



together • COVID-19 Phase 3 Lambda Results

POTENTIAL "ONE AND DONE" TREATMENT FOR NEWLY DIAGNOSED COVID-19 INFECTION

- Multi-center, investigator-sponsored, randomized, placebo-controlled Phase 3 study
- Single injection of Peginterferon Lambda vs. Placebo
- Real world patient population:
 - Non-hospitalized, mild or moderate
 - High-risk for COVID-19 disease progression
 - Vaccinated and unvaccinated
 - Pan-variant, including omicron
- Planned discussions with FDA and submission of EUA application



COVID-19:

An Evolving Pandemic

MORE TREATMENTS NEEDED

~460M

Cases to date globally

~6.1M

Deaths to date globally



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THE SECOND LARGEST STUDY OF A COVID-19 THERAPEUTIC

- Final analysis evaluating data from 1,936 patients
- Patients randomized to a single injection of Lambda vs. Placebo
- Real world patient population:
 - Non-hospitalized, mild or moderate
 - High-risk for COVID-19 disease progression
 - 84% vaccinated, 16% unvaccinated
 - Pan-variant, including omicron
- Well-controlled trial with robust data set



Peginterferon Lambda for COVID-19

POTENTIAL AS A CONVENIENT, OUTPATIENT THERAPY FOR NEWLY DIAGNOSED PATIENTS

- 300,000 doses of Lambda by end of 2022
- Plan to scale up manufacturing for additional doses
- Positive results facilitate discussions with potential partners including government, non-government and pharma





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SECOND LARGEST TREATMENT STUDY IN COVID-19

- Multi-center, investigator-sponsored, randomized, placebo-controlled Phase 3 study in Brazil (12 sites)
- Single injection of Peginterferon Lambda vs. Placebo
- Randomized within 7 days of symptom onset and positive SARS-CoV-2 test
- Enrolled 1,936 high-risk, non-hospitalized, 84% vaccinated patients from Jul 2021 Feb 2022
- High-risk criteria defined by patients having at least one of the following criteria, including but not limited to:
 > age 50, diabetes, hypertension, CV disease, lung disease, kidney disease, obesity, etc.
- Primary endpoint is reduction of COVID-19 –related hospitalizations or emergency room visits through Day 28

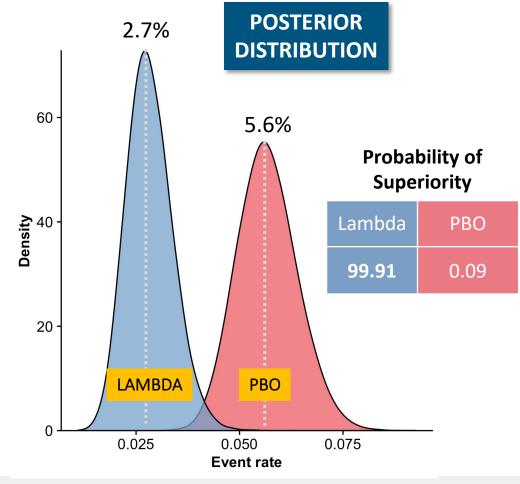


Lambda Highly Superior Compared to Placebo

99.91% PROBABILITY OF SUPERIORITY, SURPASSING PRESPECIFIED SUPERIORITY THRESHOLD OF 97.6%

Risk	Lambda n=916	Placebo n=1020	Risk Reduction (95% BCI)	Probability of Superiority*
Hospitalizations or ER visits	25 (2.7%)	57 (5.6%)	50% (23 - 69%)	99.9%
Hospitalizations	21 (2.3%)	41 (4%)	42% (5 - 66%)	98.4%

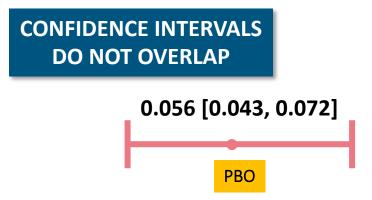
- 1 death in Lambda group; 4 deaths in Placebo group
- 84% patients were vaccinated
- Incidence of any adverse event was indistinguishable between Lambda and Placebo group

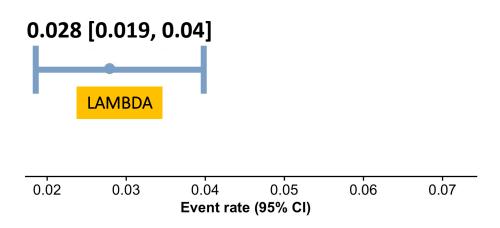




Lambda Highly Superior Compared to Placebo

NON-OVERLAPPING CONFIDENCE INTERVALS







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REPRESENTATIVE OF CURRENT, REAL-WORLD COVID-19 POPULATION

Risk	# Days of Symptoms Before Treatment	Risk Reduction (95% BCI)	Probability of Superiority*
Hospitalizations or ER visits	≤ 7 days	50% (23 - 69%)	99.9%
	≤ 3 days	67% (19 - 79%)	99.6%
Hospitalizations or Deaths	≤ 7 days	39% (1 – 64%)	97.7%
	≤ 3 days	60% (17 – 82%)	99.4%

