NeuroBo
PHARMACEUTICALS

Company Presentation
January 8, 2021

Confidential

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COMPANY OVERVIEW AND MERGER WITH ANA THERAPEUTICS

NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases.

Repurposing ANA-001 as a rapid COVID-19 treatment (Priority)

ANA-001 – COVID-19 Trial

- Compelling in-vitro data showing efficacy, with 50+ years of safety
- Shows great broad-spectrum antiviral activity
  - Effective against other viruses such as influenza
  - Likely effective against novel COVID-19 variants
- Shows great anti-inflammatory properties, without suppressing immune response
- Shows promise as a prophylactic

Pipeline Programs Addressing Large Unmet Needs

NB-01 – Targeting Pain in Orphan Indication

- Compelling Phase 2 data showing efficacy and safety for neuropathic pain
- Multimodal mechanism of action to treat pain supported by preclinical evidence

NB-02 - Targeting Alzheimer's Disease (AD) and other dementias

- IND Ready; Solid preclinical data

Gemcabene: Originally Targeting Chronic Orphan Dyslipidemia indications:

- Reassessing target for acute COVID-19 indication
- 25 Phase 1 and Phase 2 trials completed

PROVEN LEADERSHIP TEAM

Richard J. Kang, PhD
President & CEO

- Founder of JK BioPharma Solutions and senior management at companies including NeoImmuneTech in immuno-oncology
- Visiting Fellow at NIH and senior research experience in host-disease pathogen interactions

Akash Bakshi, MsC.
Chief Operating Officer

- Founder and CEO of ANA Therapeutics
- Founder and CEO of YourChoice Therapeutics
- Previously Assistant Director of Marketing and Technology Analysis at UC Berkeley.

Nikki Shannon, RegN, BA
VP, Clinical Operations

- 26 years of drug development experience from Phase 1 to Phase 4 at Vertex (Kalydeco), Cubist/Merck, AstraZeneca, Tetraphase
- Leadership roles at 4 pharma companies; >55 studies including 14 Phase 3
- Drug approvals: 2 NDAs, 2 MAAs

EXPERT SCIENTIFIC ADVISORY BOARDS

NEUROPATHIC PAIN SCIENTIFIC CHAIR

Roy Freeman, M.D.
Expert in peripheral nerve disorders and neurodegenerative diseases

- Professor of Neurology, Harvard Medical School
- Director of the Center for Autonomic and Peripheral Nerve Disorders

COVID-19

Warner Greene, M.D., Ph.D.
Expert in virology

- Director of the Gladstone Institute
- Professor at UCSF
- Member of the national Academy of Medicine

Gunda Georg, Ph.D.
Expert in medicinal chemistry

- Professor and Head of the Department of Medicinal Chemistry at University of Minnesota
- Member of the national Academy of Medicine

Christopher Davis, Ph.D.
Expert in virology and clinical aspects

- Ex-BARDA
- Managed a NATO drug development program
- 10 years at British Intelligence as principal bioweapons anaylst

