

Novel, synergistic combination antiviral approach delivers clinical benefits for patients suffering from suspected viral mediated illness



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Experienced Team with Extensive Drug Development and Commercialization Experience

EXECUTIVE TEAM

DIRECTORS



Greg Duncan Chairman & CEO





R. Michael Gendreau MD, PhD CMO





Angela Walsh SVP of Finance





Ralph Grosswald SVP of Operations



Rich Whitley, MD

- Distinguished Professor, UAB
 Remdesivir was originally developed by Dr. Whitley's team at UAB
- DSMB Chair, Operation Warp Speed



Rick Keefer

 30-year Pharma industry veteran with broad-based experience in leading commercial operations
 Executive roles at Pharmacia,

- Executive roles at Pharmacia, Pfizer, Wyeth, Biovail and Publicis Health
- Seven-time winner of Pharma Voice's top 100 healthcare leaders

Abel De La Rosa, PhD

- Chairman, Co-Founder Anitos
 Therapeutics
- Led Bus Dev for Pharmasset acquisition by GILD for \$11.5 billion in 2012
- Leadership for Development Programs for the Treatment of HIV, Hepatitis B & C, including Sofosbuvir

John Thomas, CPA

- CorMatrix Inc., MiMedx Group, Inc., DARA BioSciences, GMP Companies
- MRI Interventions, EnterMed, Inc.,Medicis Pharm Corp., CytRx Corp

Rick Burch

30 years at PFE including SVP

Skip Pridgen, MD

with Tuscaloosa Surgical

Board-certified surgeon practicing

· Served as a physician and surgeon

VIRI Founder

Company Founder

Associates, P.C.

in the U.S. Navv

- VP and GM UCB Pharmaceuticals
 Former President of VIRI. Inc.
- Former President of VIRI, Inc.
 Product launches include Lyrica & Celebrex























Virios Therapeutics, Inc. Summary

Two novel, late-stage clinical stage development assets:

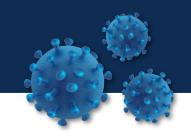
IMC-2 (valacyclovir + celecoxib) Phase 2 Long-COVID study ongoing:

- Proof of concept completed in study 2023, new IP filed with protection potential to 2044
- We have clarity from FDA on the development requirements associated with advancing IMC-2 into Phase 2 development as a treatment for Long-COVID symptoms
- Three-arm, Phase 2 investigator-initiated study of IMC-2 enrolling, topline data expected summer 2024

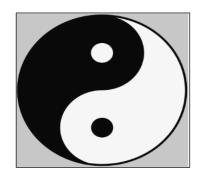
IMC-1 (famciclovir + celecoxib) ready for Phase as treatment for FM:

- Phase 2a and Phase 2b in FM
- FDA agreement to enter Phase 3 post EoP2 meeting
- Exploring Phase 3 partnership and extended-release dosage formulation to extend IP



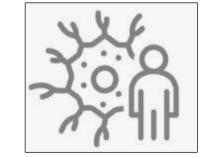


Synergistic Antiviral Mechanism Serves as the Basis for Proposed IMC1 and IMC-2 Treatment Effect



Generally Healthy Patient:

- Everyone previously infected with herpes viruses of some kind
- Virus lies dormant in nerves and a range of human cells



Infection/Other Stressor:

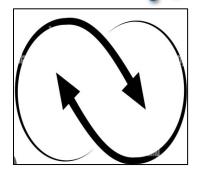
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- Activation of dormant virus
- Immune response produces inflammatory mediators, including cyclooxygenase-2 (COX-2)



Reactivated Herpes Virus:

- Replicates using viral DNA polymerase
- Activated virus increases
 COX-2 production
- COX-2 further accelerates viral replication



Combination Antiviral Treatment:

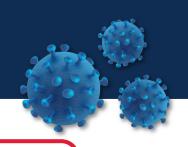
- <u>DNA polymerase inhibitor</u> reduces herpes virus replication
- <u>Celecoxib</u> inhibits Cox-2, thus
 - Reduces inflammation
 - Inhibits viral replication
 - Blunts viral accelerant
- Synergistic combination converts virus back into a dormant state
- Delivers clinical response

