

Company Presentation

March 2021

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Developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases

Repurposing ANA001 as a rapid COVID-19 treatment (Priority)

ANA001–COVID-19 Trial

- Compelling in-vitro data showing evidence of efficacy, with 50+ years of safety data
- Shows great broad-spectrum antiviral activity
 - Data suggests effectiveness against other viruses such as influenza
 - Likely effective against novel SARS-CoV-2 variants
- Shows anti-inflammatory properties, without suppressing immune response
- Shows promise as a prophylactic

Pipeline Programs Addressing Large Unmet Needs

Gemcabene: Assessing for acute COVID-19

- 25 Phase 1 and Phase 2 trials completed in Chronic Orphan Dyslipidemia indications

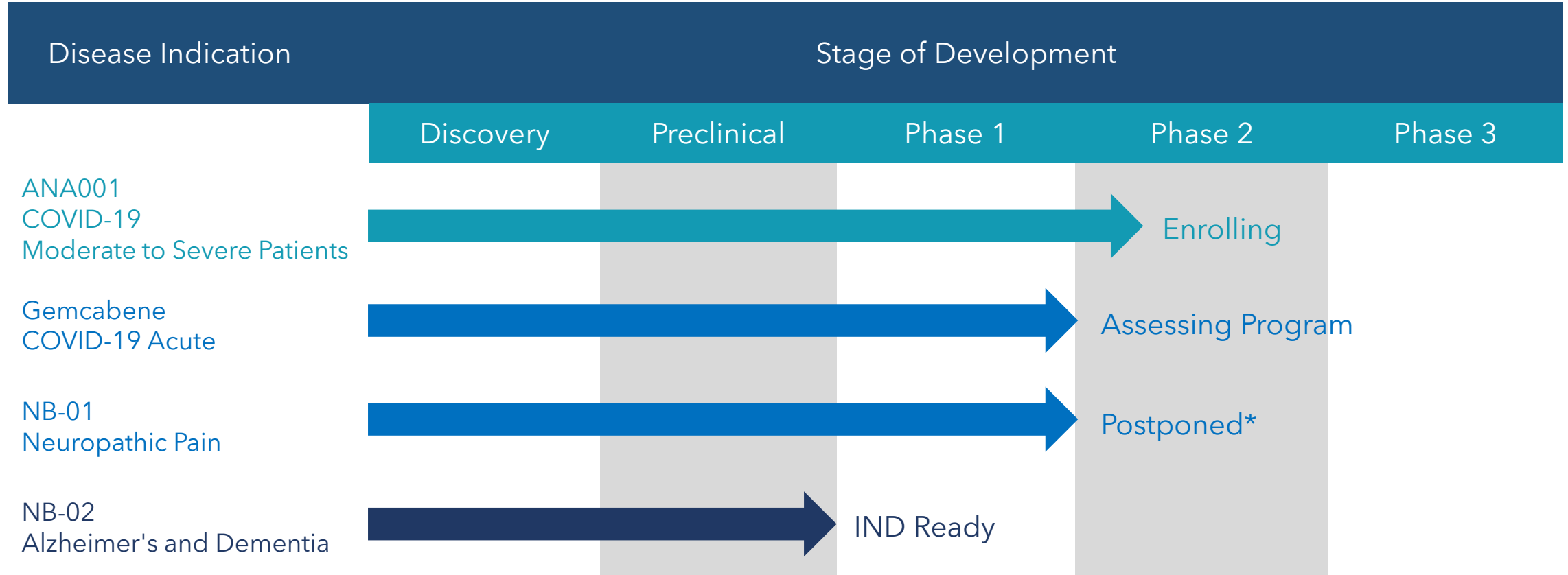
NB-01–Targeting Pain in Orphan Indication

- Compelling Phase 2 data showing evidence of 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; compelling preclinical data

Development Pipeline



*Due to constraints on initiating and conducting clinical studies during pandemic