ALZHEIMER'S DISEASE & OTHER DEMENTIAS

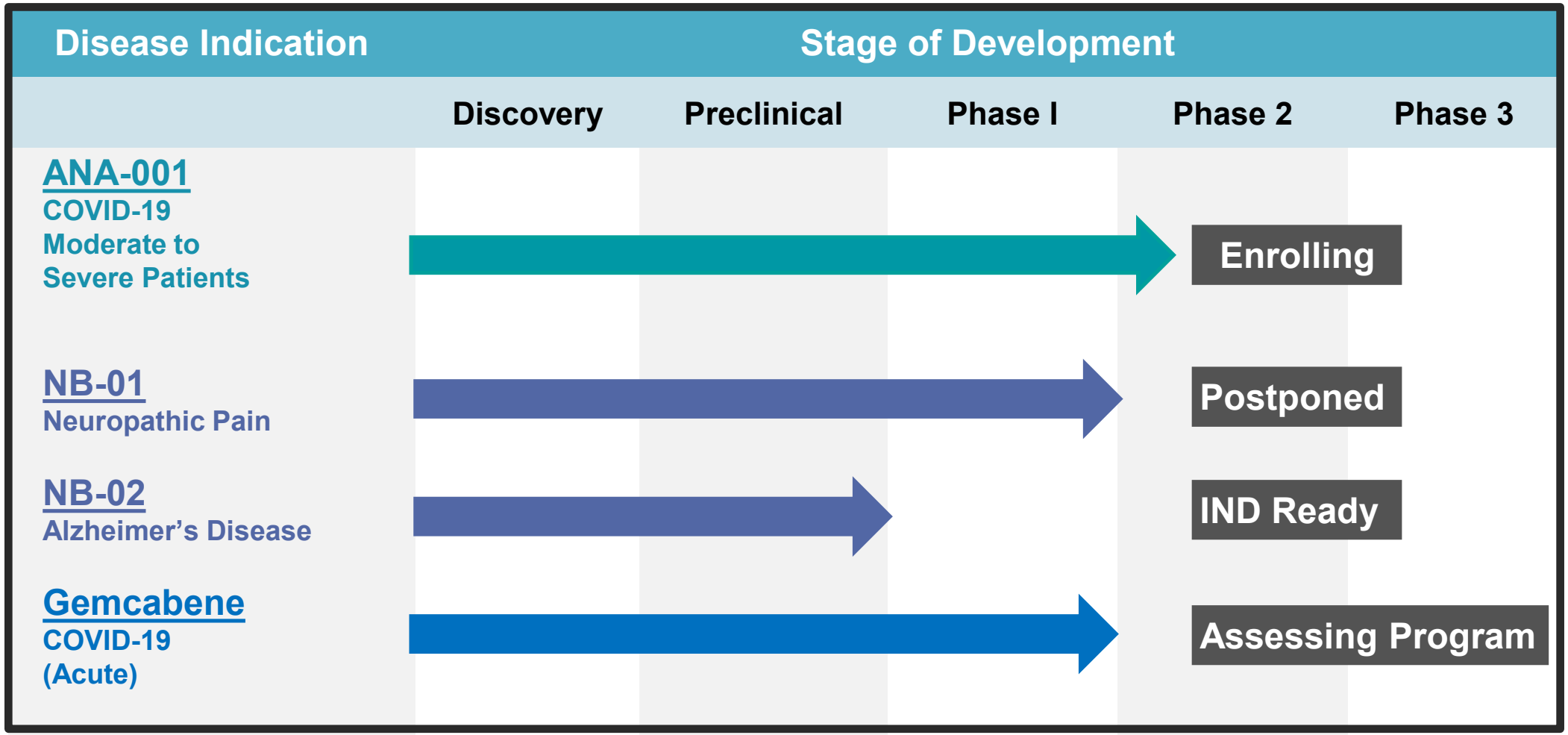
Brian Bacskai, PhD
Expert in Alzheimer's Disease Research

- Professor of Neurology, Harvard Medical School
- Principal Investigator, Neurology, Massachusetts General Hospital

