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Results of a Phase III Trial in Patients with PIDD Using an IVIG Containing High Titer Neutralizing Antibody to Respiratory Syncytial Virus (RSV).

James Mond, MD, PhD, ADMA Biologics, Ramsey, NJ, Roger H. Kobayashi, MD, MS, Department of Pediatrics UCLA School of Medicine, Division of Pediatric Immunology and Allergy UCLA School of Medicine, Los Angeles, CA, Charlotte Cunningham-Rundles, MD, PhD, The Immunology Institute, Mount Sinai School of Medicine, New York, NY, William Lumry, MD, AARA Research Center, Dallas, TX, Ai Lan Kobayashi, MD, Midlands Pediatrics, Papillion, NE, James Harris III, MD, The South Bend Clinic, LLP, South Bend, IN, Robyn Levy, MD, Family Allergy & Asthma Center, PC, Atlanta, GA, Mark Stein, MD, Allergy Associates of the Palm Beach, P.A., North Palm Beach, FL, Lisa R. Forbes, MD, Texas Children's Hospital Center for Human Immunobiology, Houston, TX, Isaac Melamed, MD, IMMUNOe Health Centers, Centennial, CO, Kaitlin Kestenberg, ADMA Biologics, Inc., Ramsey, NJ and Richard L. Wasserman, MD, Dallas Allergy Immunology, Dallas, TX

Bacterial infections such as *S. pneumonia* and viral infections such as RSV continue to pose life threatening risks for immune suppressed and immune deficient patients. While palivizumab has been shown to be effective in limited circumstances for the prevention of RSV in premature born infants, it does not have the ability to restore the absent or deficient immune compartments of these individuals. RI-002 is an IVIG derived from plasma donors selected to have high titers of neutralizing antibody to RSV and is effective in treating immune suppressed cotton rats infected with RSV. RI-002 also contains significantly elevated levels of antibodies to many other respiratory viruses. We have now completed a phase III trial in 59 patients with PIDD who received RI-002 over the course of one year with the primary objective of preventing serious bacterial infections. Patients were enrolled between the ages of 3 and 74 and received doses ranging from 291-1008 mg/kg every 21 or 28 days for the duration of one year. There were no serious adverse events attributable to the study drug and there were no serious bacterial infections (SBI) reported during the trial. 29 subjects were enrolled in the pharmacokinetic component of the trial and total Ig, Ig isotypes, *S. pneumonia* serotypes and other antibody determinations were measured. These results support the use of this product in immune deficient patients.