Ethnobiology drug development for COVID-19 and future pandemics

ARTIVEDA™/ OT-101/ COVID-19

DEC 1, 2020

WWW.MATEON.COM

Forward-looking Statements

This document contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words “will,” “may,” “would,” “approximate,” “expect,” “intend,” and similar expressions and their variants, as they relate to the Company, Oncotelic or the management of either company, before or after the Merger, may identify forward-looking statements. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, uncertainties as to the timing of financing and the outcome of the clinical program and the outcome of FDA interactions. This review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company’s Annual Report on Form 10-K filed with the SEC on April 10, 2019. Forward looking statements are based on information available and assumptions as of the date of this report. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

MATEON THERAPEUTICS

Building the next generation biotech focusing on speed and efficiency

PointR.AI

ONCOTELIC

Cluster-computing

Antisense Drug

TGF-β target

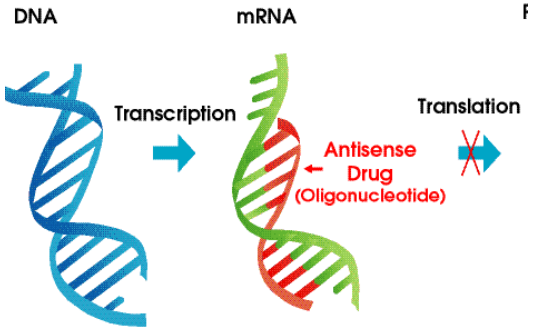
Covid-19 Therapeutics

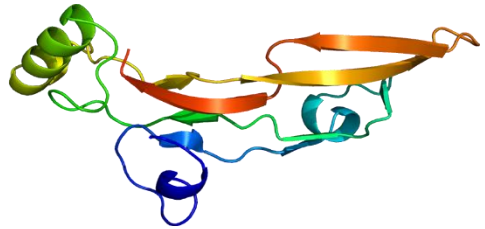
1) **OT-101**

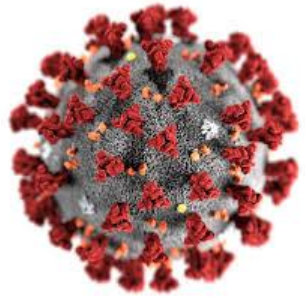
TGF-β antisense

2) **Artemisinin**

TGF-β inhibitor







Yes, we need a vaccine to control Covid-19. But we need new treatments, too

By Karen Mulligan and Karen Van Nuys/August 5, 2020 and John Whyte, MD, MPH; Davey Smith, MD/October 06, 2020

A vaccine is not a silver bullet

- Even if proven safe and effective, vaccines are difficult to make and distribute.

Treatments are an essential part of the Covid-19 fight for two reasons.

- First, they are an indispensable tool for managing the pandemic before a vaccine is available. And second, even after a vaccine is available, treatments will be the essential backstop to manage illness resulting from imperfections in vaccine effectiveness and uptake.

An economic model from USC Schaeffer Center

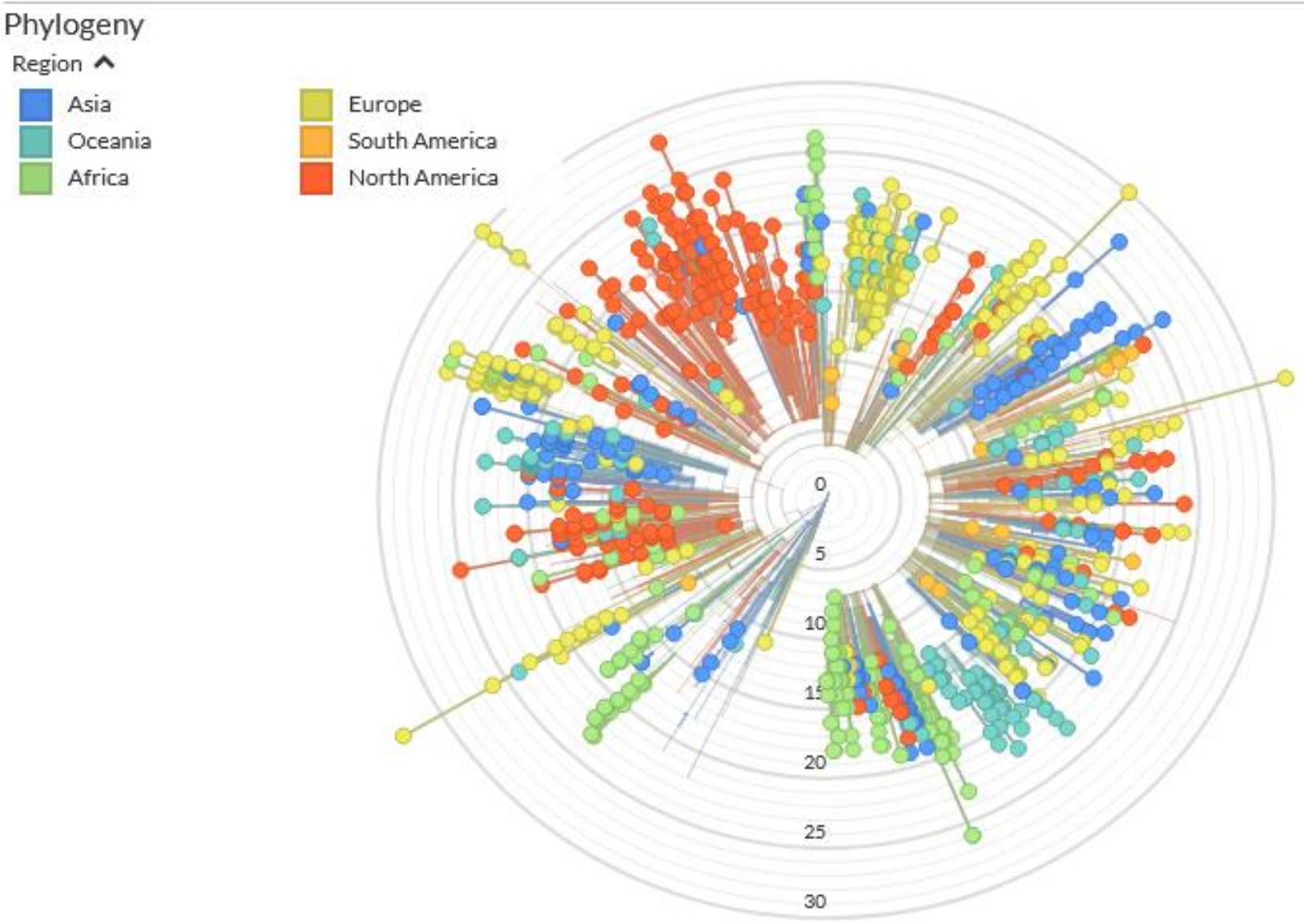
- A treatment that can cut the need for hospitalization by 50% would result in 285,000 fewer admissions for Covid-19 and up to 71,000 fewer deaths by the end of 2021, assuming that 20% of the population becomes infected and half of those with symptoms get the treatment.

Economic Offset Model

- An effective treatment would also offset the economic losses. Given the $7.9 trillion negative impact Covid-19 has had on the U.S. economy, if a treatment could offset the economic losses by even 5% (or almost $400 billion), the economic benefit would be 5X-7X larger than the health benefits in the model.

https://www.statnews.com/2020/08/05/we-need-a-covid-19-vaccine-but-we-need-new-treatments-too/