Pierre N. Tariot, M.D.
Award-Winning Leader in Dementia

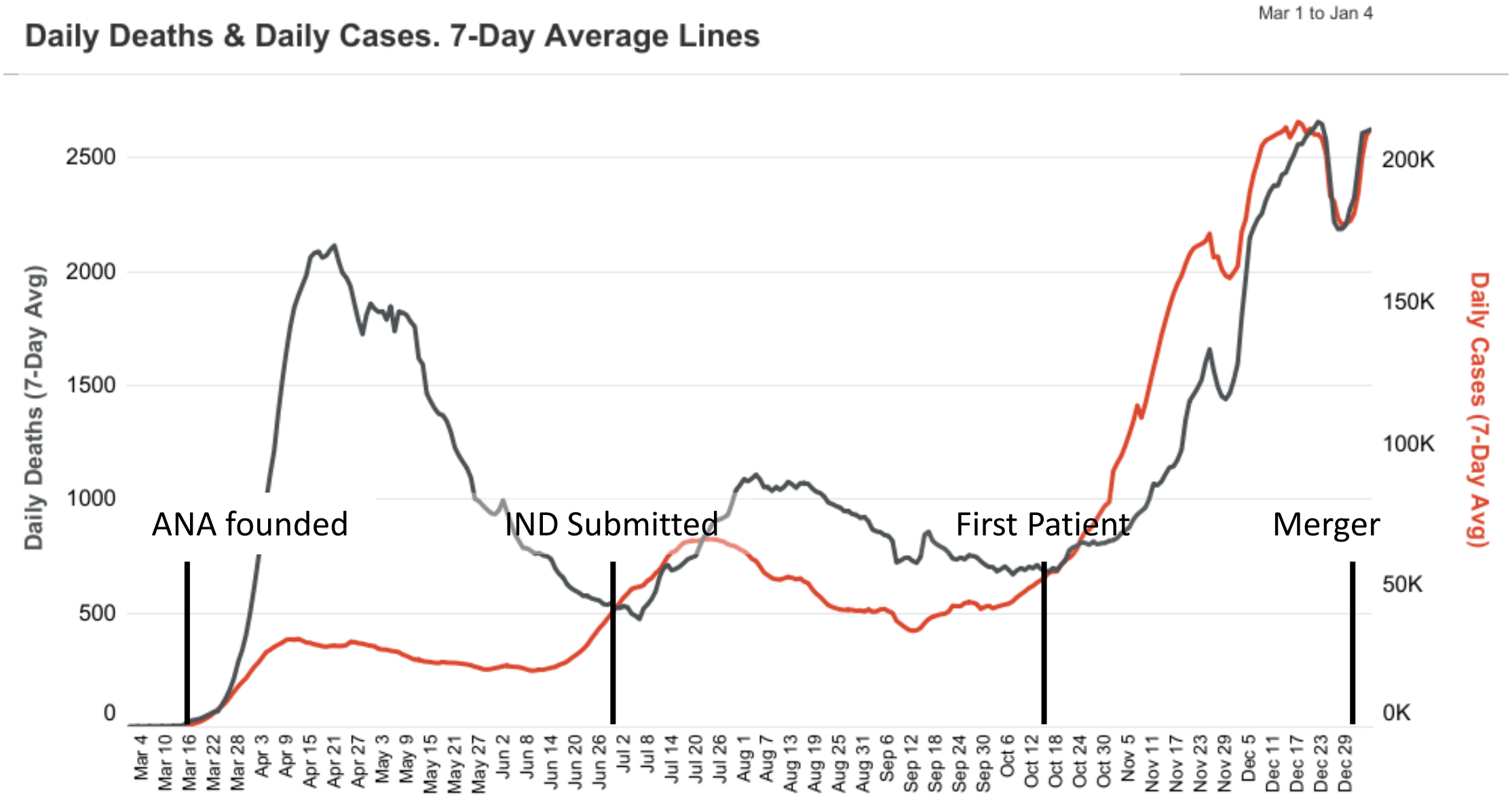
- Director, Banner Alzheimer's Institute, Arizona
- Research Professor of Psychiatry, University of Arizona College of Medicine

NEUROBO DEVELOPMENT PIPELINE




Moderate/Severe Covid-19

Daily Deaths & Daily Cases. 7-Day Average Lines



The COVID Tracking Project

Left Axis	Right Axis	States Included	Regions Included
DAILY DEATHS	DAILY CASES	All	All

What is Niclosamide?

Background

- **On World Health Organization's (WHO) list of essential medicines**
- **Safely treated millions of patients**
- **Currently used to treat tapeworm**

Niclosamide

- **Well-established drug: oral administration known to be safe for 50+ years**
- **Very few, non-severe side effects**
- **Appealing characteristics for most at risk population: elderly patients, high comorbidity, and children**

ANA-001

ANA Therapeutics has developed a proprietary capsule formulation of niclosamide for COVID-19 treatment and prophylaxis