Richard J. Kang, PhD
President & CEO

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

Nadja Mannowetz, PhD
SVP, Scientific Affairs

- Co-Founder and CSO of ANA Therapeutics
- Co-Founder and CSO of YourChoice Therapeutics, a Y Combinator backed startup
- PhD in Infectious Biology from Eberhard Karls University, Tübingen, Germany

Akash Bakshi, MsC.
Chief Operating Officer

- Co-Founder and CEO of ANA Therapeutics
- Co-Founder and CEO of YourChoice Therapeutics, a Y Combinator backed startup
- Previously Assistant Director of Marketing and Technology Analysis at UC Berkeley

Andrew Bartynski, PhD
SVP, Manufacturing and CMC

- Co-Founder and COO of ANA Therapeutics
- Founding CEO for AesculaTech, a Y Combinator backed startup
- PhD in Chemical Engineering from the University of Southern California

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 analyst

ALZHEIMER'S DISEASE & OTHER DEMENTIAS

[Brian Bacsikai, Ph.D.](#)

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

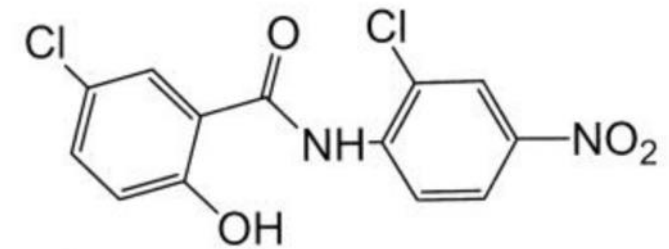
ANA001 Targeting COVID-19



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

Safety Profile

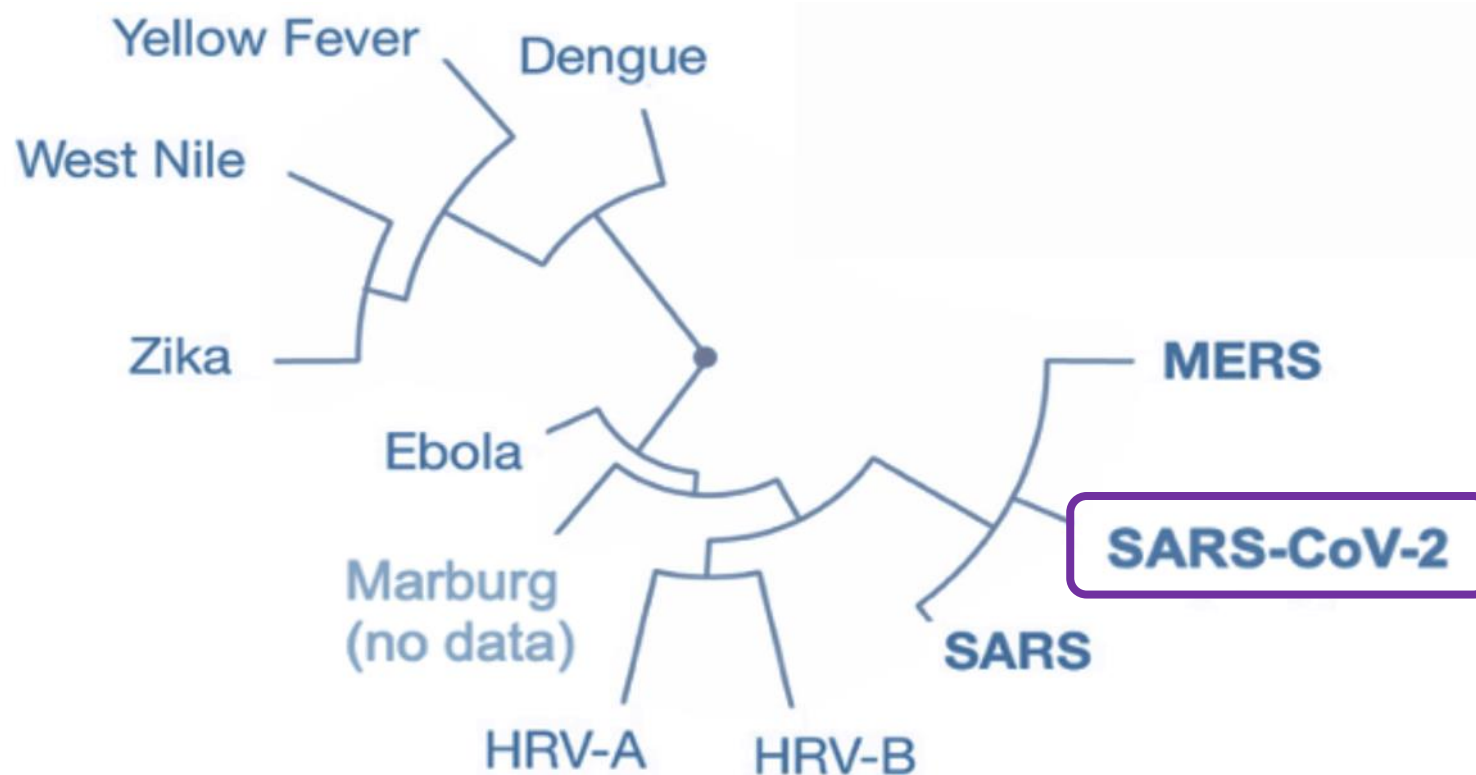
- Well-established drug: oral administration known to be safe for 50+ years
- Very few, non-severe side effects
- Appealing characteristics for most at risk population: elderly patients, high comorbidity, and children