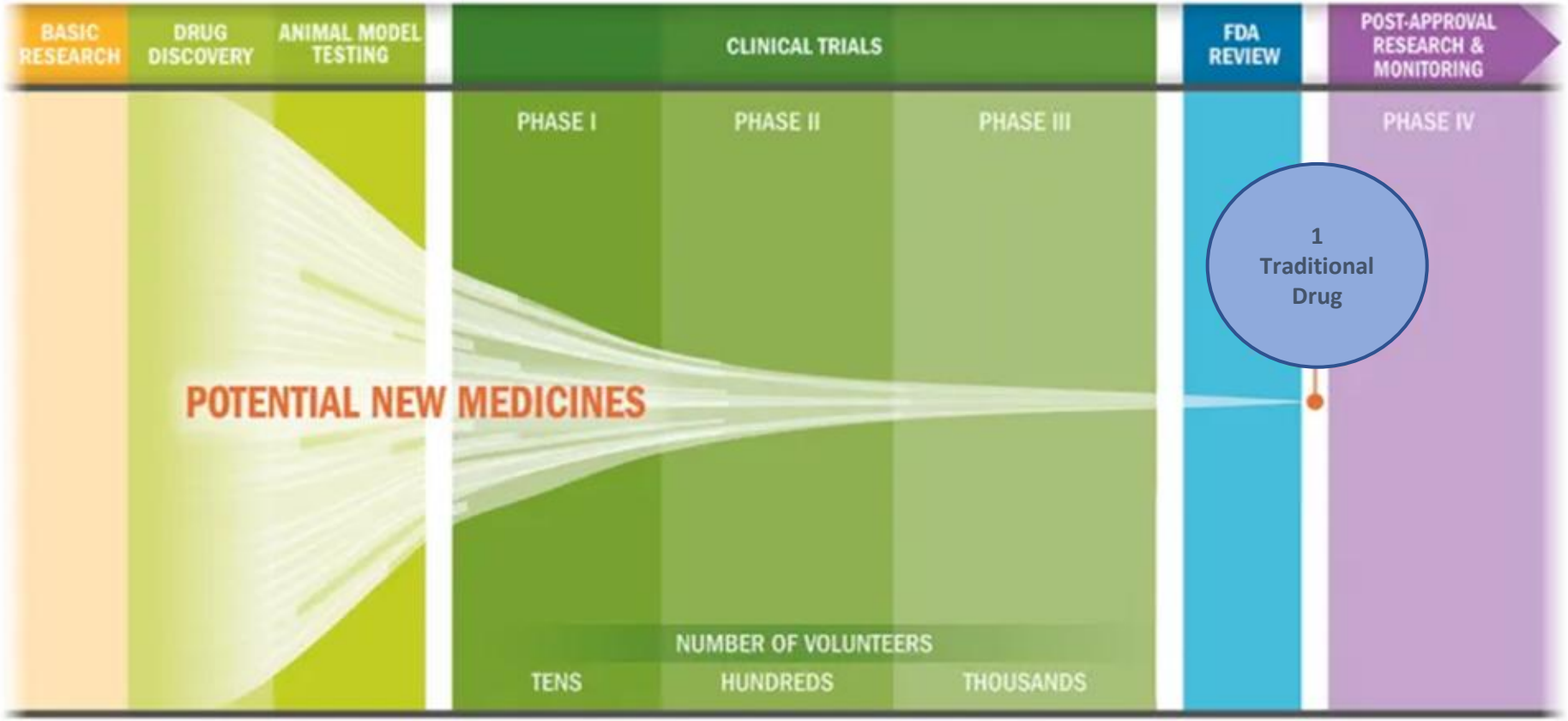
And the virus will keep mutating



Fourth state confirms mink farm coronavirus outbreaks as U.S. looks to avoid Denmark's disaster. Oregon had become the fourth state to confirm a coronavirus outbreak on a domestic mink farm.

Danish minks were culled en masse weeks earlier after scientists discovered they carried a mutated strain of the virus that if spread back to humans could reduce the efficacy of a potential vaccine.

Conventional COVID-19 Response Programs



Trillions of dollars/ Countless manhours without a therapeutic in sight

Time to revamp the conventional approach

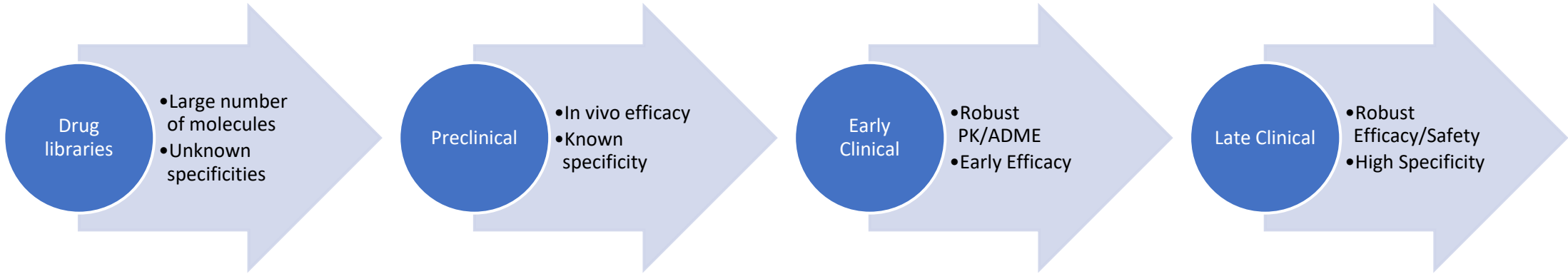
Conventional COVID-19 Therapeutics

Drug Name	Mechanism/ Target	Outcome	Trial Name/N
Lopinavir	Antiviral/ Protease Inhibitor	Fail	WHO SOLIDARITY/ 1411 UK RECOVERY/ 1616
Hydroxychloroquine	Antiviral/ Antimalarial/ TRL	Fail	WHO SOLIDARITY/ 954 UK RECOVERY/ 790
Remdesivir	Antiviral/ RNA Polymerase	Fail	WHO SOLIDARITY/ 2750
Interferon	Antiviral/ Immune Activation	Fail	WHO SOLIDARITY/ 2063
Kevzara® (sarilumab)	mAb against IL-6 receptor	Fail	Sanofi Phase 3/ 420 Total
Actemra (tocilizumab)	mAb against IL-6 receptor	Fail	COVACTA/ 450 Total
laris® (canakinumab)	mAb against IL-1β	Fail	CAN-COVID/ 454 Total
Bamlanivimab/ LY-CoV555	anti-SARS-CoV-2 mAb (Spike Protein)	Fail	BLAZE-2/ 350 Total
Convalescent plasma	Anti-SARS-CoV-2 antibodies	Fail	India PLACID/ 464 Total
Dexamethasone	**Anti-Inflammatory**	**Success**	**RECOVERY/ 2104**

Large WHO SOLIDARITY Trial and UK RECOVERY Trial – only DEXAMETHASONE was effective – but only for severe COVID

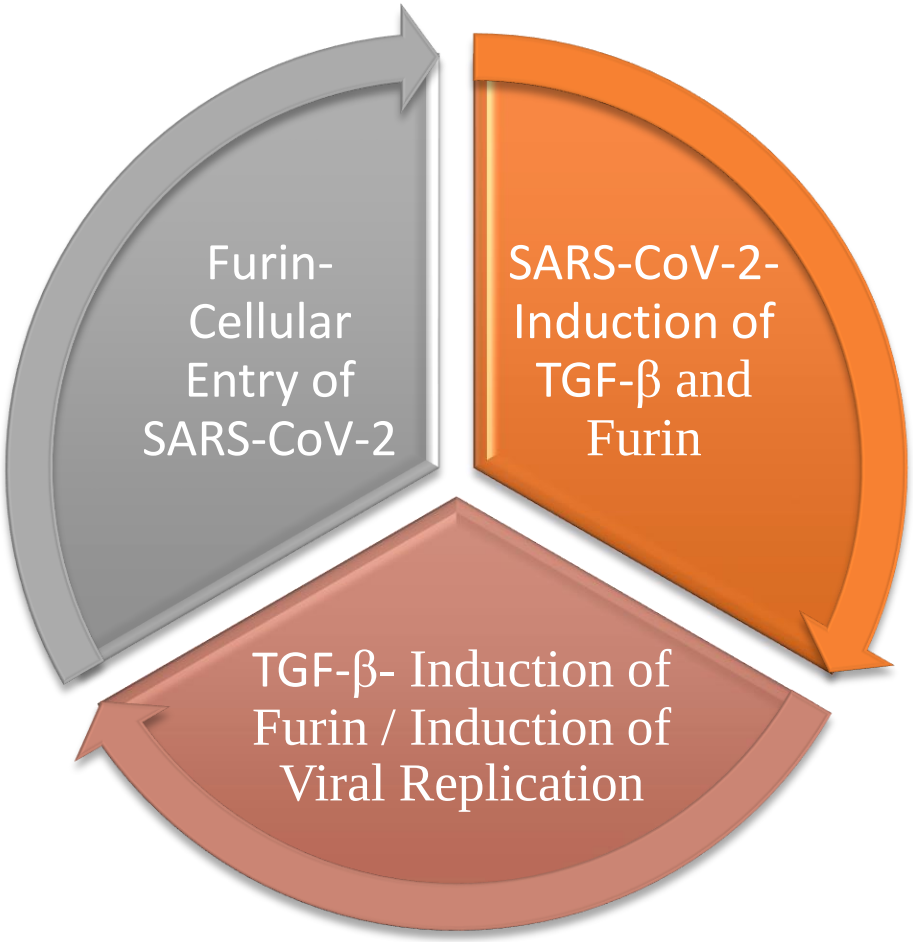
Plus and Minus with conventional pathway

- Highly bureaucratic and Expensive infrastructure
  - IRB Approval/ Regulatory Approval /Import permit
  - Logistics/ Site training/ Pts Recruitment
  - Solidarity Trial- Example of a rapid reponse trial: 11 Feb/ Concept => 6 Mar/ Protocol => 18 Mar/ Launch => 17 Jun HCQ failed => 15 Nov/ Interim Read/ Remdesivir failed
- **Strength in the data to conclusively prove whether the drug is working or not**
- **Singular focus on one drug for one disease**
- **The further down the road the more unlikely the drug can be repositioned for novel infectious agent**
- **Most important- regulatory authorities do make mistakes ie. Remdesivir**
- **Everyone was chasing the wrong targets**

