Rapid Proof of Concept for Gilead

Verifies promising treatment for deadly Respiratory Syncytial Virus (RSV)

Landmark study verifying the potential of Gilead's antiviral treatment (GS-5806) for Respiratory Syncytial Virus (RSV), which currently has no effective cure

- **1st study** published of a small molecule against RSV
- Demonstrated **3x reduction** in viral load
- **Largest RSV study** in isolation facility
- Completed in **6 months**

The Need

RSV has no effective cure and is the top reason for hospitilisation for kids under the age of 1.

Among children **less than 2 years of age,** the annual rate of RSV-related:

Outpatient visits is
66–177 per 1,000

Emergency Department encounters is
32–57 per 1,000

Hospitalization is
5.2 per 1,000

Among infants **younger than 1 year of age:**

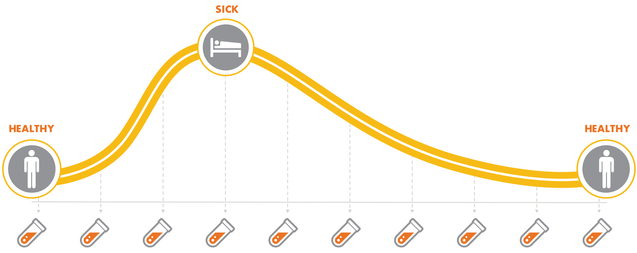
Risk of death from respiratory causes is **9x more likely** for infants who have an RSV infection vs. influenza.

RSV infection

Influenza

Study Design

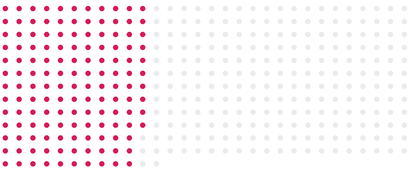
Randomised, double-blind, placebo-controlled study for oral RSV-entry inhibitor (GS-5806)
Largest RSV study at time, run in a custom built isolation facility.
Study completed in 6 months. A typical phase II field study can take years.



Volunteers were screened, then quarantined in our state-of-the-art unit, and were **studied for a total of 15 days (12 days after inoculation)**

Study Process

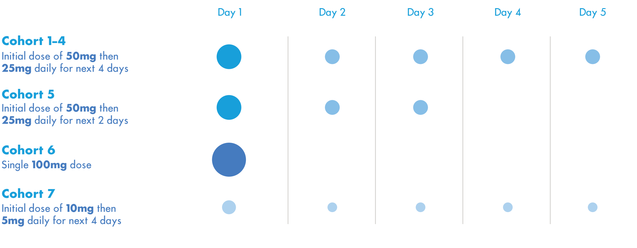
Study participants were healthy adults 18-45 years old



372 screened participants
↳ 140 randomised and dosed following inoculation

Dosing Regimens

Quick TAT and local lab facilities enabled Gilead to utilise triggered dosing protocols to identify dosing regimen



The Results

For all participants infected with RSV, active treatment was associated with:

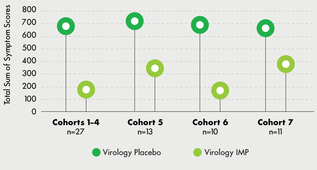
- Lower viral load
- Lower total mucus weight
- Lower Area Under the Curve (AUC) for the change from baseline in symptom scores

Treatment with GS-5806 clearly reduced the severity of clinical disease in a challenge study of healthy adults.

"...This study is actually pivotal in terms of informing how we design future studies especially when we start going into populations where the prevalence of RSV is actually quite low ... any kind of dose ranging studies that you would do in such populations would significantly increase the amount of time that's required to conduct those studies and this will dramatically hopefully decrease the timeline and help us get an answer even faster."

Jason Chien, Gilead

Total Sum of Symptom Scores



For more information **visit hvivo.com**

References
1. Boyce TG, Mellen BG, Mitchel EF Jr, Wright PF, Griffin MR. Rates of hospitalization for respiratory syncytial virus infection among children in Medicaid. J Pediatr 2000; 137: 865-70.
2. N ENGL J MED 371;8

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