Acquired proprietary capsule formulation of niclosamide for COVID-19 treatment and prophylaxis

- ANA001 being studied in U.S. Phase 2/3 trial (currently enrolling patients)
- Generic niclosamide used safely for 50+ years globally as a treatment for tapeworm infections
- Niclosamide prevents replication of SARS-CoV-2 at very low concentrations
- Niclosamide also shown to have three distinct mechanisms of action:
 - **Potential Antiviral:** Lowers SARS-CoV-2 and a broad homology of other virus including Influenza.
 - **Anti-Inflammatory:** Unique MOA does not suppress immune system while reducing inflammation.
 - **Bronchodilation:** Useful mechanism for at-risk patients with underlying cardio/pulmonary conditions.

Mutations / Another Corona Virus / Influenza

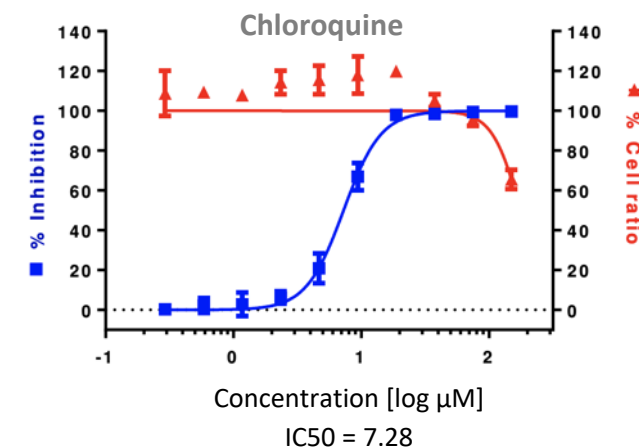
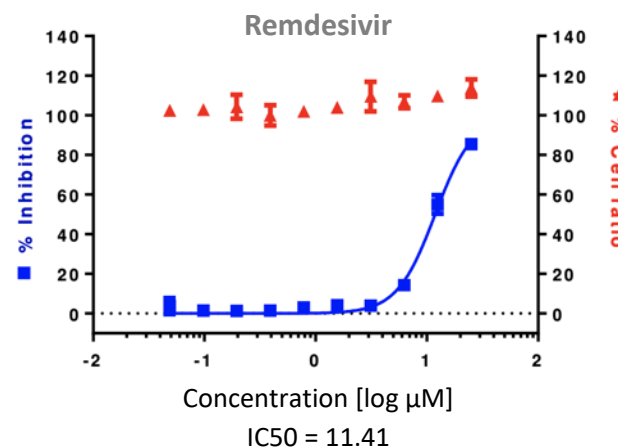
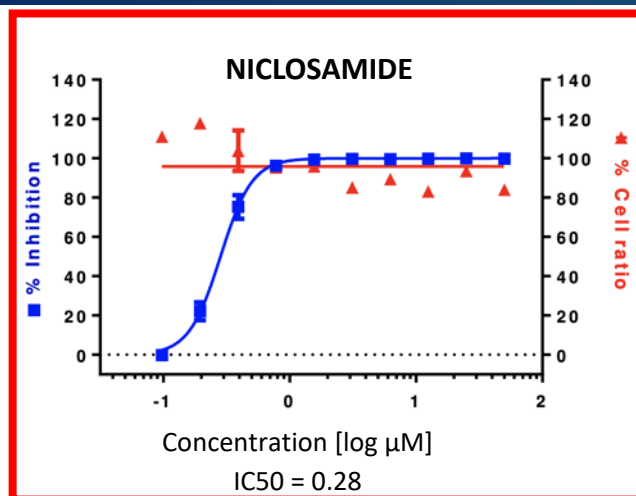
Niclosamide is effective against diverse virus families *in vitro*.