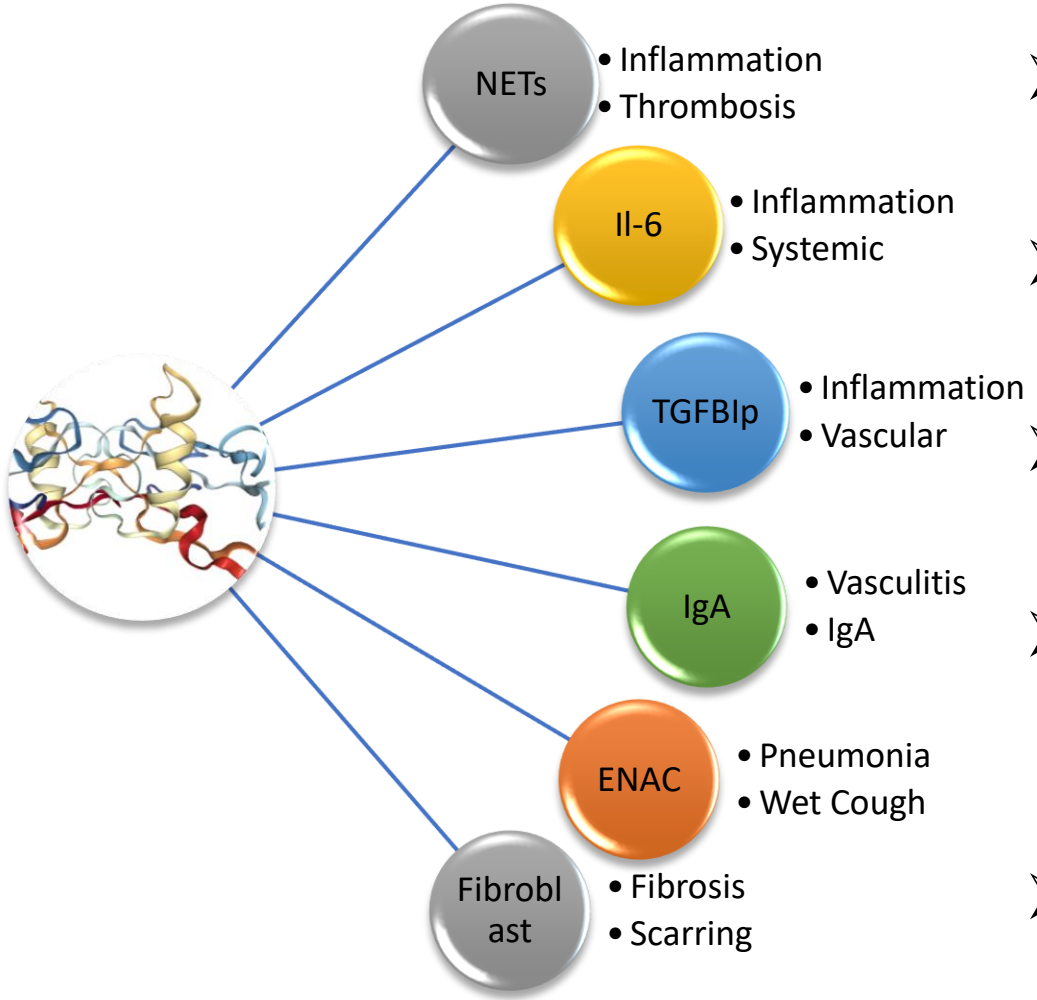


TGF-β Positive Feedback Loop

- SAR-CoV-2 infection upregulates TGF-β and Furin. Stukalov A et al. bioRxiv.2020.06.17.156455
- TGF-β locks cell cycle allowing the virus to replicate.
- TGF-β drives the expression of Furin- a protease required for the cellular entry of SARS-CoV-2. In well-differentiated primary human 1 bronchial epithelial cells, TGF-β1 and TGF-β2 induce expression of furin. Michael J. O'Sullivan, Jennifer A. Mitchel, Chimwemwe Mwase, Maureen McGill, Phyllis Kanki, Jin-Ah Park
- Furin /SARS-CoV-2/ TGF-β constitutes the positive loop that keeps spinning off TGF-β resulting in TGF-β surge
- Nothing is more dangerous than a out of control positive feedback loop



Impacts of TGF-β Surge

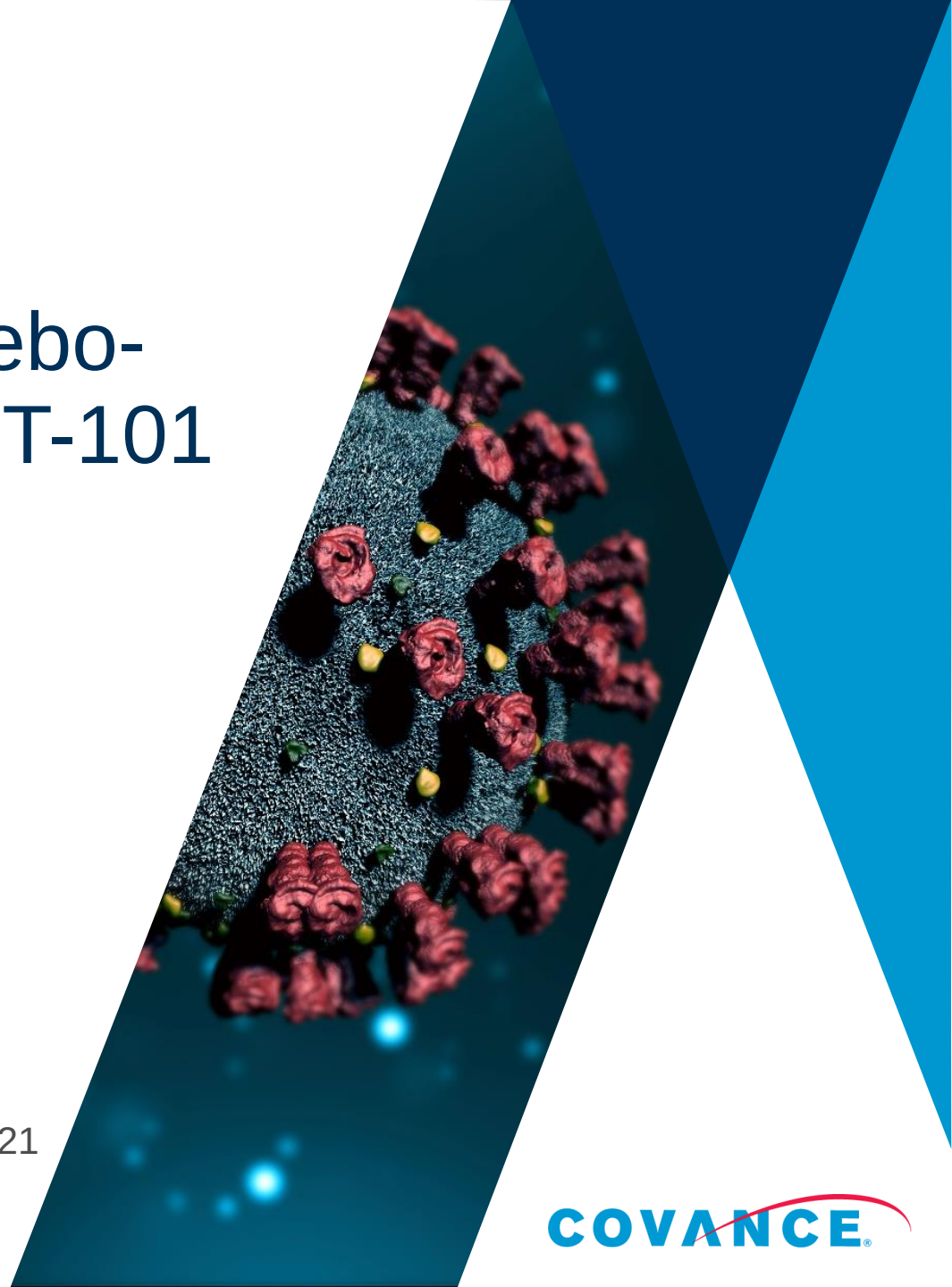


- TGF-β recruits neutrophils into the site of inflammation laying down neutrophil extracellular traps (NET's) responsible for capillaritis, fibrin deposition, mucositis in COVID-19 [Barnes BJ et al. J Exp Med. 2020;217(6):e20200652.].
- TGF-β inhibits ENaC and causes fluid accumulation in the lung and ARDS/pneumonia. [Pittet JF et al. J Clin Invest. 2001;107(12):1537-1544.].
- TGF-β induces late stage fibrosis compromising lung capacity even after recovery [Wang L et al. Int J Clin Exp Pathol. 2019;12(7):2604-2612. Published 2019 Jul 1].
- TGF-β induces IL-6 leading to systemic inflammation and "cytokine storm". [Turner M et al. Cytokine. 1990;2(3):211-216.].
- TGF-β induces TGFBIp leading to vascular inflammation. Park et al. found that TGFBIp and its derivative TGFBIp K676Ac, acetylated 676th lysine TGFBIp, are elevated in the blood of SARS-CoV-2 pneumonia patients (n=113); especially in intensive care unit (ICU) patients than non-ICU patients [Park HH et al. Sci. Adv. 2020; DOI: 10.1126/sciadv.abc1564.].
- TGF-β induces IgA class switching leading to IgA vasculitis/ Kawasaki Disease syndrome. A significant positive association was found between SARS-CoV-2 specific IgA level and the APACHE II score in critically ill patients with COVID 19 (r=0.72, P=0.01) [Yu HQ et al. Eur Respir J. 2020;2001526.].

