

# Review of ASCENIV in Two Young Males with Immune Abnormalities and RSV-Induced Respiratory Failure: A Case Series



Constance Bindernagel DO MBA<sup>1</sup>, Shannon Sullivan MD<sup>1,2</sup>, Mary Ann Miranda MD<sup>1,2</sup>, Priya Timothy MD<sup>1,2</sup>, Gene Wetzstein PharmD<sup>3</sup>, Panida Sriaroon MD<sup>1,2</sup>, Jolan Walter MD PhD<sup>1,2</sup>  
<sup>1</sup>Department of Pediatrics, University of South Florida Morsani College of Medicine,  
<sup>2</sup>Division of Allergy/Immunology, University of South Florida at Johns Hopkins All Children's Hospital, <sup>3</sup>ADMA Biologics



## Background

- Respiratory syncytial virus (RSV) can cause severe respiratory disease in young children.
- Intravenous immunoglobulin (Ivlg) has been utilized as part of the acute treatment in immunocompromised individuals
- ASCENIV is a novel Ivlg subtype with high-titer neutralizing anti-RSV antibodies (1.9-fold higher compared to conventional Ivlg) [1-2].
- It is enriched with antibodies to several other viral pathogens and approved for adults and adolescents ≥12 years with primary immunodeficiency (PI).
- The safety and efficacy of ASCENIV has not been well studied under 3 years of age [3-4].

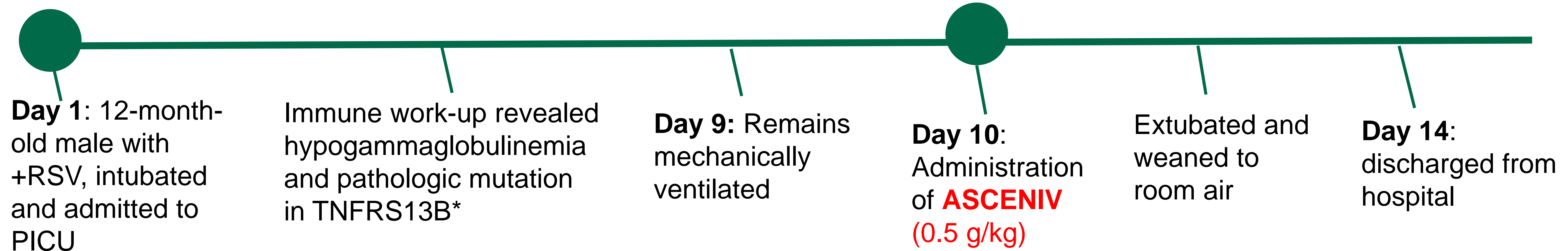
## Methods

- Chart review on two previously healthy children ≤ 3 years of age who suffered from severe courses of RSV bronchiolitis.
- Both patients required mechanical ventilation in the pediatric intensive care unit (PICU) setting, were diagnosed with immune abnormalities, and received one dose of ASCENIV at 0.5g/kg.

## Discussion

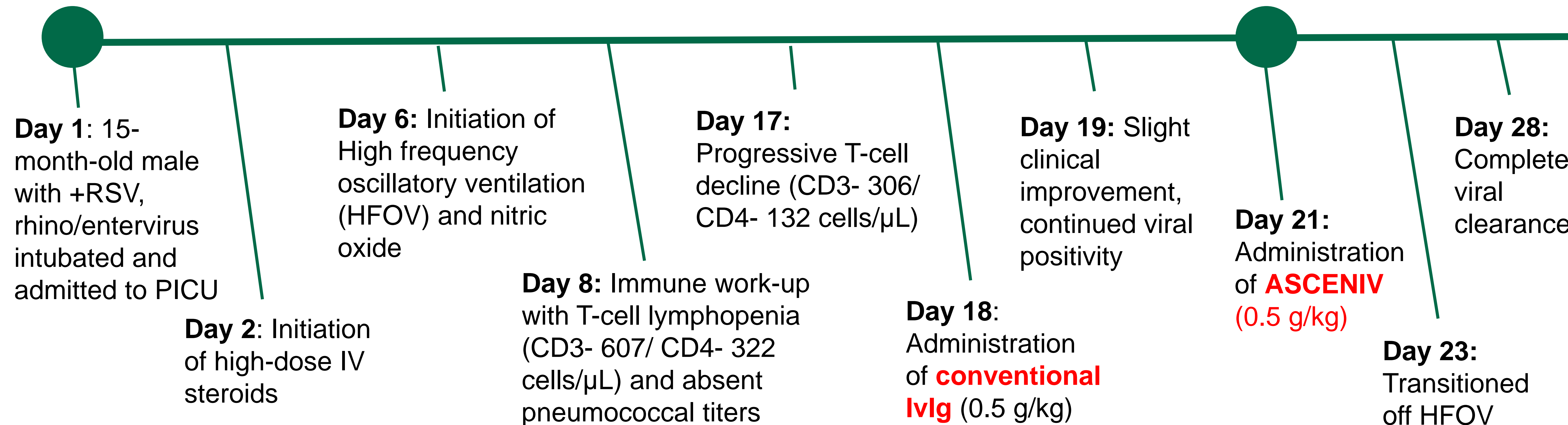
- The severity of RSV/multi-viral bronchiolitis raised concern for contributing immune dysregulation.
- ASCENIV (0.5g/kg) may have had notable benefit in the treatment courses of this less well studied age-cohort of patients.
- Regarding safety, there were no adverse side effects associated with ASCENIV administration.
- Further analysis of the benefits of ASCENIV for patients younger than 3 years of age with immune dysregulation should continue to be explored.

## Patient 1: Clinical Course



\*TNFRS13B is associated with autosomal recessive common variable immunodeficiency (CVID) [5]

## Patient 2: Clinical Course



## References

1. Orange JS, Du W, Falsey AR. Therapeutic Immunoglobulin Selected for High Antibody Titer to RSV also Contains High Antibody Titers to Other Respiratory Viruses. *Front Immunol.* 2015;6:431.
2. Wasserman RL, Lumry W, Harris J 3rd, et al. Efficacy, safety, and pharmacokinetics of a new 10 % liquid intravenous immunoglobulin containing high titer neutralizing antibody to RSV and other respiratory viruses in subjects with primary immunodeficiency disease. *J Clin Immunol.* 2016;36(6):590-599
3. Rizk A, Gorson KC, Kenney L, Weinstein R. Transfusion-related acute lung injury after the infusion of IVIG. *Transfusion.* 2001;41(2):264-268.
4. Falsey AR, Koval C, DeVincenzo JP, Walsh EE. Compassionate use experience with high-titer respiratory syncytial virus (RSV) immunoglobulin in RSV-infected immunocompromised persons. *Transpl Infect Dis.* 2017;19(2). doi:10.1111/tid.12657
5. Poodt AE, Driessen GJ, de Klein A, van Dongen JJ, van der Burg M, de Vries E. TAC1 mutations and disease susceptibility in patients with common variable immunodeficiency. (2009). *Clin Exp Immunol*, 156(1):35-39. doi:10.1111/j.1365-2249.2008.03863.x