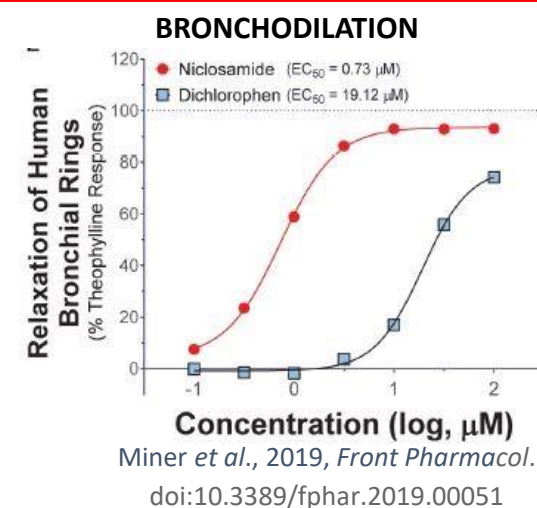
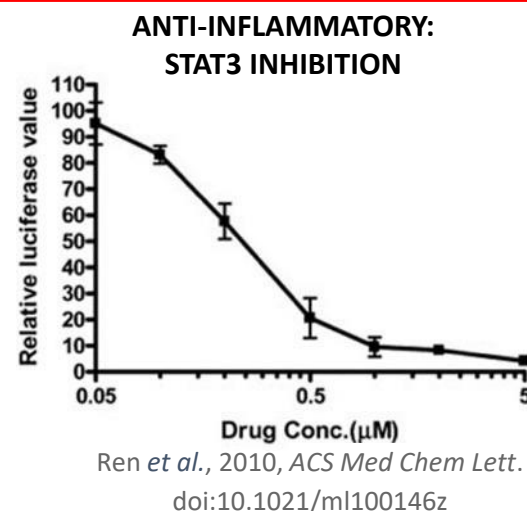
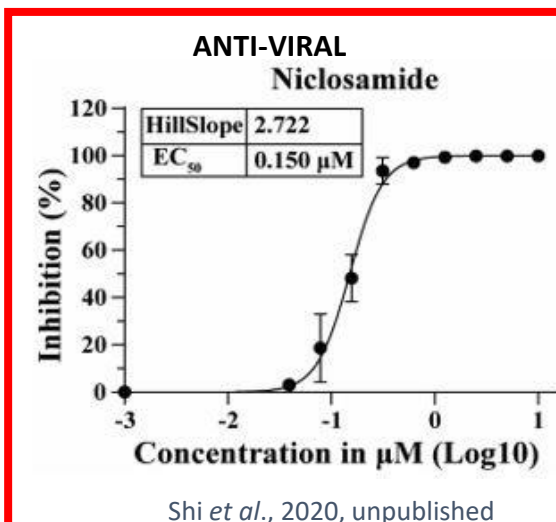
Evidence: *In-Vitro* Efficacy Related to COVID-19

