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FLCCC Alliance Response to Merck's public statements on ivermectin's efficacy in COVID-19

FLCCC Alliance, Inc

2001 L St NW Suite 500
Washington, DC 20036

☎ 513-486-4696
support@flccc.net

Employer ID number: 85-2270146
501(c)(3) nonprofit organization

The FLCCC Alliance wishes to respond to Merck's public statements on February 4th, claiming a lack of sufficient evidence for ivermectin's efficacy in COVID-19.*

Merck's assessments of ivermectin's efficacy in COVID-19 are in striking contrast with the findings reported by multiple expert group's systematic reviews from across the globe, including meta-analyses of the updated scientific literature:

- a. The Front-Line Covid-19 Critical Care Alliance¹
- b. UNITAID/W.H.O Expert Consultant, Dr. Andrew Hill²
- c. The Evidence Based Medicine Consultancy³
- d. The National Institutes of Health Treatment Guidelines Panel⁴
- e. Kalfas et al, University of Melbourne⁵
- f. Padhy et al, All India Institute of Medical Sciences⁶
- g. Covid-19 Study Group at <https://ivmmeta.com/>⁷
- h. University of Lyon Dept. of Pharmacology: www.metaevidence.org⁸

Merck Statement 1: "No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies."

FLCCC Response: The above publications cite in vitro and animal studies demonstrating anti-viral and anti-inflammatory mechanisms of action with ivermectin.⁹⁻¹⁴ Further, eight trials in COVID-19 patients reported a dose-dependent significant reduction in both viral load and time to viral clearance.²

Merck Statement 2: "No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease."

FLCCC Response: The above publications cite ten trials that consistently reported a sizable significant reduction in time to clinical recovery, length of hospitalization, or mortality.^{2,15-18} Further, epidemiologic analyses reported consistent and large population-wide reductions in case-fatality rates and excess deaths in regions with ivermectin distribution campaigns.¹⁹

* <https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/>

Merck Statement 3: "A concerning lack of safety data in the majority of studies."

FLCCC Response: The above publications cite numerous safety studies over decades of use, reporting an extremely low incidence of severe side effects.^{20,21} Further, many studies and case series demonstrate the safety of both escalating and prolonged dosing of ivermectin in both healthy and ill patients.^{22,23}

Unfortunately, Merck's website did not provide the scientific data or bibliography to support its brief posted statements. The above reviewed in vitro, clinical, and epidemiologic evidence indicates that the current evidence base strongly contradicts Merck's conclusions. Merck's stated mission is *"to discover, develop and provide innovative products and services that save and improve lives around the world."* Merck's historic impact on the discovery of ivermectin and their subsequent decision to donate hundreds of millions of doses to W.H.O programs led to the eradication of a scourge of parasitic diseases across many parts of the world.²⁴ Many experts recognized Merck's partnership with public health care agencies decades ago as one of last century's most significant medical accomplishments. We remind Merck of the words of their founders' son, George W. Merck, who, in 1950, stated, *"We try never to forget that medicine is for the people. It is not for profits. The profits follow, and if we have remembered that they have never failed to appear. The better we have remembered it, the larger they have been"*.

Our sincere hope is that the mounting evidence in favor of ivermectin's efficacy and safety in COVID-19 will lead Merck to support the design and conduct of ethically appropriate clinical trials to identify the best timing, dose, and duration of ivermectin in the prophylaxis and treatment of COVID-19. Now more than ever, during the worst pandemic of the last 100 years, the world would benefit from Merck's scientists and organization's resources to advance knowledge with the hope of recreating in this century the most significant medical accomplishments of the last century.

Sincerely,

The Front Line Covid-19 Critical Care Alliance

Pierre Kory, MD	Keith Berkowitz, MD
Paul E. Marik, MD	Howard Kornfeld, MD
G. Umberto Meduri, MD	Fred Wagshul, MD
Joseph Varon, MD	Scott Mitchell, MBChB
Jose Iglesias, DO	Eivind Vinjevoll, MD
	Eric Osgood, MD