COVID-19 Clinical Trials- Hypercompetitive

- 3,807 studies on ClinicalTrial.gov
- 753 studies on CTRI- India clinical trial registry
- US COVID 19
  - Highly competitive environment.
    - Low infection rate => too many trials competing
    - High infection rate => too busy treating patients
- Ex-US COVID-19
  - Less competitive.
  - Need to pair up with a strong local CRO
  - Logistics/Importing issues
  - Central lab issues
- Australia
  - Few infection => shut down in hot spots
- UK- COVID-19
  - UK Recovery trial

A Double-Blind, Randomized, Placebo-Controlled, Multi-Center Study of OT-101 in COVID-19 Subjects



27 Oct 2020----------First patient in expect Dec 15 and top line data 1Q21

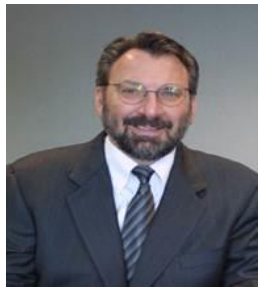
C001 Leads

Kathy Carter

Covance Senior Project Manager, Project Lead

Vuong Trieu

Oncotelic Chief Executive Officer



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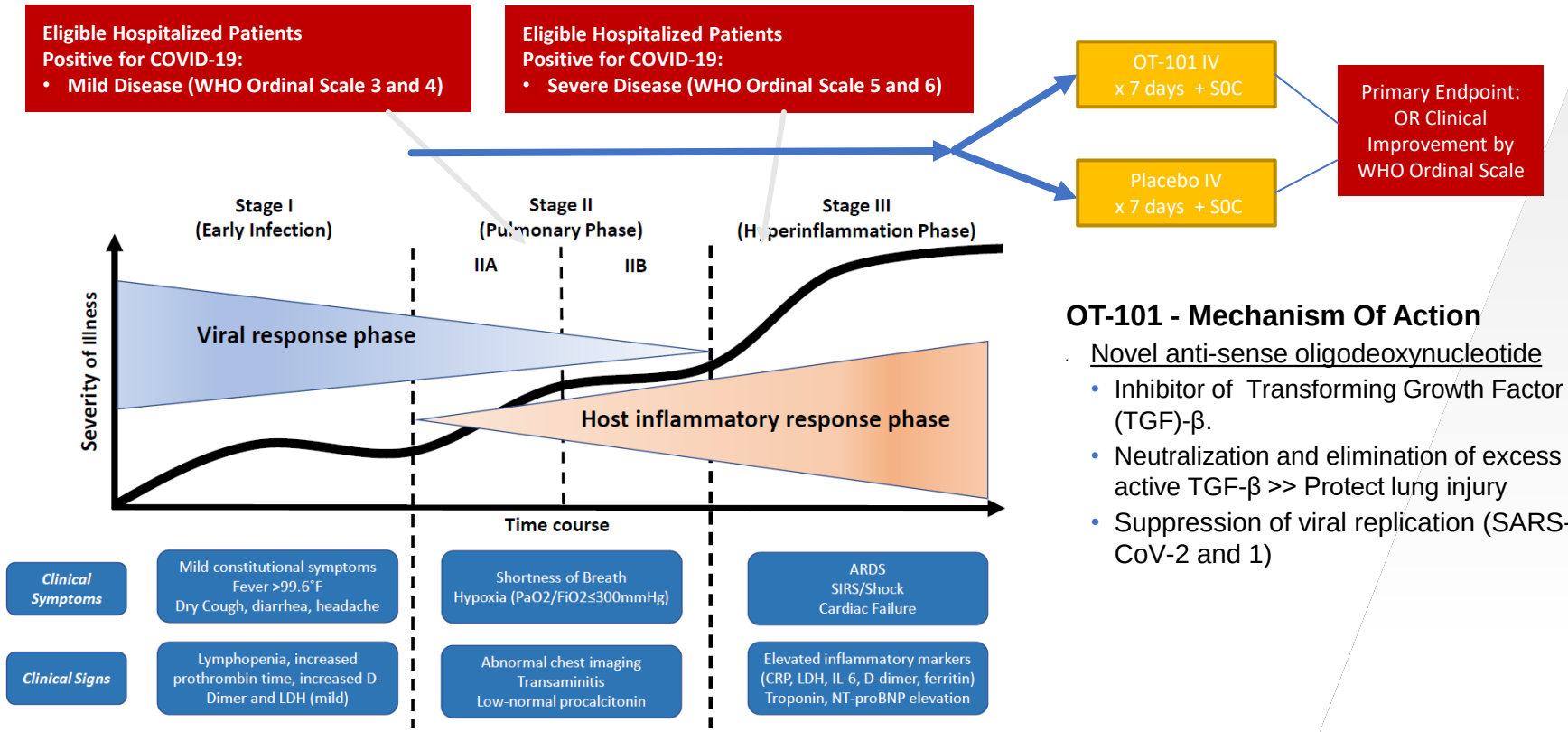
COVID-19 CLINICAL COURSE AFTER SARS-COV-2 INFECTION AND THE OT-101 TRIAL



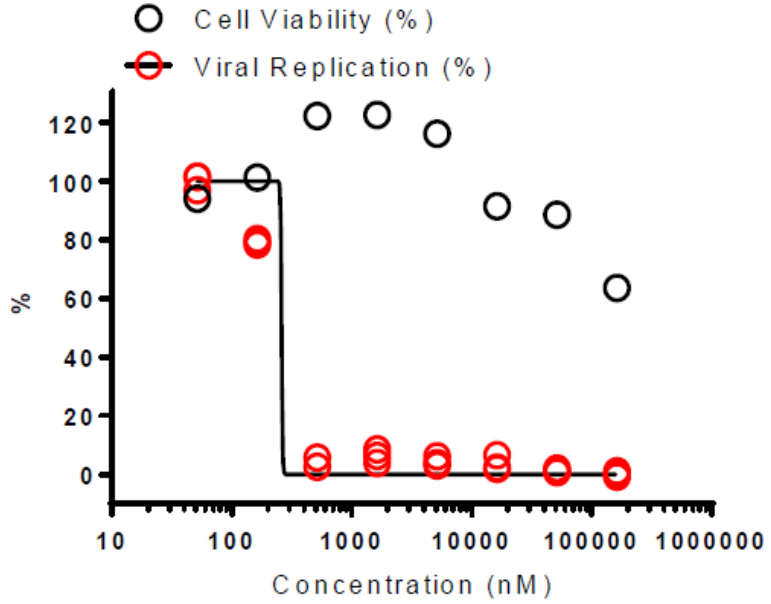
OT-101 - Mechanism Of Action

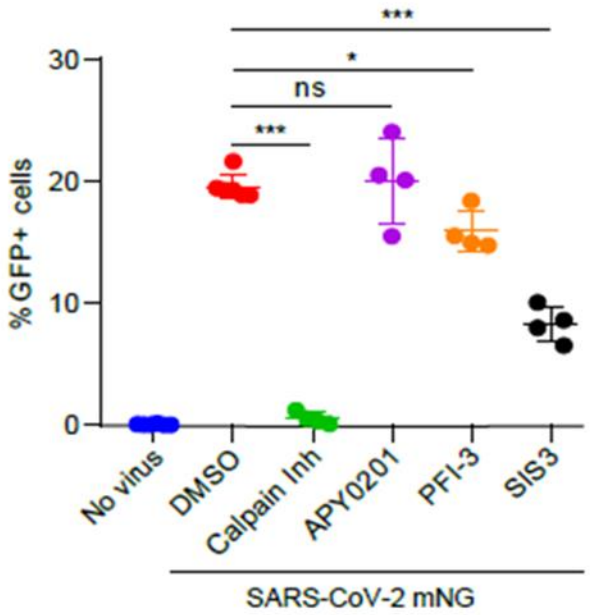
Novel anti-sense oligodeoxynucleotide

- Inhibitor of Transforming Growth Factor (TGF)-β.
- Neutralization and elimination of excess active TGF-β >> Protect lung injury
- Suppression of viral replication (SARS-CoV-2 and 1)

UCKUN FM, TRIEU V. ANNA PUL AND CRI CAR MED..2020; 3(1); 01-09.

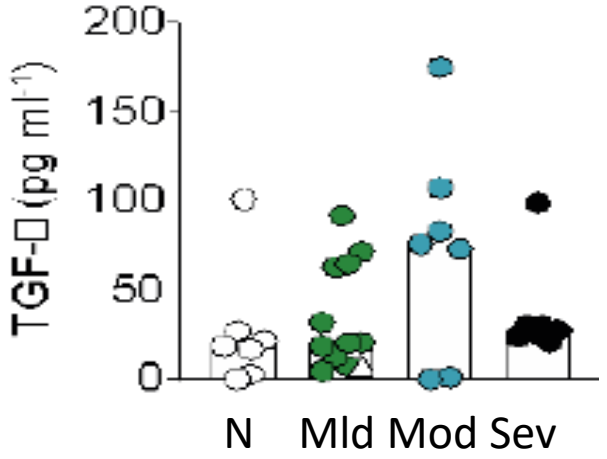
- The in vitro antiviral activity against SARS-CoV-2 (USA_WA1/2020 strain) was tested in Vero 76 cells in collaboration with Dr. Brett Hurst at Utah State University that is part of the NIAID Antiviral Testing Consortium.
- OT-101- an antisense against TGF-β- was effective against both SARS-CoV and SARS-CoV-2.
- After our disclosure in April 2020, other investigators have come forward with similar results
- Wei J. et al. Preprint. bioRxiv. 2020;2020.06.16.155101. SIS3, an inhibitor of SMAD3 of the TGF-β pathway, exhibited dose dependent protection from virus-induced cell death and also inhibited SARS-CoV-2 replication
- Stukalov A et al. bioRxiv.2020.06.17.156455. Upon virus infection, there was an upregulation of TGF-β and EGFR pathways.

