



mgc pharma 

***Cimetra™ by MGC—a Revolution in Fighting  
the COVID-19 Pandemic (IP Protected)***

October 2021

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# COVID-19 Pandemic – Clinical Challenges



Rapid clinical deterioration in multiple mild and moderate COVID-19 cases



Acute need for fast and massive extension of medical facilities and staffing, especially for ICU wards



Wide extension of social services and governmental support for patients who survived severe and critical forms of COVID-19



High mortality rate linked to ARDS



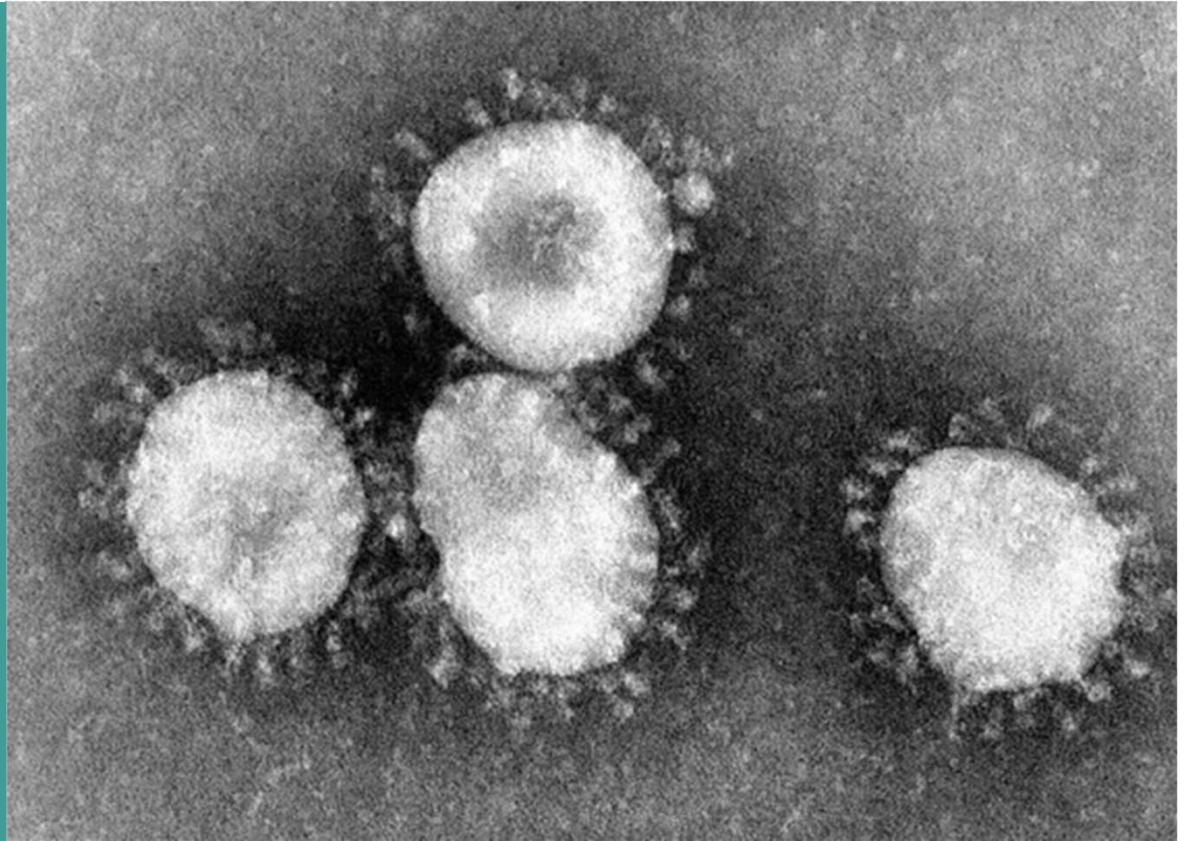
Lack of effective treatment protocols for mild and moderate cases in community healthcare



# COVID-19 Related Cytokine Storm



- Cytokine Storm has been identified as a main reason for mortality in COVID-19 patients.
- The Severe Acute Respiratory Syndrome coronavirus, associated coronavirus disease 2019 (COVID-19) is a syndrome of viral replication in concert with a host inflammatory response.
- Systemic pro-inflammatory Cytokines and Biomarkers are elevated as the disease progresses towards its advanced stages, and correlate with lower chances of survival.