References

- Kory P, Meduri GU, Varon J et al. Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19. *Frontiers in Pharmacology*. 2021. doi: 10.3389/fphar.2021.643369
- Hill A, Abdulmir AS, Ahmed A et al. Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection. *Research Square*. 2021. 10.21203/rs.3.rs-148845/v1
- Lawrie T. Ivermectin reduces the risk of death from COVID-19 - a rapid review and meta-analysis in support of the recommendation of the Front Line COVID-19 Critical Care Alliance. *ResearchGate*. 2021. https://b3d2650e-e929-4448-a527-4eeb59304c7f.filesusr.com/ugd/593c4f_1b1399cb64514dc4bdcbef0cd15f7878.pdf
- NIH Treatment Guidelines Panel. The COVID-19 Treatment Guidelines Panel's Statement on the Use of Ivermectin for the Treatment of COVID-19. 2021. <https://www.covid19treatmentguidelines.nih.gov/statement-on-ivermectin/>
- Kalfas S, Visvanathan K, Chan K, Drago J. The therapeutic potential of ivermectin for COVID-19: A review of mechanisms and evidence. *medRxiv*. 2020. doi.org/10.1101/2020.11.30.20236570
- Padhy BM, Mohanty RR, Das S, Meher BR. Therapeutic potential of ivermectin as add on treatment in COVID 19: A systematic review and meta-analysis. *Journal of pharmacy & pharmaceutical sciences: a publication of the Canadian Society for Pharmaceutical Sciences, Societe canadienne des sciences pharmaceutiques*. 2020;23:462-469.
- COVID-19 Studies Group. Ivermectin is effective for COVID-19: real-time meta analysis of 37 studies. 2021. <https://ivmmeta.com/>
- University Hospital of Lyon -Pharmacology and Toxicology Department CRDatPHC. Meta-evidence COVID-19. 2021. <http://www.metaevidence.org/viewMApredictive2.aspx?expositio n=684&comparator=649&pathology=87&domain=12&selfocus=2>
- Caly L, Druce JD, Cattton MG, Jans DA, Wagstaff KM. The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro. *Antiviral Res*. 2020;178:104787.
- Dayer MR. Coronavirus (2019-nCoV) Deactivation via Spike Glycoprotein Shielding by Old Drugs, Bioinformatic Study. 2020.
- Hussien MA, Abdelaziz AE. Molecular docking suggests repurposing of brincidofovir as a potential drug targeting SARS-CoV-2 ACE2 receptor and main protease. *Network Modeling Analysis in Health Informatics and Bioinformatics*. 2020;9(1):1-18.
- Dasgupta J SU, Bakshi A, Dasgupta A, Manna K, Saha, C De, RK, Mukhopadhyay S, Bhattacharyya NP. Nsp7 and Spike Glycoprotein of SARS-CoV-2 Are Envisaged as Potential Targets of Vitamin D and Ivermectin. *Preprints*. 2020.
- Lehrer S, Rheinstein PH. Ivermectin Docks to the SARS-CoV-2 Spike Receptor-binding Domain Attached to ACE2. *In Vivo*. 2020;34(5):3023-3026.
- Swargiary A. Ivermectin as a promising RNA-dependent RNA polymerase inhibitor and a therapeutic drug against SARS-CoV2: Evidence from in silico studies. 2020.
- Chaccour C, Casellas A, Blanco-Di Matteo A, et al. The effect of early treatment with ivermectin on viral load, symptoms and humoral response in patients with mild COVID-19: a pilot, double-blind, placebo-controlled, randomized clinical trial. 2020.
- Elgazzar A, Hany B, Youssef SA, Hafez M, Moussa H. Efficacy and Safety of Ivermectin for Treatment and prophylaxis of COVID-19 Pandemic. 2020.
- Niaee MS, Gheibi N, Namdar P, et al. Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: A randomized multi-center clinical trial. 2020.
- Spoorthi V SS. Utility of Ivermectin and Doxycycline combination for the treatment of SARS-CoV2. *International Archives of Integrated Medicine*. 2020;7(10):177-182.
- Chamie J. *Real-World Evidence: The Case of Peru. Causality between Ivermectin and COVID-19 Infection Fatality Rate*. 2020.
- Kircik LH, Del Rosso JQ, Layton AM, Schaubert J. Over 25 Years of Clinical Experience With Ivermectin: An Overview of Safety for an Increasing Number of Indications. *J Drugs Dermatol*. 2016;15(3):325-332.
- Gardon J, Gardon-Wendel N, Demanga N, Kamgno J, Chippaux J-P, Boussinesq M. Serious reactions after mass treatment of onchocerciasis with ivermectin in an area endemic for Loa loa infection. *The Lancet*. 1997;350(9070):18-22.
- Guzzo C, Furtek C, Porras A, et al. Safety, Tolerability, and Pharmacokinetics of Escalating High Doses of Ivermectin in Healthy Adult Subjects. *Journal of clinical pharmacology*. 2002;42:1122-1133.
- de Castro Jr CG, Gregianin LJ, Burger JA. Continuous high-dose ivermectin appears to be safe in patients with acute myelogenous leukemia and could inform clinical repurposing for COVID-19 infection. *Leukemia & Lymphoma*. 2020;61(10):2536-2537.
- Tambo E, Khater EI, Chen JH, Bergquist R, Zhou XN. Nobel prize for the artemisinin and ivermectin discoveries: a great boost towards elimination of the global infectious diseases of poverty. (2095-5162 (Print)).

Media: For more information, or to arrange for an interview, please contact press@flccc.net.

The FLCCC Alliance was organized in March, 2020 by a group of highly published, world renowned Critical Care physician/scholars – with the academic support of allied physicians from around the world – to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. Their **MATH+ Hospital Treatment Protocol** – introduced in March, 2020, has saved tens of thousands of patients who were critically ill with COVID-19. Now, the FLCCC's new **I-Mask+ Prophylaxis and Early At-Home Outpatient Treatment Protocol with Ivermectin** has been released – and is a potential solution to the global pandemic.