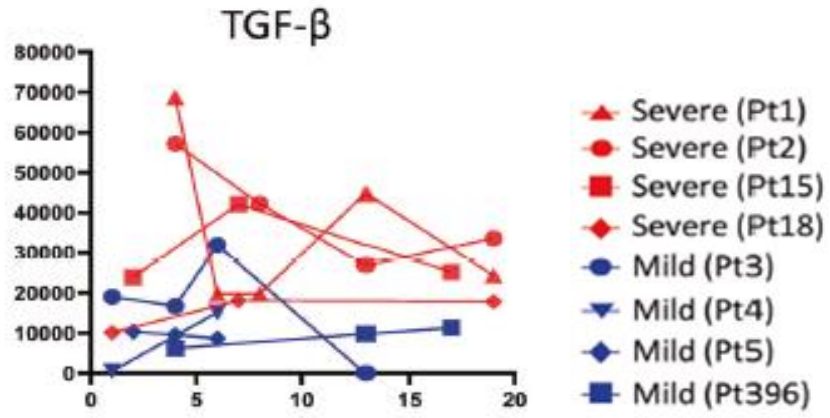




TGF-β Surge in COVID-19

- Elevated TGF-β2 expression among RNAs isolated from the bronchoalveolar lavage (BAL) fluid of COVID-19 patients versus normal controls has been reported [Xiong Y et al. Emerg Microbes Infect. 2020;9(1):761-770].
- TGF-β is higher among severe COVID-19 patients. Normal TGF-β level is 4000 pg/ml. The TGF-β level in COVID-19 patients is in 10,000 and above [Agrati C et al. Cell Death Differ. 2020;1-12.]
- Levels of systemic TGF-β in serum from healthy individuals (n=7) and COVID-19 patients with mild (n=12), moderate (n=7) and severe (n=7) disease using LEGENDplex assay [Mann ER et al. Sci. Immunol. 2020. 10.1126/sciimmunol.eabd6197] .
- COVID-19 induces a chronic, TGF-β-dominated adaptive immune response [Ferreira-Gomes M et al. medRxiv. 2020. doi:https:// doi.org/ 10.1101/2020.09.04.20188169]





Objectives

Primary

Evaluate the safety and efficacy of OT-101 when used in combination with SoC:

Efficacy: Proportion of subjects with clinical improvement score (measured by an 8 point WHO COVID 19 Clinical Improvement Ordinal Scale) at Day 14

Safety: Adverse events, clinical labs, ECG, vital signs, physical exam, radiology tests

Secondary

Further evaluate the efficacy of OT-101 compared to placebo:

Odds ratio, ventilator requirements, clinical improvement / worsening, mortality, hospitalization (duration/ICU)

Exploratory

Assessment of inflammatory biomarkers

Assessment of viral dynamics

Study Design

Randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of OT-101 when used in combination with SoC in hospitalized subjects with mild or severe COVID-19.

Sites and Subject Population

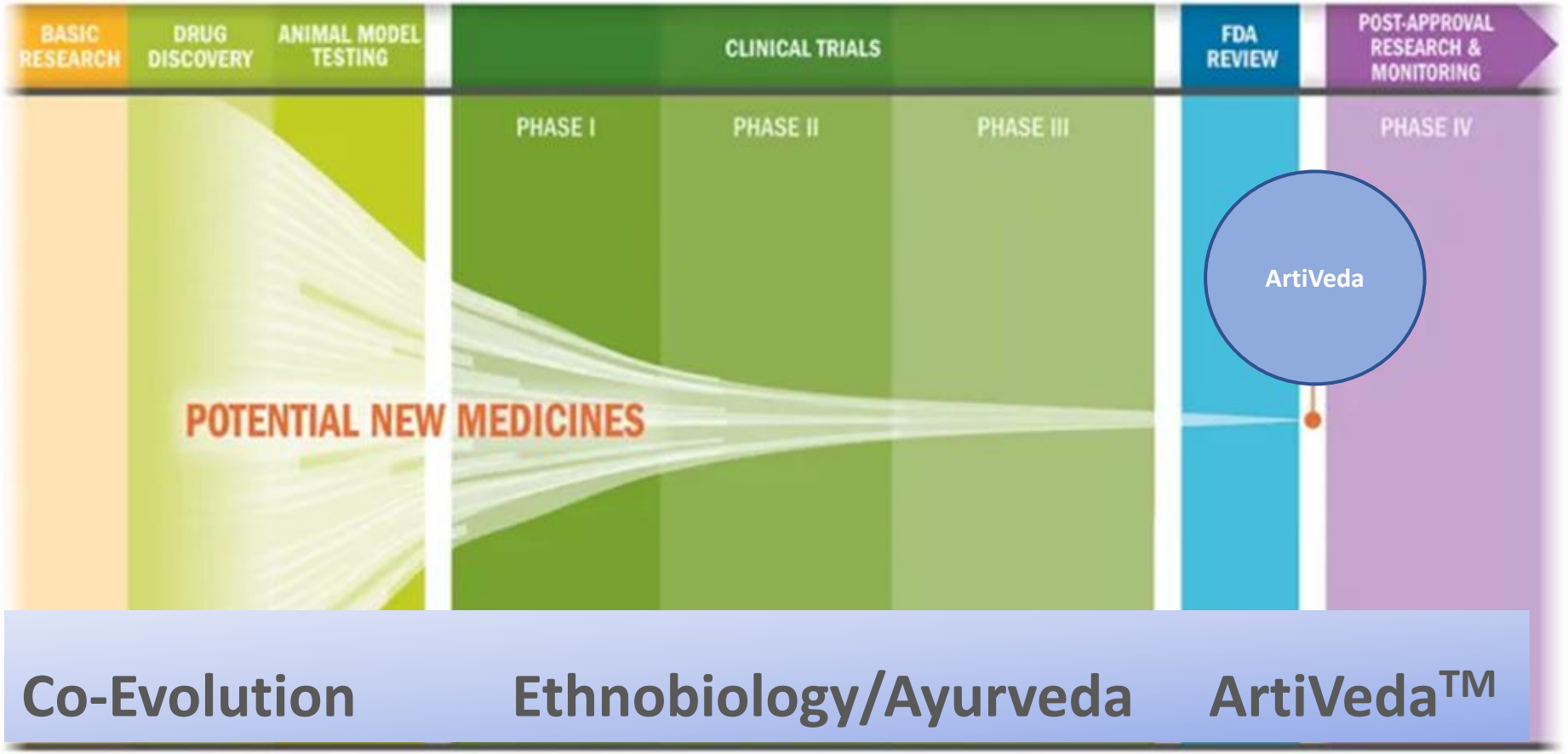
- Approximately 6 sites in Peru and Argentina.
- Adult subjects with mild (Part 1) or severe (Part 2) COVID-19 with a positive PCR test within the last 1 week for Part 1 and 2 weeks for Part 2 prior to randomization.
- Approximately 36 to 72 subjects are planned to be enrolled.

Double-blind Treatment and Assessment Period

- 3-day screening period.
- Randomization and treatment to start on Day 1 to either receive OT-101 or placebo in a 2:1 ratio for 7 days in combination with SoC therapy per local SoC policies, followed to Day 28.