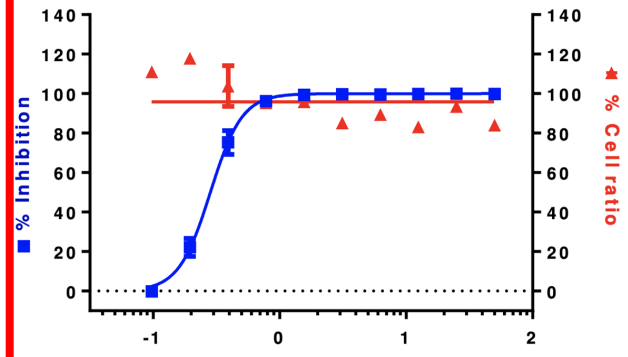
- ANA-001 is being studied in a Phase 2/3 trial in the US that is currently enrolling patients
- Generic niclosamide has been used safely for 50 years globally as a treatment for tapeworm infections
- Niclosamide prevents replication of SARS-CoV-2 at very low concentrations
- Niclosamide has also been shown to have three distinct mechanisms of action:
  - Potent Anti-Viral at lowering SARS-CoV-2 and a broad homology of other virus including **Influenza**.
  - Anti-Inflammatory – Unique MOA that does not suppress immune system while reducing inflammation.
  - Bronchodilation – Useful pulmonary mechanism for at-risk patients with underlying cardio/pulmonary conditions.

Evidence: *In-Vitro* Efficacy Related to COVID-19

Inhibition of SARS-CoV-2 replication

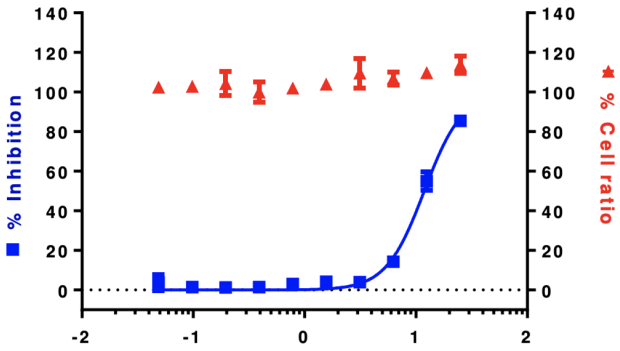
(Jeon *et al.*, 2020, *Antimicrob. Agents Chemother.* doi:10.1128/AAC.00819-20)