Sources: P.A. Bond, Medical Hypotheses, 1993; R. A Vere Hodge and Y.-G. Cheng, Antiviral Chemistry & Chemotherapy, 1993; Liu Y, et al, Scientific World Journal, 2014; Higaki S, et al Current Eye Research, 2009; Francisco Javier Ibañez et al, Frontiers in Microbiology, 2018



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IMC-1 and IMC-2 Deliver Consistent Efficacy Across Multiple Clinical Studies



Endpoint/ Study	Placebo/Control CFB	IMC-1/ IMC-2 CFB	Contrast	P Value	
PROMIS Fatigue - NIH Patient Reported Outcomes Measurement Information System					
P2A (Fam/Cel) FM Patients	-4.15	-7.62	-3.47	0.020	
P2B (Fam/Cel) New FM Patients	-1.94	-5.64	-3.70	0.001	
P1 (Val/Cel) Long-COVID	-0.34	-7.24	-6.90	0.008	
NRS Pain – Numerical Rating Scale 0-10					
P2A (Fam/Cel) FM Patients	-1.05	-1.85	-0.80	0.031	
P2B (Fam/Cel) New FM Patients	-1.02	-1.69	-0.67	0.016	
P1 (Val/Cel) Long-COVID	0.32	-1.14	-1.45	0.041	
Global Health: Percentage of patients with at least a 2 degree improvement on the PGIC scale*					
P2A (Fam/Cel) FM Patients	19%	33%	14%	0.040	
2B (Fam/Cel) New FM Patients	20%	38%	18%	0.010	
P1 (Val/Cel) Long-COVID*	12%	55%	43%	0.006	

*- PGIC responder calculation for P1 is based on 3 degrees of improvement vs. 2 degrees in PRID studies

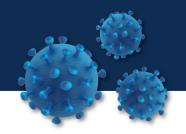




IMC-2 for Long-COVID (in Phase 2)



Long-COVID Represents a Major Unmet Medical Need



 ♦ Center for Disease Control (CDC) Long-COVID diagnosis criteria: New, recurring or continuation of symptoms ≥ 4 weeks after acute COVID infection

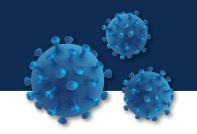
✤ Up to 30% of Long-COVID patients were asymptomatic during acute COVID illness

- A 2022 CDC estimate revealed 3.4% of adults exhibited active Long-COVID sequelae, representing 11.2M US citizens
 - Up to 6 million children and 1 in 10 pregnant women develop Long-COVID
 17.6% of all adults in the US have ever experienced Long-COVID (44 million people)
- Most notable Long-COVID symptoms include fatigue and post exertional malaise
- Majority of COVID morbidity is associated not with acute COVID, but with Long-COVID

Sources: Anthony L. Komaroff and W. Ian Lipkin, *Frontiers in Medicine*, June 2023; Ford et al, *CDC Morbidity/MortalityWeekly*, 2023; *NCHS Data Brief*, 2023; Cutler, *Harvard Kennedy Center Review*, 2022; Perumal, 2023; Gearhart-Serna, Ph.D, *NIH Research Matters*, 2022; Rao et al, *Pediatrics*, 2024; <u>https://www.medscape.com/viewarticle/new-data-Long-covid-cases-surge-2024a10005vv?src=</u> <u>https://www.cdc.gov/nchs/covid19/pulse/Long-covid.htm</u>



Logical Approach to Treating Long-COVID



- Recent studies support concept that reactivated herpes virus infection leads to Long-COVID illness, not residual SARS-CoV-2 virus after the acute infection
- No approved treatments for Long-COVID illness
 - Only approved COVID treatment Paxlovid failed to improve Long-COVID sequelae
- Reactivated herpes viruses, such as Epstein-Barr virus (EBV) and HSV-1, are associated with fatigue and cognitive dysfunction, the predominant symptoms of Long-COVID
- Nucleoside analogs (i.e. valacyclovir and famciclovir) suppress herpesvirus reactivation