MATEON THERAPEUTICS

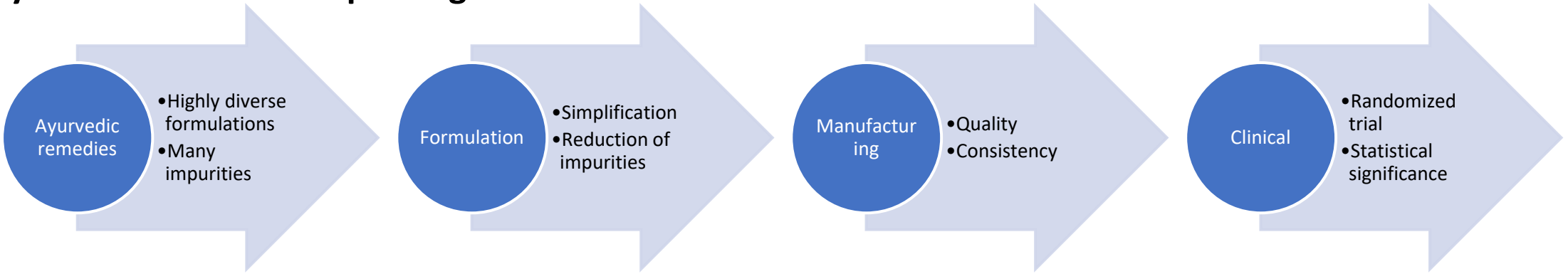
Ethnobiology COVID-19 Response Program



- Masks
- Social Distancing
- Hand Washing
- Dexamethasone
- **ArtiShield™/ARTIVeda™/ Artemisinin**

Plus and Minus with Ayurvedic pathway

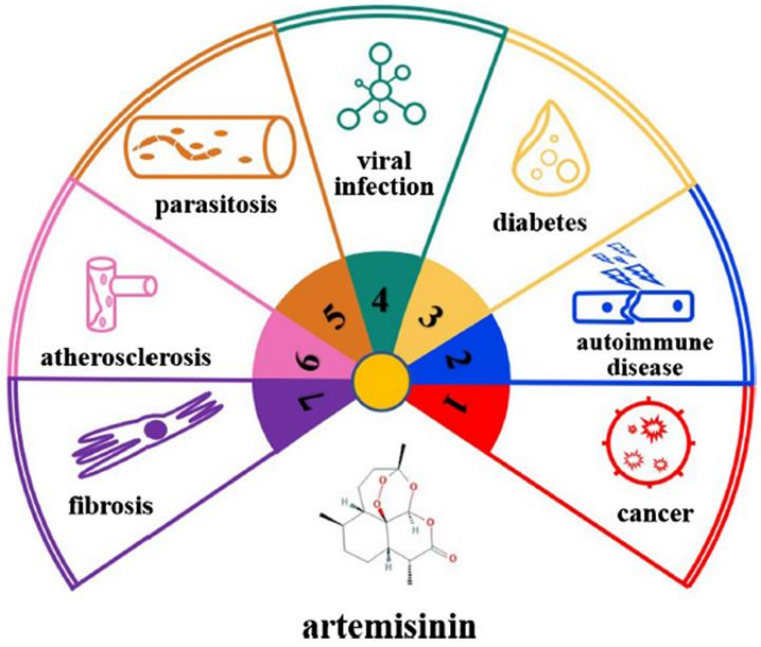
- Manufacturing- Marked variations are observed amongst the same formulations manufactured by different companies and by the same company. This raises questions on the quality standards.
  - Nearly 21% of commercially available formulations contained detectable levels of lead, mercury, and arsenic.
- Clinical trial- Often difficult to perform as per strict Ayurvedic principle. Almost all are without control arm making interpretation difficult if not impossible.
- **Strength in eons of coevolution and millennia of ethnobiology. Holistic focus. Broad clinical activities. Can be positioned for novel infectious agent**
- **Need to strengthen composition, manufacturing, and clinical testing.**
- **Ayurvedic text needs updating.**



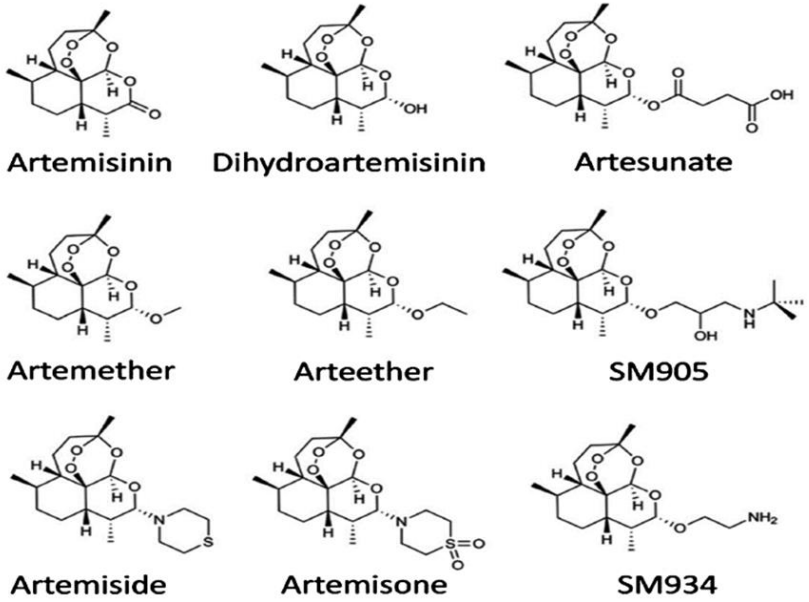
MATEON THERAPEUTICS

Artemisinin vs. Artemisinins

- Ayurveda- Broad Activity/ Low Specificity
- Appropriate for rapid response to pandemic



- Allopathic- Narrow Activity/ High Specificity
- Appropriate for safe and effective drugs



Malaria

Financial Cost – Artemisinin versus Remdesivir

- The ideal therapies should be inexpensive and prophylactic and should be able to be administered to: 1) non-hospitalized persons at the time of their initial diagnosis. 2) individuals with appearance of potential symptoms. 3) healthy individuals exposed to the virus

	Population	Drug cost/Person	Total Cost
India	1,380,004,385	$2,000	2.7 Trillions
		$20	27.6 Billions
		$10	13.8 Billions
		Targeting 10% of Population that are exposed to the virus	1.4 Billions
Global	7,794,798,739	$2,000	15.6 Trillions
		$20	155.8 Billions
		$10	77.9 Billions
		Targeting 10% of Population that are exposed to the virus	7.8 Billions

Allopathic drug cost = **Remdesivir = $2,000**/ **Ayurvedic drug = ArtiVeda™ = $10**/ **Vaccine = $20**

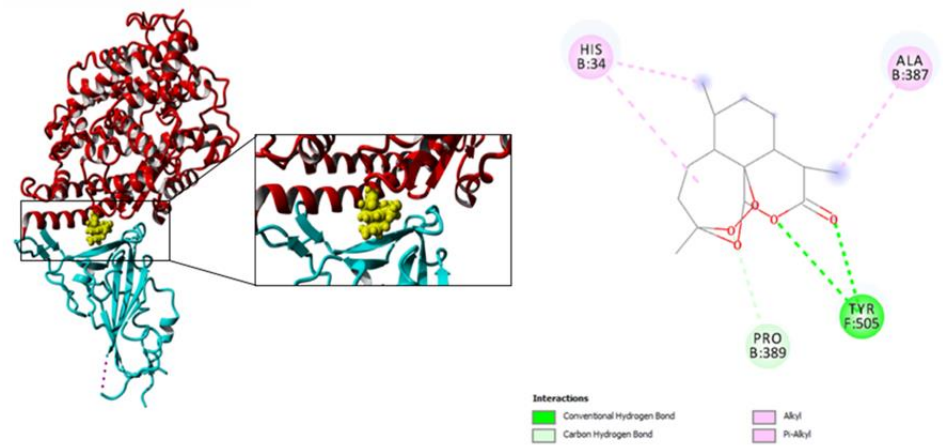
Ayurveda - Dvipaantara Damanaka

- ArtiVeda™ is the Ayurveda - Dvipaantara Damanaka- and is labeled as capsule containing Artemisia Powder 500mg.
- Its approved use is per Ayurvedic text: fever and inflammation. Ayurveda is part of the principal medicinal system in India for centuries.
- The application of Ayurvedic agent to treat the symptoms of COVID-19 such as fever, headache, and inflammation is appropriate.
- Dvipaantara Damanaka is the pharmacopoeial name equated with Artemisia absinthium Linn./ A. nilagirica (Clarke) Pam., syn./ A. vulgaris Linn. Var. nilagarica Clarke. [2,3]
- Artemesia nilagarica and Artermesia vulgaris – are found throughout the hilly regions of India, ascending to an altitude of 3600 m in the Western Himalayas and to 1500-2400 m in Sikkim and Khasi hills.

- [2] C. Khare, Evidence-based Ayurveda.Defining a new scientific path, Routledge, 2020.
- [3] C. P. Khare, Ayurvedic Pharmacopoeial Plant Drugs: Expanded Therapeutics, CRC Press, 2016.

In Silico Activities against SARS-CoV2

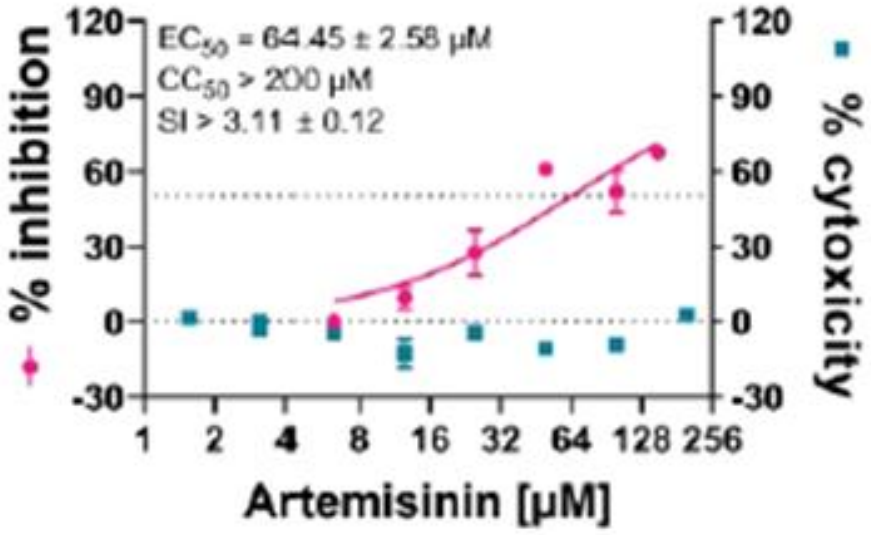
- Molecular basis for drug repurposing to study the interface of the S protein in SARS-CoV-2 and human ACE2 through docking, characterization, and molecular dynamics for natural drug candidates. Meshari Alazmi & Olaa Motwalli
- ZINC natural library with a total of ~ 203,458 drug molecules were screened in silico through blind docking against the S protein: human ACE2 complex.
- Four drugs— Andrographolide, Artemisinin, Pterostilbene, and Resveratrol—were selected on the basis of multiple criteria such as binding score, hydrophobic, electrostatic, and pi-pi cationic interactions with the protein.