- Superior efficacy in a predominantly vaccinated population
- 60% reduction in hospitalizations or death with early treatment
- Pan-variant efficacy in variants tested, including omicron
- Potential for efficacy to new arising variants

Demonstrated risk reduction in COVID-19-related hospitalizations or deaths in a predominantly vaccinated population;

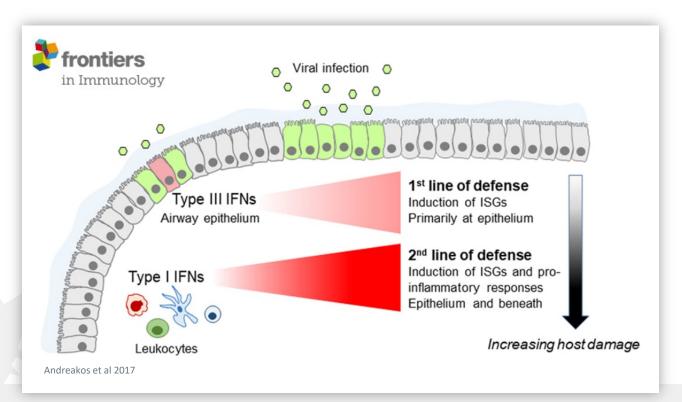
NO OTHER INVESTIGATIONAL DRUG HAS ACHIEVED THIS



VIEWPOINT

COVID-19 and emerging viral infections: The case for interferon Lambda

Prokunina-Olsson et al J. Exp. Med. April **2020** Vol. 217 No. 5





- Type III IFNs: First line of defense upon infection of airways
- Lambda IFN produced first to limit virus spread at epithelial barrier without triggering inflammation



Potential "One and Done" for Newly Diagnosed COVID-19 Outpatients

EMERGENCY USE APPLICATION UNDERWAY



Demonstrated efficacy in a relevant patient population, regardless of vaccination status or SARS-CoV-2 variant



Peginterferon Lambda for COVID-19

POTENTIAL "ONE AND DONE" TREATMENT FOR NEWLY DIAGNOSED COVID-19 OUTPATIENTS

Threat Persists

- COVID-19 cases continue to be high around the globe
- Experts expect SARS-CoV-2 will continue to mutate, posing challenges to current treatments
- Vulnerable patient populations still face hospitalization and death

Additional Therapies Needed



Peginterferon Lambda

- Single outpatient sub-q injection
- Stimulates host immune responses
- Agnostic to variants and resistance



Oral

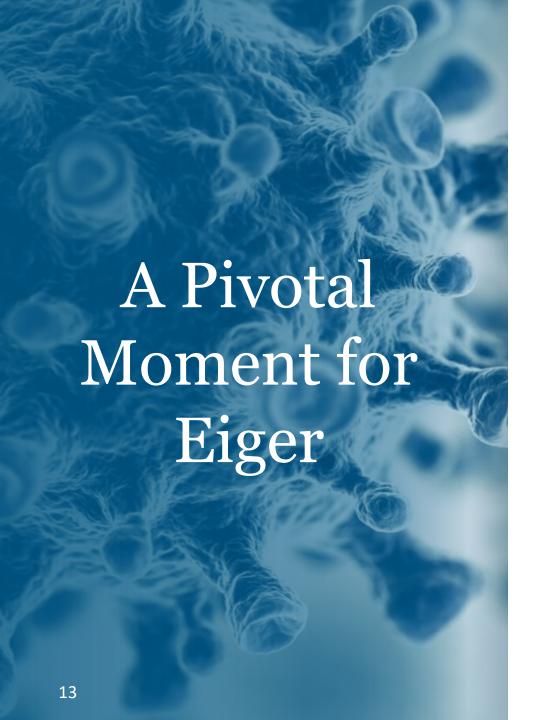
- 30 capsules over 5 days, ritonavir DDI risk
- Potential for resistance



Antibodies

- In-clinic IV infusion
- Potential for resistance





Potential for "One-and-Done" Therapy for COVID-19

- Positive Phase 3 TOGETHER results
- Lambda highly superior to placebo in hospitalizations or ER visits
- Plan to discuss data with FDA and submit EUA

Delivering Needed Wins for HDV Patients

- Phase 3 *D-LIVR* Lonafarnib data by end of 2022
- Phase 3 LIMT-2 Lambda study enrolling
- Phase 2 LIFT-2 combination study initiating

Five Breakthrough Therapy Designated Orphan Programs

- HDV (Lonafarnib and Lambda)
- Congenital Hyperinsulinism
- Post-Bariatric Hypoglycemia
- Progeria

