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Corporate Presentation

# **Forward-Looking Statements**

Some of the statements included in this presentation may be forward-looking statements that involve a number of risks and uncertainties. Among other things, for those statements, we claim the protection of safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. We are in various stages of seeking to determine whether Ampligen will be effective in the treatment of multiple types of viral diseases, cancers, and immune-deficiency disorders and the presentation sets forth our current and anticipated future activities. These activities are subject to change for a number of reasons. Significant additional testing and trials will be required to determine whether Ampligen will be effective in the treatment of these conditions. Results obtained in animal models do not necessarily predict results in humans. Human clinical trials will be necessary to prove whether or not Ampligen will be efficacious in humans. No assurance can be given as to whether current or planned clinical trials will be successful or yield favorable data and the trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the institutions sponsoring other trials. In addition, initiation of planned clinical trials may not occur secondary to many factors including lack of regulatory approval(s) or lack of study drug. Even if these clinical trials are initiated, we cannot assure that the clinical studies will be successful or yield any useful data or require additional funding. Some of the world's largest pharmaceutical companies and medical institutions are racing to find a treatment for COVID-19. Even if Ampligen proves effective in combating the virus, no assurance can be given that our actions toward proving this will be given first priority or that another treatment that eventually proves capable will not make our efforts ultimately unproductive. Even if Ampligen proves effective in combating the virus, no assurance can be given that our actions toward proving this will be given first priority or that another treatment that eventually proves capable will not make our efforts ultimately unproductive, as multiple vaccines are now available and major pharma companies are working to develop their own disease treatments. We recognize that all cancer centers, like all medical facilities, must make the pandemic their priority. Therefore, there is the potential for delays in clinical trial enrollment and reporting in ongoing studies. No assurance can be given that future studies will not result in findings that are different from those reported in the studies referenced in the presentation. Operating in foreign countries carries with it a number of risks, including potential difficulties in enforcing intellectual property rights. In addition, many countries, including Argentina, are dealing with COVID-19 outbreaks and have made that their primary focus. We believe that this may be delaying our commercialization of Ampligen in Argentina until COVID-19 is more under control. We cannot assure that our potential foreign operations will not be adversely affected by these risks.

Please review the "Risk Factors" section in our latest annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. Our filings are available at www.aimimmuno.com. The information found on our website is not incorporated by reference into this presentation and is included for reference purposes only.



## **Investor Highlights**

We are an immuno-pharma company focused on the development of therapeutics to treat multiple types of cancers, viral diseases and immune-deficiency disorders

Lead program Ampligen is an immuno-modulator with broad spectrum activity potentially applicable in multiple high-value indications

Approved in Argentina as safe and effective for the treatment of severe Chronic Fatigue Syndrome (CFS) Six (6) ongoing oncology clinical trials with multiple data readouts expected over the next 6-12 months Antiviral studies, including COVID-19, either underway or in development. Initial COVID-19 clinical data expected by Q2

## Broad Oncology Pipeline Across High-Value Indications

Indications	Approach	Partner	Preclinical Phase 1 Phase 2 Phase 3 Approval
Ovarian Cancer (Advanced, Recurrent)	Chemokine Modulatory Regimen	UPPMC LIFE CHANGING MEDICINE	
Colorectal Cancer (Metastatic)	Chemokine Modulatory Regimen	ROSWELL PARK. COMPETENSING CONCEPTION	
Breast Cancer (Metastatic Triple-Negative)	Chemokine Modulatory Regimen / Pembrolizumab	ROSWELL PARK. COMPETENSINE CARCEL ELSINES	
Ovarian Cancer (Advanced, Recurrent)	Combination: Pembrolizumab		
Prostate Cancer (Early-Stage)	Combination: Intron A	ROSWELL PARK. COMPERISANCE ONCE EXPERIE	
Pancreatic Cancer	Single Agent	Erasmus MC University Medical Center Batterian	EAP
Breast Cancer (Early-Stage Triple- Negative)	Chemokine Modulatory Plus Neoadjuvant Chemo	ROSWELL PARK.	
Pancreatic Cancer	Single Agent	University of Nebraska Medical Center <sup>-</sup> BREAKTHROUGHS FOR LIFE*	
Melanoma (Refractory)	Combination: Intron A	ROSWELL PARK.	Under Development

## Extensive Viral and Immune System Disorder Pipeline

Indications	Approach	Preclinical	Phase 1	Phase 2	Phase 3	Approval
Viral Infections						
COVID-19 in Cancer Patients	Combination: Interferon Alpha-2b and Ampligen Alone					
Immune System Disorder						
Severe CFS	Single Agent					Approved in Argentina
ME/CFS	Single Agent			Planning 2 <sup>nd</sup> Phase 3 Confirmatory Tria		
Long COVID-19*	Single Agent					
Post-COVID-19 Cognitive Impairment	Single Agent	Under Development				



# **Proven Management Team**



Thomas K. Equels, M.S., J.D. Chief Executive Officer





GT GreenbergTraurig





David R. Strayer, M.D. Chief Scientific & Medical Officer









Peter W. Rodino III, J.D.