Doczking Pose for Artemisinin docked with human ACE2: S protein complex in the interface between both proteins. (Right) Ligand interaction diagram showing important interactions involved in the complex.

Artemisinin/ TGF-β Inhibitor/ In Vitro Antiviral Activity

- Artemisinin is an active component of ArtiVeda™.
- Artemisinin is able to inhibit **human** TGF-β and is able to neutralize SARS-CoV-2 (COVID-19) in vitro at an EC50 of 0.45 ug/ml (based on Mateon's test result at Utah State University), and a Safety Index of 140, which is better than remdesivir and chloroquine.
- The unpurified herb extract has no anti-viral activity.
- As a TGF-β inhibitor it should target multiple viral threats including COVID-19 by suppressing both viral replication and clinical symptoms that arise from viral infection.
- TGF-β is an ancient master regulator in both human and plant



ACS Infectious Diseases

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Article

Anti-SARS-CoV-2 Potential of Artemisinins In Vitro

Ruiyuan Cao, Hengrui Hu, Yufeng Li, Xi Wang, Mingyue Xu, Jia Liu, Huanyu Zhang, Yunzheng Yan, Lei Zhao, Wei Li, Tianhong Zhang, Dian Xiao, xiaojia Guo, Yuexiang Li, Jingjing Yang, Zhihong Hu, Manli Wang, and Wu Zhong

ACS Infect. Dis., **Just Accepted Manuscript** • DOI: 10.1021/acsinfecdis.0c00522 • Publication Date (Web): 31 Jul 2020

New Results

Comment on this paper

***In vitro* efficacy of Artemisinin-based treatments against SARS-CoV-2**

Kerry Gilmore, Yuyong Zhou, Santseharay Ramirez, Long V. Pham, Ulrik Fahnøe, Shan Feng, Anna Offersgaard, Jakob Trimpert, Jens Bukh, Klaus Osterrieder, Judith M. Gottwein, Peter H. Seeberger

doi: https://doi.org/10.1101/2020.10.05.326637

"SAFETY AND EFFICACY OF ARTEMISININ-PIPERAQUINE (AP) FOR TREATMENT OF COVID-19" INT J ANTIMICROBIAL AGENTS. 2020 NOV 2

- **Two groups:** artemisinin-piperaquine (AP) group (n=23) and control group (n=18).
- **Primary outcome:** time taken to reach undetectable levels of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) and the percentage of participants with undetectable SARS-CoV-2 on day 7, 10, 14, and 28.
- **Control group:** Hydroxychloroquine/Arbidol. Hydroxychloroquine sulfate (Shanghai Zhongxi Pharmaceutical Co., Ltd.) was orally administered as a loading dose of 800mg/day for the first three days, followed by a maintenance dose of 400mg daily for the next five days. Arbidol hydrochloride (CSPC Ouyi Pharmaceutical Co., Ltd.) was orally administrated 600 mg/day for eight days, divided into three doses daily.
- **AP group:** AP (ARTEPHARM Co., Ltd) was orally administrated with a loading dose of two tablets (artemisinin 125mg and piperaquine 750mg) for the first day and followed by a maintenance dose of one tablet/day (artemisinin 62.5mg and piperaquine 375mg) for the next six days. The total dose was eight tablets in 7 days.

"SAFETY AND EFFICACY OF ARTEMISININ-PIPERAQUINE (AP) FOR TREATMENT OF COVID-19" INT J ANTIMICROBIAL AGENTS. 2020 NOV 2

- Piperaquine and hydroxychloroquine are members of the quinoline family and they both have marginal activity against SARS-CoV-2 *in vitro only. HCQ failed clinical trials against COVID-19.* Therefore Artemisinin is the main difference between the two arms
- Time to Undetectable SARS-CoV-2 RNA in the AP group was **significantly less** than the control group (**AP**: 10.6±1.1 days), **Control**: 19.3±2.1 days). P value is highly significant (**p=0.001).**
- **Length of hospital stay** for **AP group** was 13.3±4.8 days, and **Control** was 21.3±9.1 days

Table 3

The time of patients to undetectable viral RNA

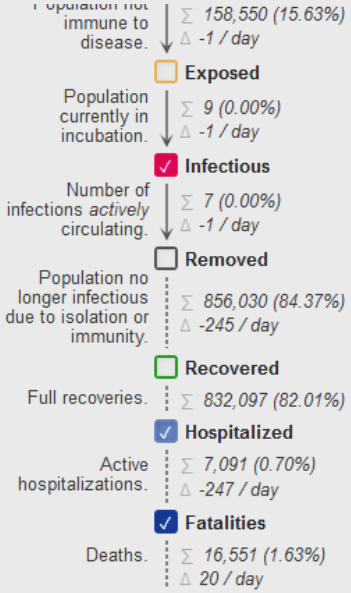
	AP (N=23)	Control (N=18)
Time to undetectable viral RNA of days(Mean±SD)	10.6±1.1	19.3±2.1
Patients with undetectable viral RNA, N(%)		
Day 7	6(26.1)	1(5.6)
Day 10	10(43.5)	3(16.7)
Day 14	18(78.3)	8(44.4)
Day 21	23(100.0)	10(55.6)
Day 28	23(100.0)	13(72.2)
Duration of hospitalization (Days, Mean±SD)	13.3±4.8	21.3±9.1

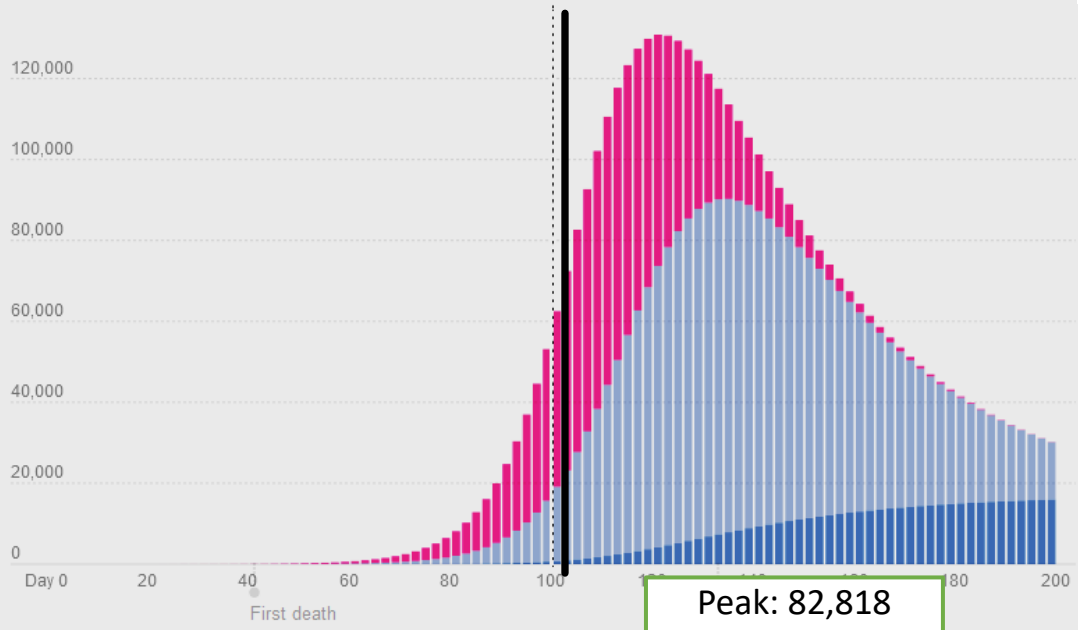
AP: Artemisinin + Quinoline (Piperaquine),
Control: Quinoline (Hydroxychloroquine or HCQ)