Niclosamide



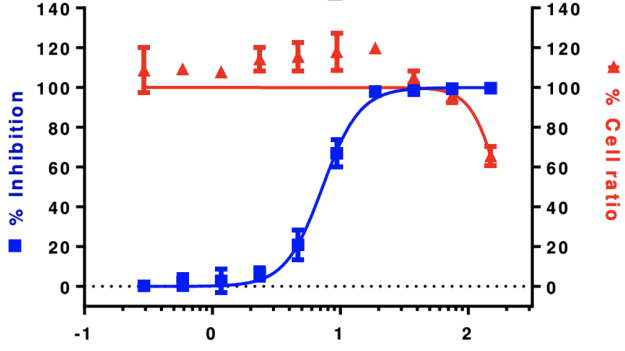
IC50 = 0.28

Remdesivir



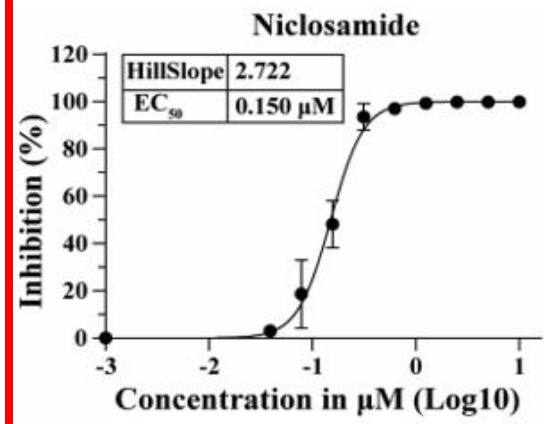
IC50 = 11.41

Chloroquine



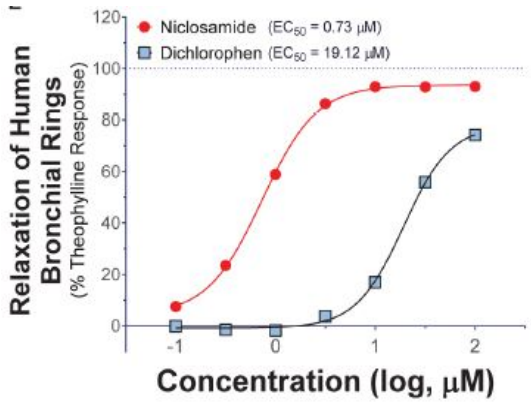
IC50 = 7.28

Anti-Viral



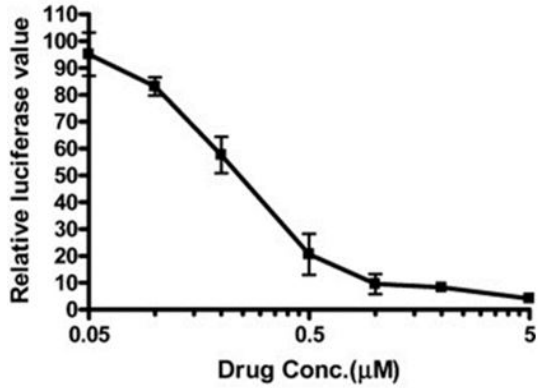
Shi et al., 2020, unpublished

Bronchodilation



Miner *et al.*, 2019, *Front Pharmacol.* doi:10.3389/fphar.2019.00051

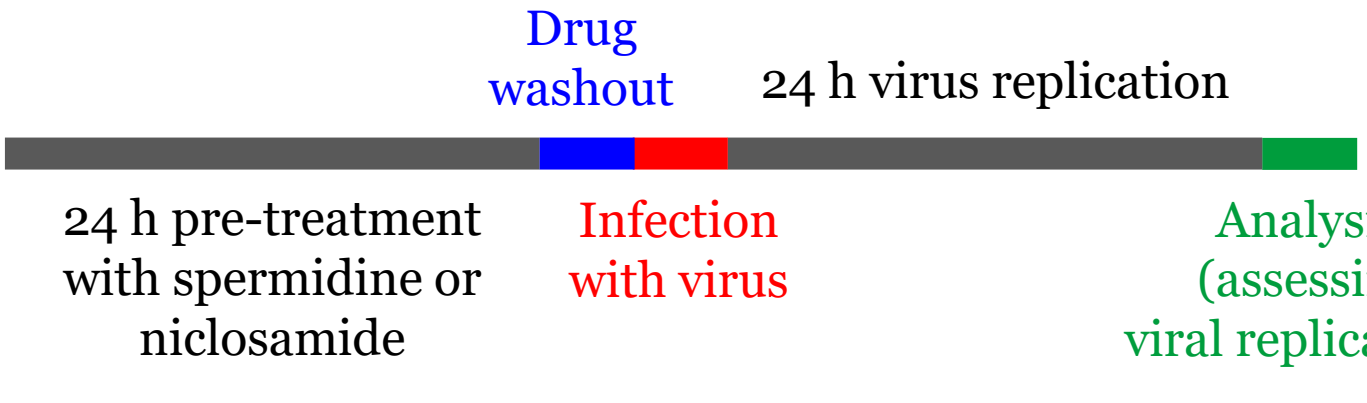
Anti-Inflammatory: STAT3 inhibition

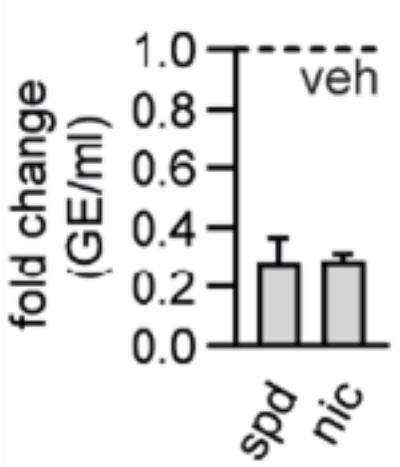


Ren *et al.*, 2010, *ACS Med Chem Lett.* doi: 10.1021/ml100146z

Niclosamide as COVID-19 Prophylaxis

- VeroFM cells were pre-treated with spermidine (spd, 100 µM), niclosamide (nic, 5 µM) or control (veh) 24 h prior to infection with SARS-CoV-2
- Spermidine is a natural enhancer of autophagy to protect the body
- 24 h after infection, viral replication was assessed (normalized to control)
- **Main result: Pre-treating cells with niclosamide reduces viral replication by ~70%**