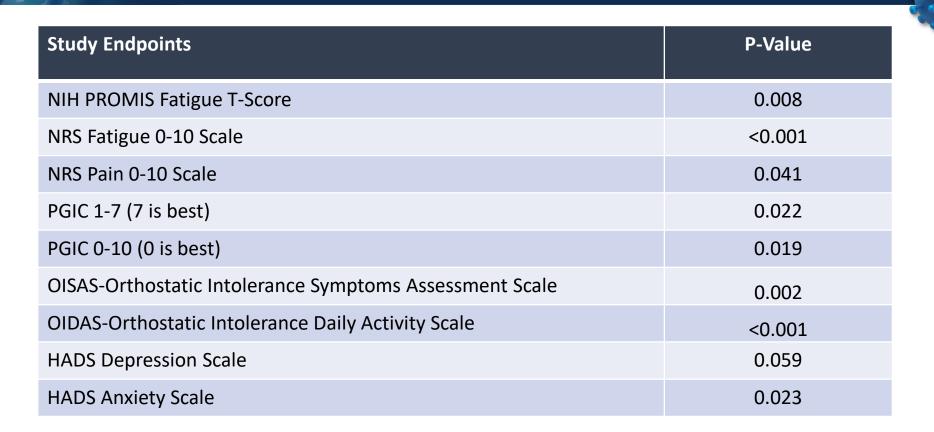
IMC-2 Long-COVID Study Exploratory Study

- Study Supported by Unrestricted Investigational Grant to Bateman Horne Center (BHC)
- Patients were recruited from the BHC database, website and Utah Long Haulers Facebook group

Valacyclovir + Celecoxib Treated Patients	Matched Controls
n=22	n=17
 All female, mean age = 43, mean duration of Long-COVID symptoms at enrollment = 2.0 years 86% SARS CoV2 vaccination rate Washed out of NSAIDs 	 No placebo Matched controls based on treatment group enrolled participants All female, mean age = 47, mean duration of Long-COVID symptoms at enrollment = 2.1 years 82% SARS CoV2 vaccination rate No wash out

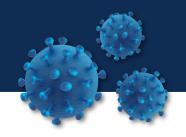


Val/Cel Combination vs Control in Long-COVID Patients at Week 14





Safety: Val/Cel vs Control in Long-COVID Patients



System Organ Class	Control	Val/Cel
Preferred name	(N=17)	(N=21)
Nausea	0 (0.0%)	6 (28.6%)
Headache	3 (17.6%)	3 (14.3%)
Back Pain	0 (0.0%)	3 (14.3%)
Upper respiratory tract infection	1 (5.9%)	2 (9.5%)
Dizziness	1 (5.9%)	2 (9.5%)
Fatigue	1 (5.9%)	2 (9.5%)
Myalgia	2 (11.8%)	1 (4.8%)
Pain in Extremity	1 (5.9%)	1 (4.8%)
Cough	1 (5.9%)	0 (0.0%)
Nasal Congestion	1 (5.9%)	0 (0.0%)
Oropharyngeal Pain	1 (5.9%)	0 (0.0%)
Sinus Congestion	1 (5.9%)	0 (0.0%)
Hypertension	1 (5.9%)	0 (0.0%)

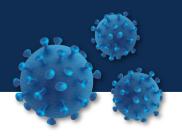
• Treatment with Val/Cel was extremely well tolerated, with an observed safety profile consistent with the known safety profiles of valacyclovir and celecoxib, nausea being the most common adverse event.

• There were no serious adverse events observed in this study and only one treated patient discontinued treatment due to worsening fatigue, considered possibly related to Val/Cel treatment.