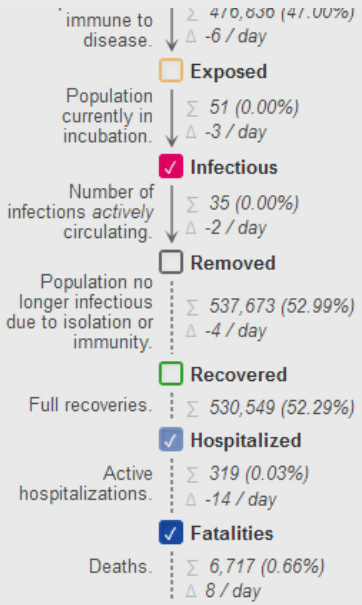
MATEON THERAPEUTICS

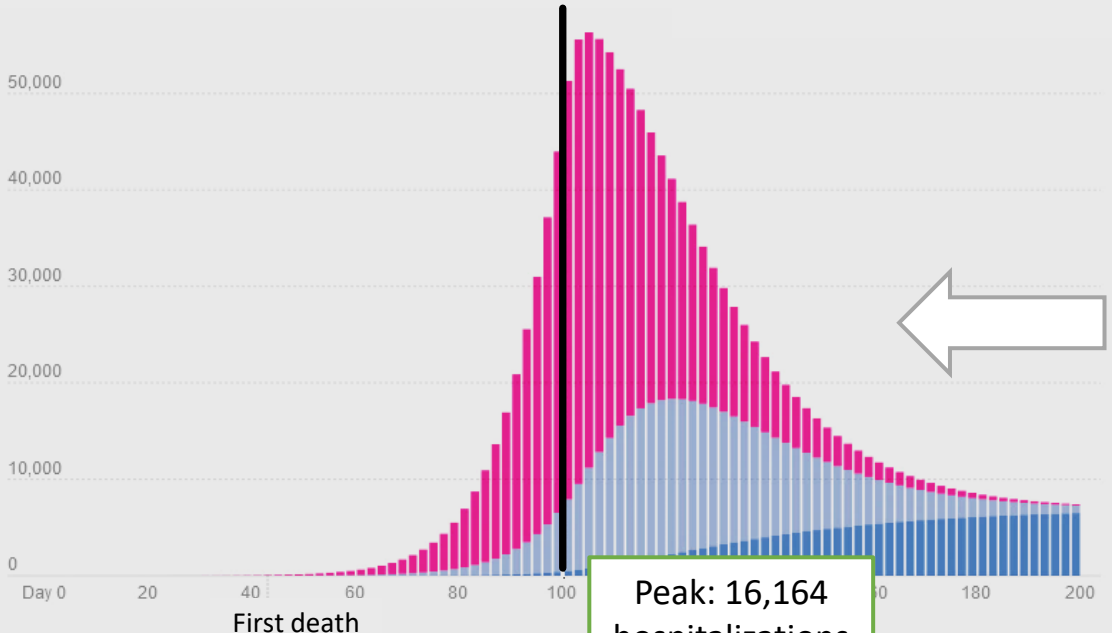
WE CAN STOP THE PANDEMIC WITH 50% REDUCTION IN DAYS BEING INFECTIOUS

- w/o intervention/ per 1M populace
- Continuing growth in infection
- Fatalities =16,000
- Peak Hospitalization = 82,000









- w/ intervention/ per 1M populace
- Almost immediate cease in infection
- Fatalities =6,700
- Peak Hospitalization = 16,000

Current Clinical Program for Artemisinin/ArtiVeda

ARTI-19

A PROSPECTIVE, RANDOMIZED, MULTI-CENTER, OPEN LABEL, INTERVENTIONAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF DAMANAKA 500 MG CAPSULE IN TREATMENT OF ADULT SUBJECTS WITH COVID-19

Global trial with 3 sites open in India:

- **Maharashtra**
- **Andhra Pradesh**
- **Utter Pradesh**

- **Number of Subjects: 120**
- **Expanding to 300 subjects at 6 sites**

Arms opening in:

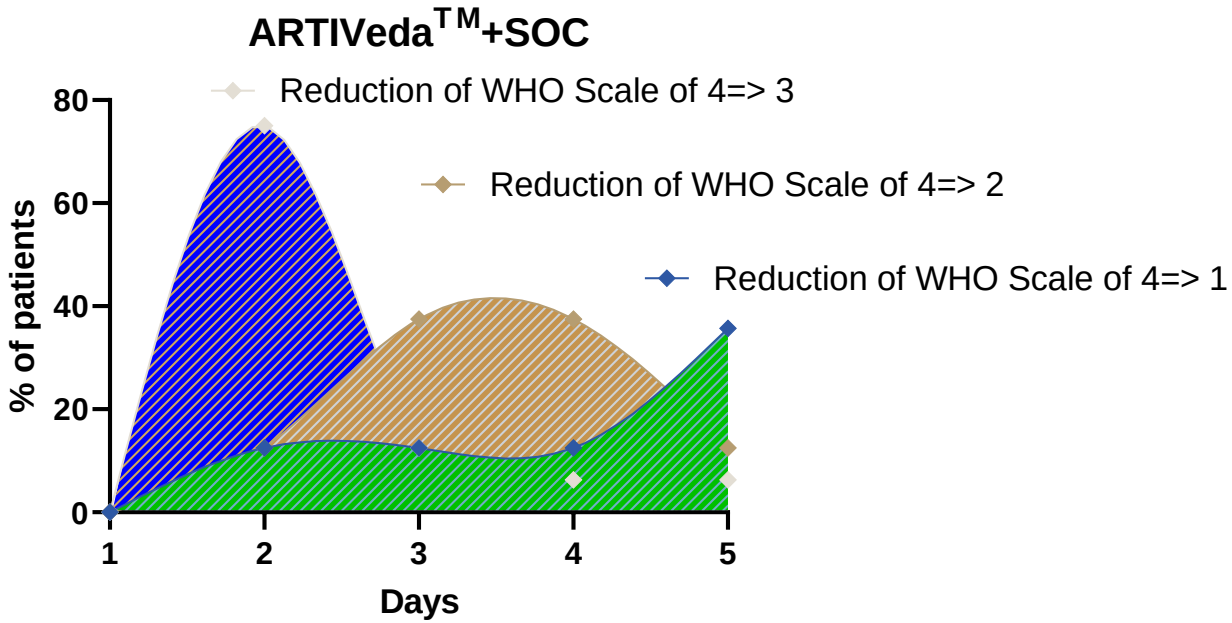
- **Nigeria**
- **Peru**

ARTI-19 CLINICAL TRIAL IN INDIA

- Open label, 2nd Arm control, multi-center Phase IV study
  - Compares the efficacy of ORAL doses with standard-of-care (SOC) versus SOC alone.
  - SOC is per Clinical Management Protocol
  - Moderate cases (**WHO scale 4-5**), patients skewed towards moderate
- 2:1 randomization (Damanaka capsules + SOC vs SOC)
  - Patients in study arm take 5 pills in 5 days: 1 pill per day.
  - If symptoms remain a second cycle follows after 5-day rest period
  - Duration for subject: 28 days

EFFICACY IN ARTI-19 INDIA

- At present: 78 pts randomized into ARTI-19
  - Dec 15th: Complete randomization of 120 pts/ Interim Report for 60 pts/ EUA application.
  - Beyond Dec 15th: Expansion to 6 sites and 300 pts/Global expansion 3000 pts
- Observations for current completed data set on 32 pts. Only WHO Scale 4 pts are shown here.
  - 8 pts on SOC and 16 pts on ARTIVeda™+SOC
  - SOC: No Treatment time dependent effect.
  - ARTIVedaTM+ SOC: Treatment time dependent improvement in WHO Progression Scale.
    - Majority of pts on ArtiVeda™ achieved reduction from WHO Progression Scale of 4 to WHO Progression Scale of 3 on Day 2 (2nd dosing with ARTIVeda™).
    - Scale of 3 does not have to be hospitalized



Conclusions

- Artemisinin activity against COVID-19 is well supported at all levels: in silico, in vitro, and clinical
- It is the only potentially prophylactic agent and cost-effective agent
- Such an agent is needed to stop the pandemic even in the presence of an effective vaccine
- It is active at all phases of COVID-19 infection
- It will be launch in India by year end
- OT-101 soon after as EUA against severe COVID-19

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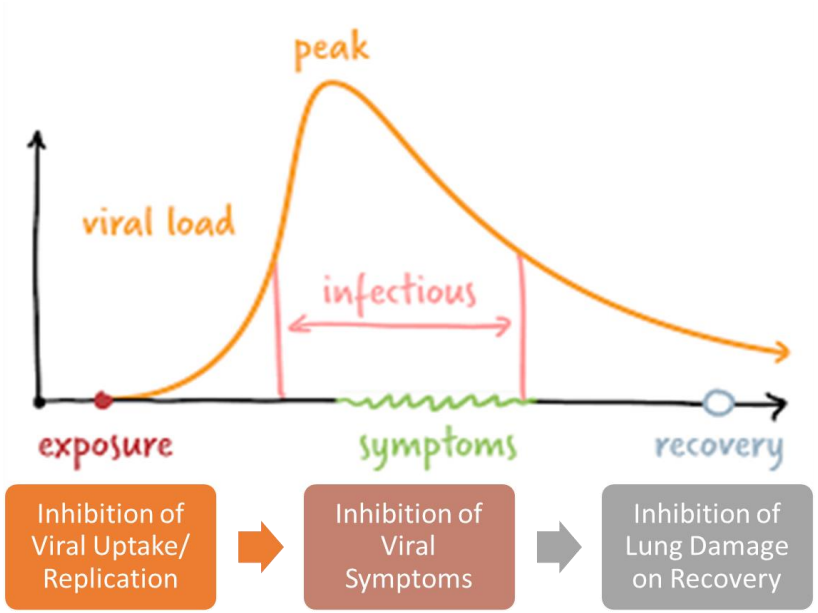

Thank You