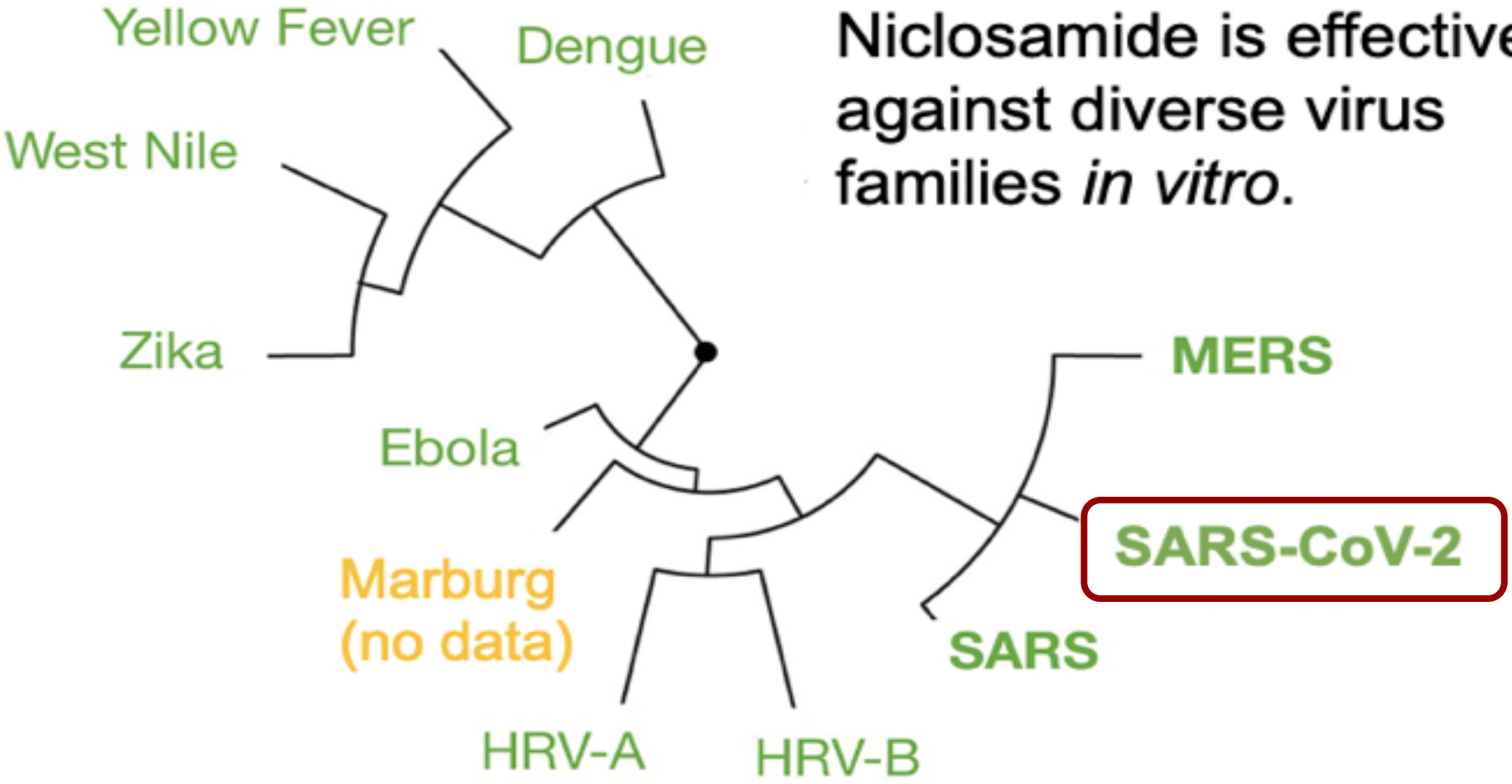




GE: SARS-CoV-2 genome equivalents (determined by real-time RT-PCR)

Gassen *et al.*, 2020, Preprint from *bioRxiv*, doi: 10.1101/2020.04.15.997254

Broad Coverage Across Viral Homology is Important Mutations/Another Corona Virus / Influenza



Niclosamide is effective against diverse virus families *in vitro*.