Chief Operating Officer, Executive Director for Governmental Relations, General Counsel, Secretary



Rodino Consulting; Rodino & Rodino; Rodino & Scalera Inc.; Foundation Health





**Ellen Lintal** Chief Financial Officer



## Lead Program Ampligen (rintatolimod) Significant Opportunity Across Multiple Disease Areas

Approved for the treatment of severe CFS in Argentina

Generally well-tolerated with over 100,000 IV doses in humans

Clinically tested as a single-agent therapeutic and in combination with other agents

Potential to enhance efficacy of PD-1 and PD-L1 checkpoint inhibitors<sup>1</sup>

### Immuno-Oncology

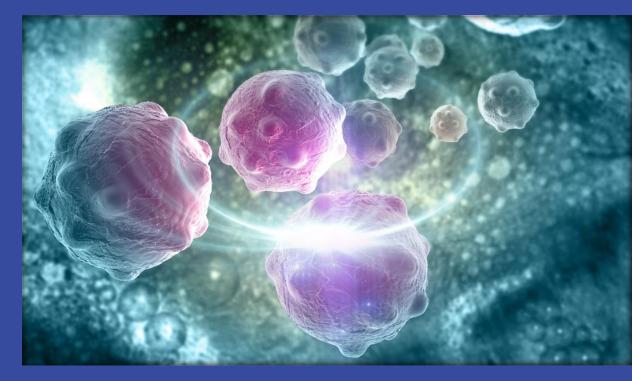
Virology

### Immune System Disorders



# Ampligen

Immuno-Therapy Targeting Multiple Cancers with High-Unmet Need





Mechanism of Ampligen Induces Wide Range of Immunologic and Antitumor Activities

Immuno-modulator that selectively activates TLR3 pathway

Exclusively activates TRIF adaptor and avoids MyD88 inflammatory pathway used by all other TLRs<sup>1</sup>

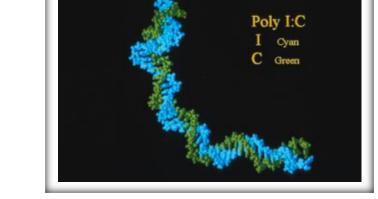
Promotes selective attraction of CTLs (Teff) with concomitant increase in Teff/Treg ratio in the TME<sup>2</sup>

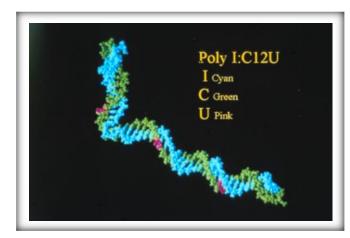
Only known TLR3 agonist to avoid helicase activation of NF-κB<sup>3</sup>

Demonstrates positive increase of ratio of CXCL10 (CTL-attractant) to CCL22 (Treg-attractant) and increased ratio of CTL/Treg markers<sup>4</sup>

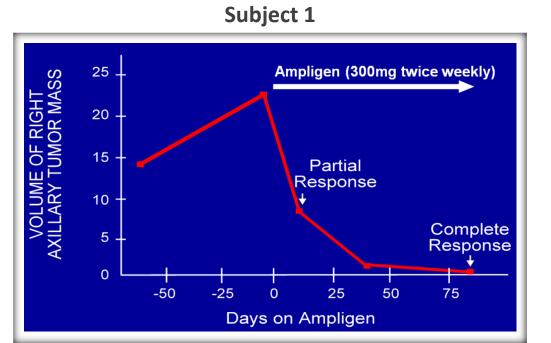
↑ Teff-attracting chemokine (CXCL10) in the tumor microenvironment (TME)<sup>5,6</sup>

