antibodies to other respiratory viruses. This product may be an effective treatment to suppress RSV induced viral load and viral induced inflammation in the lungs, suppress systemic dissemination of RSV and may also provide some level of protection to other respiratory viruses. Whether the standardized, high-titer antibody to RSV or other polyclonal antibodies against other respiratory and infectious pathogens will provide added clinical benefit requires further study.