Inhibition of SARS-CoV-2 replication

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

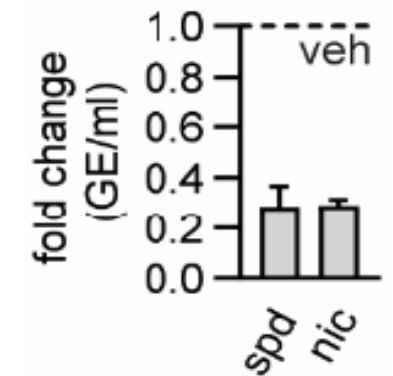
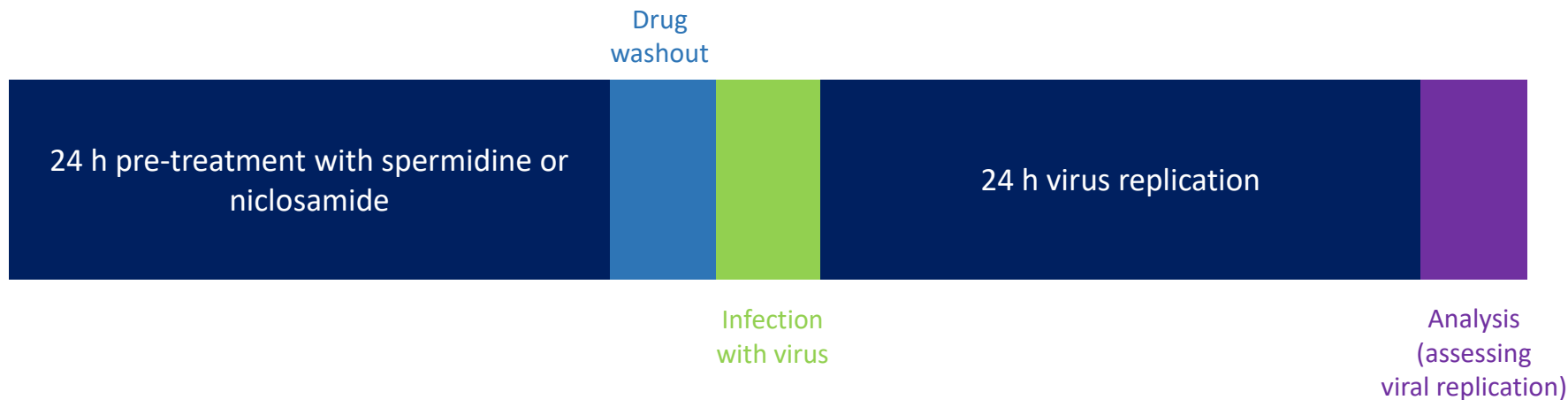


Studies highlighting properties of niclosamide as COVID-19 treatment



Pre-treating cells with niclosamide reduces viral replication by ~70%

- VeroFM cells were pre-treated with spermidine (spd, 100 μ M), niclosamide (nic, 5 μ M) 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)



GE: SARS-COV-2 GENOME EQUIVALENTS (DETERMINED BY REAL-TIME RT-PCR)

ANA001 and COVID-19

Clinical Program



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

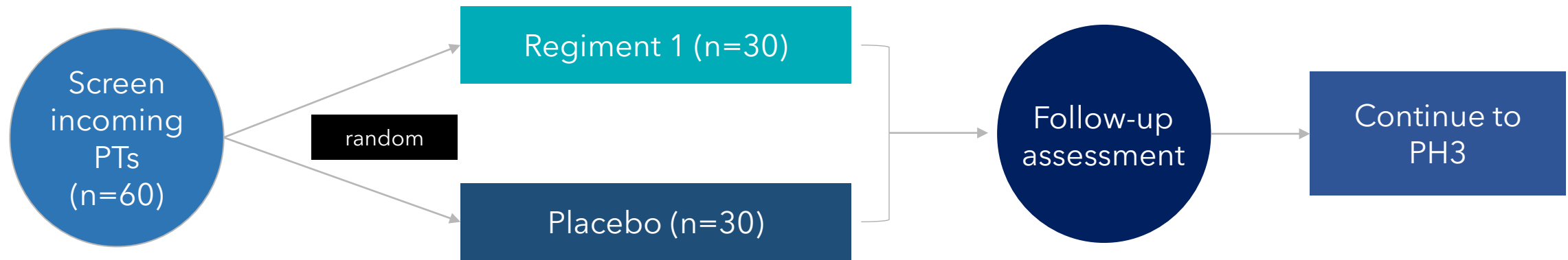
Cohort 3: 3,000 mg

Nov 24, 2020

no AEs

COMPLETED

Clinical Trial Design: Phase 2/3



Criteria:

- ✓ Age >18
- ✓ Moderate/Severe COVID-19
- ✓ Confirmed by RT-PCR
- ✓ Not on a ventilator

Primary Objective:

Evaluate effect of dosing regimen on clinical outcomes after niclosamide therapy with 60 patients

Primary Endpoint:

Safety and adverse events

Outcomes:

Continue to Phase 3 to test efficacy

Competitive Activity in Clinical Development for Niclosamide



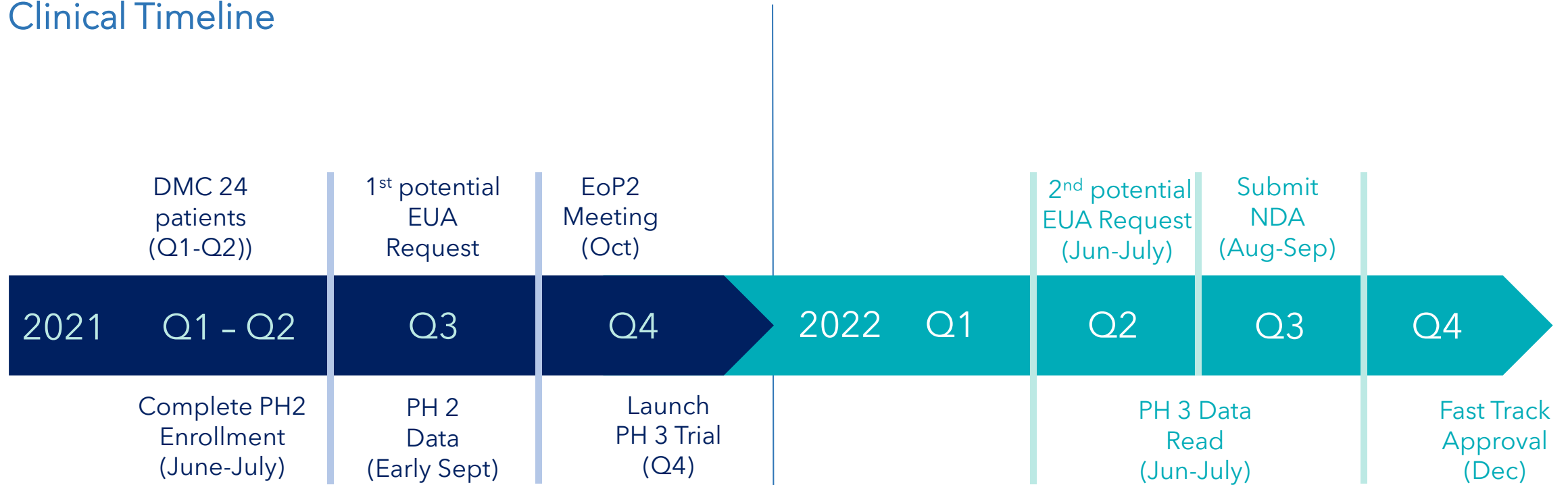
We believe NRBO is the lead program to NDA for niclosamide capsule formulation in the U.S.

