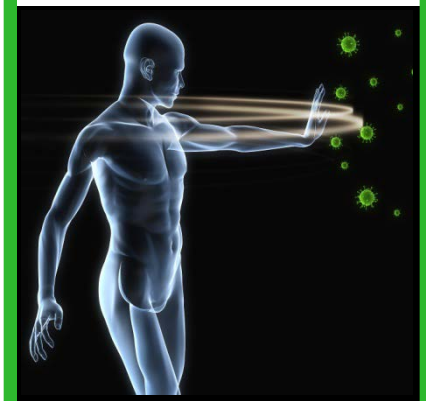
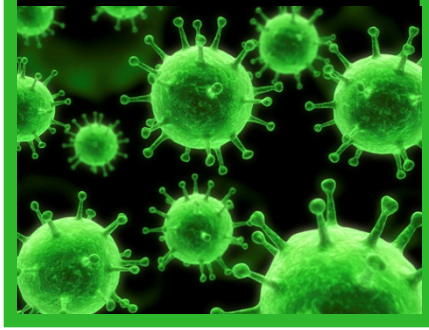
Alios BioPharma

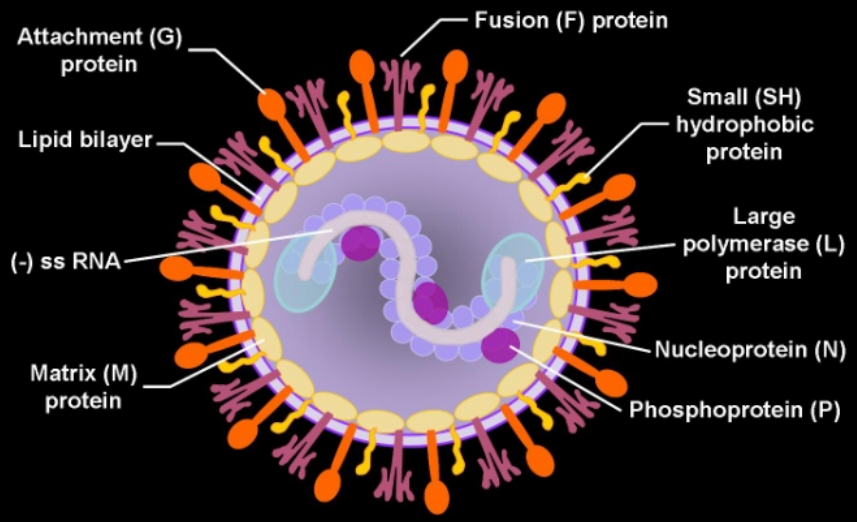


Targeting Viruses to Improve Human Health



Challenges Developing an RSV Therapeutic in Pediatrics

(And How Pediatric Networks Can Help)



An SME Perspective

Matthew W. McClure, MD
mmcclure@aliosbiopharma.com

Alios - Background

» **Autonomous, Small Enterprise based in San Francisco, USA**

- ~45 employees, 4 of which are responsible for clinical development

» **Focused on developing antiviral compounds for a variety of infections, all of which adversely affect children**

- Hepatitis C virus (HCV) – *currently in Phase 2*
- Respiratory Syncytial Virus (RSV) – *currently in Phase 1*
- Rhinovirus - *preclinical*
- Influenza virus - *preclinical*
- Norovirus – *preclinical*

Respiratory Infections

» **Development path for antivirals**

- Straightforward for HCV in adults
- Less straightforward for RSV, a disease which most adversely affects very young infants (= target population for Alios RSV therapeutic)

Clinical Challenges

» **Research Infrastructure**

- Among hospitals that care for children, there is a small percentage of institutions with needed experience performing industry-sponsored RCTs
- Even fewer institutions with experience in RCTs of RSV therapeutics

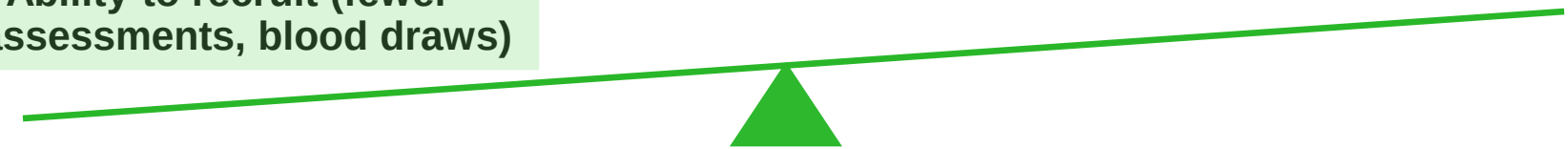
» **Difficult enrolling subjects. Pediatric studies must**

- Overcome innate hesitancy of key stakeholders (Investigators, ECs, parents) to expose infants to any risk
- Balance opposing forces, both of which are important to stakeholders

•Efficacy (higher doses; few placebo pts)

• Ability to recruit (fewer assessments, blood draws)

•Safety (lower doses; more placebo pts; more assessments, especially blood draws & PK)



What Alios is Looking for in a Partner Pediatric Research Network

- **Access to a pool of Investigators who**
  - Have an interest in RSV (Peds ID, Peds Pulmonology, Pediatricians)
  - Have done industry-sponsored RCTs in infants
    - Stakeholders more likely comfortable with critical study design elements (e.g., blood draws/safety assessments, placebo control, use of investigational drugs in children)
  - Have the needed research infrastructure (e.g., research nurses) at their institution
    - Allows them to operate more efficiently (shorter timelines, greater recruitment), deliver better quality research
- **Networks which have already identified the most productive Investigators/Institutions within their regions**
  - Especially valuable for seasonal virus like RSV, where we must follow it to many countries around the globe
    - Difficult as SME to screen and identify qualified sites across so many countries
    - Several geographically diverse Networks can significantly expedite this process

Summary

- **There are many challenges which make development of an RSV therapeutic in infants difficult**
- **Ideal partner Pediatric Research Networks can mitigate many of these challenges**
  - Offer ready access to a “pre-screened” group of Investigators with
    - An interest/ability to study investigational compounds in a vulnerable infant population
    - Prior experience conducting industry-sponsored RCTs
    - The necessary research infrastructure to successfully conduct these RCTs
  - When multiple Networks are combined, they offer instant geographic diversification for a seasonal, global disease like RSV
  - Improves Alios’ probability of success in developing an RSV therapeutic in a timely fashion