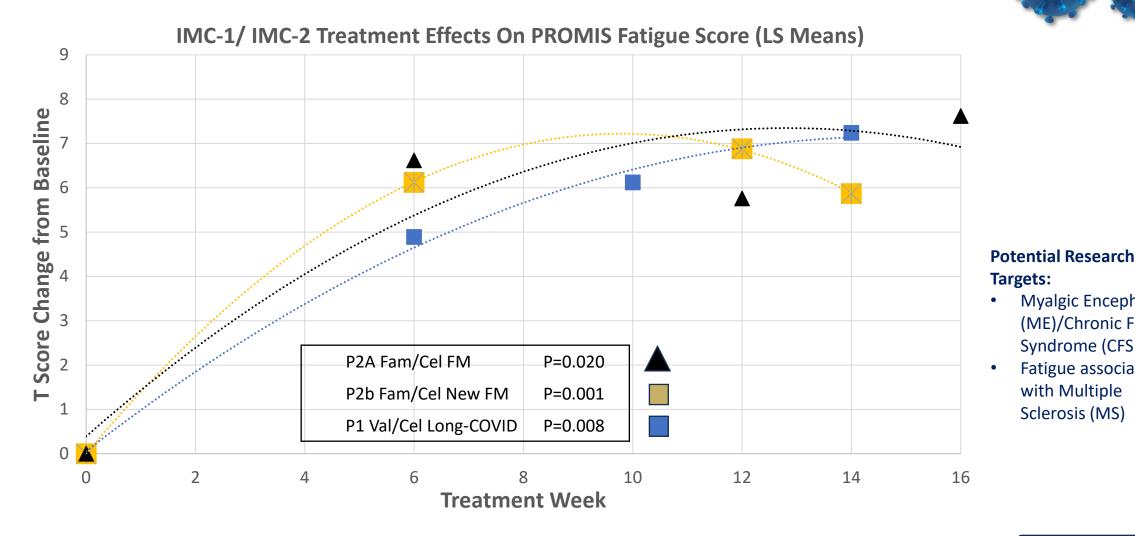
Bateman Horne Center 202 PASC Study Status



- Study run by Bateman Horne Center, Salt Lake City, Utah
 - Second IRB approved study supported by Virios via unrestricted, investigator-initiated grant
 - Dr. Lucinda Bateman, MD, a recognized leader in both Long-COVID and fatigue related clinical research, serves as BHC 202 primary investigator
- Planned enrollment commenced in December 2023: 3 Arms 1:1:1 randomization, double blinded and randomized study:
 - Val/Cel 750/200 BID (1.5g/400mg per day)
 - Val/Cel 1500/200 BID (3g/400mg per day)
 - Placebo capsules
- Primary Endpoint: fatigue reduction
- Secondary Endpoints assessments: sleep, orthostatic symptoms, anxiety, depression and overall health
- Data Summer 2024



IMC-1/IMC-2 Deliver Significant Reduction in Fatigue Across all Clinical Studies, Highlights Potential for Broader Fatigue Development Program



Myalgic Encephalitis

(ME)/Chronic Fatigue

Syndrome (CFS)

with Multiple

Sclerosis (MS)

Fatigue associated





IMC-1 for Fibromyalgia (Phase 3) Focus of Partnership Discussions



IMC-1 Phase 3 Study Designs Reviewed with FDA

Pharmacokinetic/Food Effect Study

Study 1 - 301

- Head-to-Head IMC-1 vs Placebo (n=320)
- 1:1 Randomization 160 in each group
- Primary Endpoint Reduction in Pain at 12 Weeks

Study 2 - 302

- Multifactorial Study of IMC-1 vs Placebo vs Famciclovir reference drug tablet vs Celecoxib reference drug capsule (n=640)
- 1:1:1:1 Randomization 160 each group
- Primary Endpoint Reduction in Pain at 12 Weeks

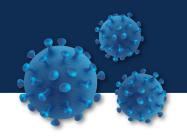
Long Term Extension - 309

- Patients from both studies above will roll over into a long-term extension study
- Treatment with IMC-1 for a year (n = 300 subjects at 6 months and 100 at 1 year)





Moving Forward



- Preparing to advance IMC-2 Phase 2 Long-COVID program independently
- We are actively exploring partnership opportunities:
 - Phase 3 IMC-1 for FM
 - Complementary opportunities to build shareholder value under VIRI team leadership
 - Pain management and anti-infective opportunities
- We will report material progress on any proposed partnership in a timely manner