Source: https://pubs.acs.org/doi/10.1021/acsinfecdis.0c00052

Potential Markets

COVID-19 Hospitalized Patients
(1M in US) [1]

COVID-19 Infected Individuals
(20M in US)[2]

Prophylaxis
Over 65 (55M in US)[3]
Front Line Healthcare
(16M in US)[4]

National Stockpile
(25% of US population)

1. COVID-19 Associated Hospitalization Surveillance Network (COVID-NET) Mar-Dec 2020
2. Johns Hopkins Coronavirus Resource Center Mar-Dec 2020
3. Statista: 16.5% of 331M
4. Center for Economic and Policy Research (CEPR) April 2020

Competitive Activity in Clinical Development
for niclosamide

- 10 total studies listed in ClinicalTrial.gov for niclosamide

Currently Active Programs

Competing Niclosamide trials on US and EU trial databases Company Clinical Trials.Gov	NCT	Phase	Start	End	Formulation	Sites	N
ANA Therapeutics	NCT04603924	2 & 3	Oct-20	Nov-22	O	20 sites	436
Imuneks Farma ilac San.Tic A. S.	NCT04558021	3	Oct-20	Feb-21	O / Suspension	8 in Turkey	200
First Wave Bio	NCT04542434	2	Nov-20	May-21	O	N/A	148
First Wave Bio	NCT04436458	2	Dec-20	Apr-21	O	not listed	100
Bayer through Charite Research Organization GmbH	2020-002233-15	2	Jun-20	Feb/Mar 2021	O	Germany	72
Tufts	NCT04399356	2	Oct-20	Feb-21	O	not listed	100
Daewoong Pharmaceutical	NCT04592835	1	Oct-20	Dec-20	IM	Australia	24
Daewoong Pharmaceutical	NCT04541485	1	Oct-20	Jan-21	IM	Phillippines	40
Daewoong Pharmaceutical	NCT04524052	1	N/A	Dec-20	IM	India	32
Union Therapeutics	EU	1	Aug-20	N/A	Inhaled	N/A	N/A

We believe ANA is estimated to be the lead program to NDA for niclosamide capsule formulation in the U.S.

Landscape of Vaccines and Therapeutics

Prevention (Vaccines)	Therapeutics (Treatment)
Pfizer – RNA / 2 shots	Hydroxychloroquine
AstraZeneca – Viral Vector / 2 shots	Convalescent Plasma
Moderna – RNA / 2 shots	Antibody- Regeneron / Lilly
Novavax – Protein Subunit / 2 shots	Remdesivir – Gilead $875M in Q3/2020
Sanofi – Protein Subunit / 2 shots	Olumiant - Lilly
Merck – Viral Vector / 1 shot	Dexamethasone
J&J – Viral Vector / 1 or 2 shots	+ Hundreds other drugs in small trials

- Vaccines have a challenge with public trust
- Cost of manufacturing is high especially for 2 shot
- Protective immunity 4-6 months = 4 shots yr.
- Cost of cold chain distribution is expensive
- Still need a therapeutic for those who get sick

- Effectiveness has been underwhelming
- Most lack mortality benefit
- Several temporally lower body's Immune System
- Some have safety concerns
- IV and injectable formulations not ideal

Vaccines are an Important Tool in Battling COVID-19 However There are Challenges to Overcome

- RNA Vaccine - Ultra Cold storage (-100° F) and “cold chain” distribution scale-up
- Manufacturing: scale-up capacity
- Essential supply of vials, syringes, etc.
- 2 administrations necessary 28 days apart
- Willingness of population to get vaccinated
- Mutation of viral sequence may require new vaccines

Unknowns:

- Long term efficacy
- Efficacy in diverse populations
- Safety – Side effects
- Long term impacts of covid infections in vaccinated individuals
- Can vaccinated individuals still spread COVID?