Company Name	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

10 Active COVID Programs for Niclosamide Trials on U.S. and EU databases–ClinicalTrials.gov

COVID-19: Timeline Slide for ANA001 Commercial Development

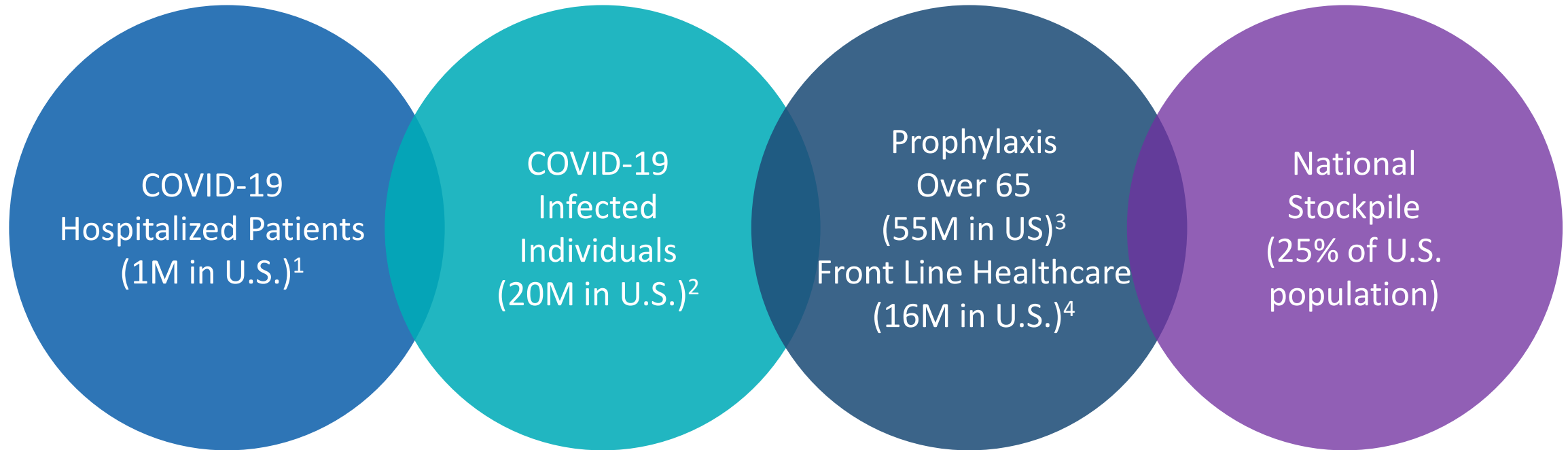
Clinical Timeline



ANA001 and COVID-19

The Changing Landscape





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

Vaccines are Just One Tool for COVID-19

Challenges:

- RNA Vaccine—Ultra Cold storage
- Manufacturing: scale-up capacity
- Most vaccines are 2 doses
- 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
- Vaccinated individuals still spread COVID
- Efficacy on new mutations

TFF Pharma and UNION Therapeutics Ink Deal to Develop Niclosamide for COVID-19

Published: Aug 14, 2020 | By Mark Terry

Under the terms of the deal, UNION is paying TFF Pharmaceuticals potential development, regulatory and sales milestones up to \$210 million, as well as tiered single-digit royalties on product sales. UNION gains an option to a worldwide exclusive license to TFF technology for niclosamide, including oral and inhaled versions of the drug, potentially for COVID-19, but also for other niclosamide-based therapies. The two companies will also collaborate on securing government contracts and grants to fund the development of the therapies for COVID-19.

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.

Corporate Highlights



- NRBO is pursuing an abbreviated regulatory pathway 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 NDA was withdrawn in 1996 due to low incidence of tapeworm in the U.S.
 - 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.
- Continue to supplement the provisional filings, which include clinical data from COVID patients.
 - Potential to strengthen IP in priority regions globally.



- Shares outstanding : 22.2 M
- Cash position: \$12.4M as of 9/30/20
- \$10M Raise in January 2021
- Debt position: No debt

Upcoming Targeted Milestones



- PK Data (SAD and MAD) (2Q 21)
- Complete Phase 2 enrollment of ANA001 in moderate to severe COVID-19 patients (Jun/Jul 21)
- Topline data from Phase 2 ANA001 in moderate to severe COVID-19 patients (Sep 21)
- Potential consideration for EUA based on Phase 2 topline data (3Q 21)
- Initiate the Phase 3 portion of the ANA001 clinical trials (4Q 21)

Thank You