Induces epitope spreading and cross-reactive IgA antibody formation<sup>7</sup>



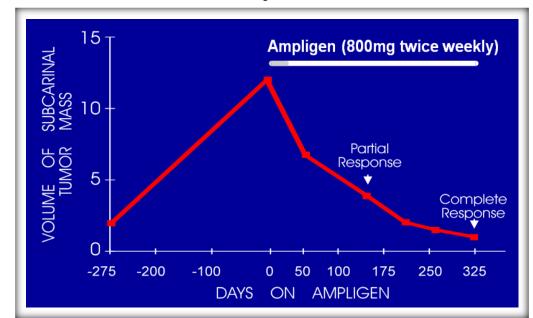


# Observed Complete Response in 2 of 9 Subjects in Phase 1 Melanoma Study



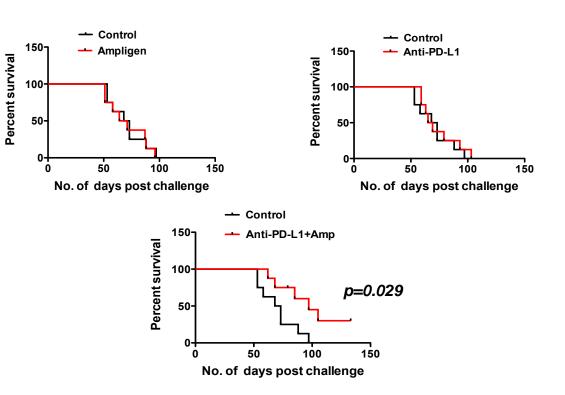
Ampligen discontinued after 2 years, complete response was durable

Subject 2



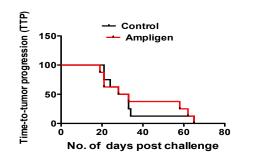
Synergistic Effects in Combination with Checkpoint Inhibitor, Anti-PD-L1

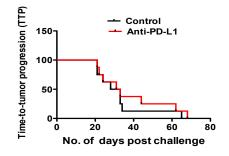
**Pancreatic Cancer Mouse Model** 

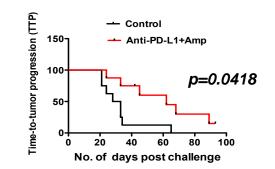


Synergistic Increase in Median Survival

#### Synergistic Increase in Time to Progression









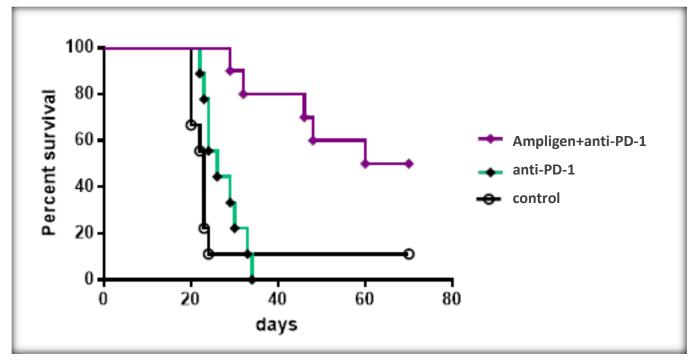
Source: University of Nebraska, Pl Hollingsworth (unpublished data)



BREAKTHROUGHS FOR LIFE."

# Increase in Median Survival Combining Ampligen with Anti-PD-1

**Colorectal Carcinoma Mouse Model** 







Phase 1/2 Advanced, Recurrent Ovarian Cancer

Phase 1 portion fully enrolled Intraperitoneal chemo-immunotherapy Data published Q1 2022 PI: Dr. R. Edwards Phase 2 Advanced, Recurrent Ovarian Cancer

Enrollment ongoing Cisplatin, pembrolizumab, plus Ampligen Data expected: Interim results Q2 2022 PI: Dr. R. Edwards



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# Ongoing Clinical Studies Sponsored by



#### Phase 2a Stage 4 Colorectal Cancer Metastatic, Liver

Enrollment ongoing Chemokine modulatory regimen Data expected: Q2 2022 PI: Dr. P. Boland

> Phase 2 Early-Stage Prostate Cancer

Enrollment ongoing

Aspirin and Ampligen with or without interferon-alpha 2b (Intron A) Data expected: not yet predictable

PI: Dr. G. Chatta

Phase 1/2 Metastatic Triple Negative Breast Cancer

Enrollment ongoing

Chemokine modulation therapy, including Ampligen and pembrolizumab

Data expected: Q2 2022

PI: Drs. M. Opyrchal/S. Ghandi

Phase 1 Early-Stage Triple Negative Breast Cancer

**Enrollment ongoing** 

Chemokine modulation plus neoadjuvant chemotherapy

Data expected: not yet predictable

PI: Dr. S. Gandhi



# Promising Results Observed in Early Access Program (EAP)

Statistically Significant Increased Overall Survival Compared to Historical Controls in Treatment of Late-Stage Pancreatic Cancer

**Site:** Erasmus University, The Netherlands, conducted by Professor Casper van Eijck

**Eligibility:** Adults with metastatic or locally advanced pancreatic carcinoma following FOLFIRINOX

#### **Survival Data:**

Median overall survival (OS) was 19 months in the Ampligen cohort compared to 12 months for a well-matched historical control group (p=0.035)

19 months OS represents 7.9 month increase survival benefit compared to current standard of care using FOLFIRINOX followed by gemcitabine, which yields 11.1 months overall survival



Phase 2 study in locally advanced pancreatic cancer patients is under development

# Ampligen

SARS-CoV-2 (COVID-19)