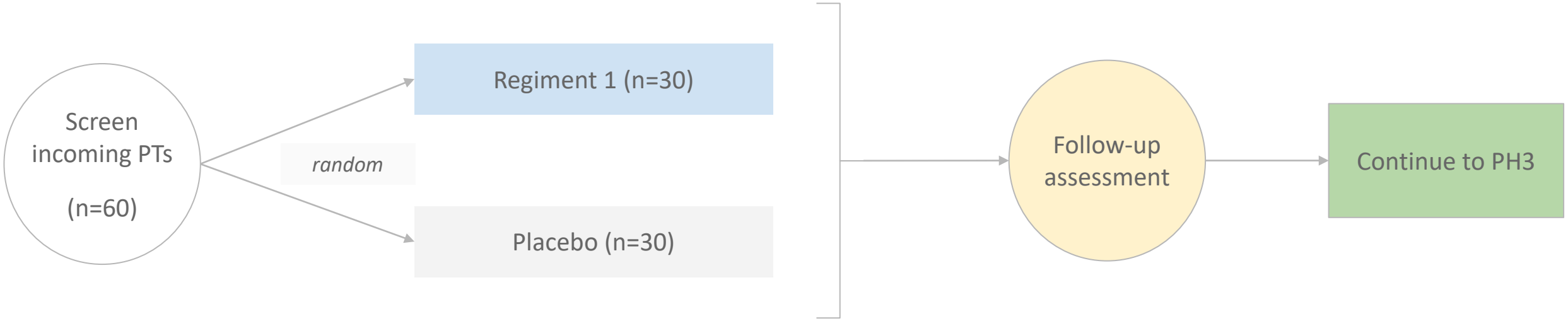
Pharma is still hungry for Antivirals

Roche Secures Covid-19 Treatment In $350 Million Deal With Boston-Based Atea

Robert Hart Forbes Staff
Business
I cover breaking news.

TOPLINE Swiss pharma giant Roche has signed a $350 million deal with Boston-based Atea Pharmaceuticals for the exclusive right to research, develop and distribute a potential Covid-19 treatment outside the U.S., Atea said Thursday — the oral antiviral is currently in phase 2 clinical trials and there are plans to study it as a way of preventing Covid-19 infection.

Clinical Trial Design: Phase 2



Criteria:

✓
✓
✓
✓

Primary objective:

Primary Endpoint:

Outcomes:

Update on ANA001-002 (Phase 1 study)

SAD n=30 (8 subjects on ANA001, 2 on placebo / per cohort)	Date	Outcomes
Cohort 1: 1,000 mg	Nov 17, 2020	no AEs
Cohort 2: 2,000 mg	Nov 20, 2020	no AEs
Cohort 3: 3,000 mg	Nov 24, 2020	no AEs

COMPLETED

Emergency Use Authorization

- The primary mechanism of FDA approval of therapeutics during the COVID-19 pandemic has been **Emergency Use Authorization (EUA)**
- EUA requires a lower level of evidence than the "effectiveness" standard that FDA uses for standard product approvals.
- None of the existing therapeutics approved under EUA have demonstrated any mortality benefit
- Key examples include:
  - Remdesivir (Gilead)
  - Convalescent plasma
  - Hydroxychloroquine
  - Remdesivir + Baricitinib (Eli Lilly)
  - Casirivimab and Imdevimab (Regeneron)
  - Bamlanivimab (Eli Lilly)

EUA Definition & Criteria

What is EUA?

During a public health emergency, the FDA may authorize the introduction of a drug into interstate commerce, including one which is not yet (or currently) approved under 505 of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Per Section 564 of the FD&C Act, EUA is appropriate in consideration of the following conditions

(1) serious of life-threatening disease or condition,

(2) evidence of effectiveness,

(3) risk-benefit analysis, and

(4) no alternatives.

Each of these conditions is met in relation to the potential for ANA001 to treat COVID-19.

Hatch-Waxman Exclusivity and Intellectual Property

- **NRBO is pursuing an abbreviated regulatory using A 505(b)(2) New Drug Application (NDA).**
    - **This allows for referencing all the safety data from niclosamide's original approval.**
- **A 505(b)(2) New Drug Application (NDA) provides 3 years of market exclusivity**
    - **Niclosamide is not currently approved in the US, so there is unlikely to be competition**
    - **Three-year exclusivity period would block the approval of any generic drugs.**
- **The three-year exclusivity period may be extended by 6 months with pediatric exclusivity**
- **NRBO will continue to supplement the provisional filing, which will include clinical data from COVID positive patients.**
    - **This is a unique opportunity in biotech/pharma and expected to be particularly valuable in priority jurisdictions.**

COVID-19: Timeline Slide for ANA-001 Commercial Development

Clinical Timeline