### Ampligen May Mount a Potentially Broad-Spectrum Immune System Response Against SARS-CoV-2 (COVID-19)

Targeting toll-like receptor 3 (TLR3) pathways, which are among the primary pathways for antiviral protection (uniquely targets TLR3 without activation of the inflammatory cytosolic helicases)

Potential efficacy may not be impacted by viral mutations, such as Delta, Omicron or future given mechanism of action

Demonstrated complete protection (100% survival) against SARS-CoV-1, Ebola virus, Western Equine Encephalitis virus and Herpes Simplex virus in preclinical studies

Identified an effective *in vitro* model using human tracheal, bronchial epithelial cells, which showed that Ampligen was able to decrease SARS-CoV-2 infectious viral yields by 90% at clinically achievable intranasal Ampligen dosage levels

# Ongoing Phase 1/2 Study for Treatment of COVID-19 Cancer Patients

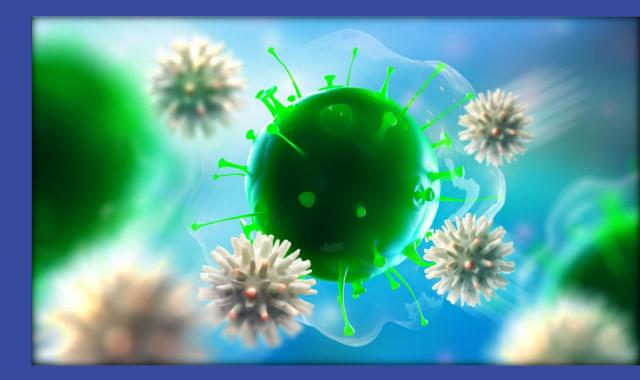
**Study Ongoing and Actively Recruiting Subjects** 

Evaluating safety and effectiveness to reduce replication of SARS-CoV-2 virus from upper airway in patients and enhance and expand natural immunity (Intravenous)



# Ampligen

#### Immune System Disorders (ISD)





# Ampligen for the Treatment of ME/CFS

Approved for the treatment of severe CFS in Argentina Developing protocol for confirmatory Phase 3 trial, required for U.S. NDA

Toll-Like Receptor 3 agonist which is known to activate the innate immune system and induce immuno-modulation



# Chronic Illness Following COVID-19

Chronic illness following recovery is prevalent

Fati	gue Brain I	og Dyspnea	Joint Pain	Chest Pain
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COVID-Induced Chronic Fatigue shares similarities to ME/CFS

COVID-Induced Chronic Fatigue (Long COVID or 'Long Haulers')

Amended ongoing open-label AMP-511 study to include up to 20 subjects with Long COVID

Results expected: Q3

Post-COVID-19 Cognitive Impairment

Planned Phase 2 two-arm, randomized, double blind, placebo controlled, multicenter study to evaluate the efficacy and safety



# Corporate Overview





# Intellectual Property Portfolio – Market Exclusivity





**Orphan Drug Designation (FDA and EMA):** 

#### Ampligen

7 years market exclusivity following FDA approval

10 years market exclusivity following EMA approval

#### **Indications:**

U.S. – Pancreatic Cancer, Melanoma, ME/CFS, Renal Cell Carcinoma, AIDS Europe – Pancreatic Cancer, Ebola

### Financial Snapshot NYSE American: AIM

### Sufficient Capital to Fund Operations Through Multiple Key Clinical Milestones



# **Upcoming Milestones Expected to Drive Value**

- Pancreatic Cancer Expressing TLR3 Receptors: Publication of Preclinical Data
- ✓ January 2022: Advanced Recurrent Ovarian Advanced Recurrent Ovarian Metastatic Triple-Negative Breast Cancer: Cancer: Phase 1 Publication of Results Oncology Phase 1/2 Results Cancer: Phase 2 Interim Results Q1 2022 Q3 2022 Q2 2022 Late-Stage Pancreatic Cancer: EAP Colorectal Cancer Metastatic to Liver: Publications of Results Phase 2a Results Locally Advanced Pancreatic Cancer: Launch Study Antiviral Q1 2022 Q2 2022 Q3 2022 • Intranasal Challenge Study: COVID-19 in Cancer Patients: Launch Phase 2a Study Phase 1/2 Interim Results SD Q1 2022 Q2 2022 Q3 2022

 COVID-Induced Chronic Fatigue: AMP-511 Interim Study Results

 Post-COVID-19 Cognitive Impairment: Launch Study

## **Investment Summary**

Immuno-Pharma Company with Broad Pipeline Across Multiple High-Value Indications in Oncology, Virology and Immune-Deficiency

Lead program Ampligen has favorable safety profile and promising efficacy Leveraging external collaborators to fund ongoing clinical studies Growing body of data potentially supports development strategy

**Strong Balance Sheet** 

Multiple Potentially Game-Changing Clinical and Regulatory Milestones Expected Q2 2022



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