# Early Prevention of COVID-19 Cytokine Storm



Cytokine Storm Early Prevention appears to be an effective method of treatment in mild and moderate COVID-19 cases

Use of existing Cytokine Storm Prevention protocols comes with:



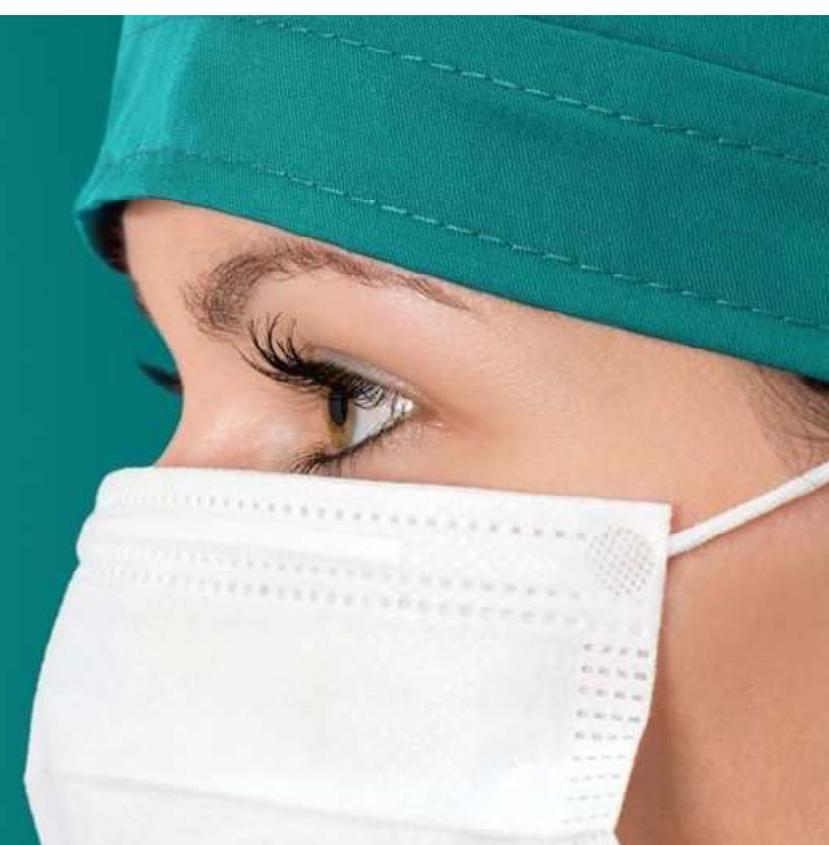
High treatment costs



Administration (requires long hospitalisation and trained medical staff)



Potential serious side effects



# CimetrA™ – A New Investigational Drug by MGC Pharma



## The Drug



- Compounds – combination of Curcumin and Boswellia Serrata
- Administration – Medical oral spray
- Mechanism of action – Immunomodulation in inflammatory conditions
- Delivery System – GraftBio™ SNEDDS
- Administrated twice a day for 2 days
- Dose – 2 ml per day
- Storage conditions – refrigerate
- Treatment cost - ~US100 RRP with no additional clinical costs

## Target Market



- Over 230m COVID-19 cases worldwide
- Over 4.8m deaths worldwide
- The average cost of COVID-19 hospital stays in the US is \$40,000<sup>1</sup>
- Meaning for every 1,000 patients you keep out of hospital you save \$40m and countless lives
- Healthcare workers say they need more tools to treat people before they are so sick and in need of oxygen



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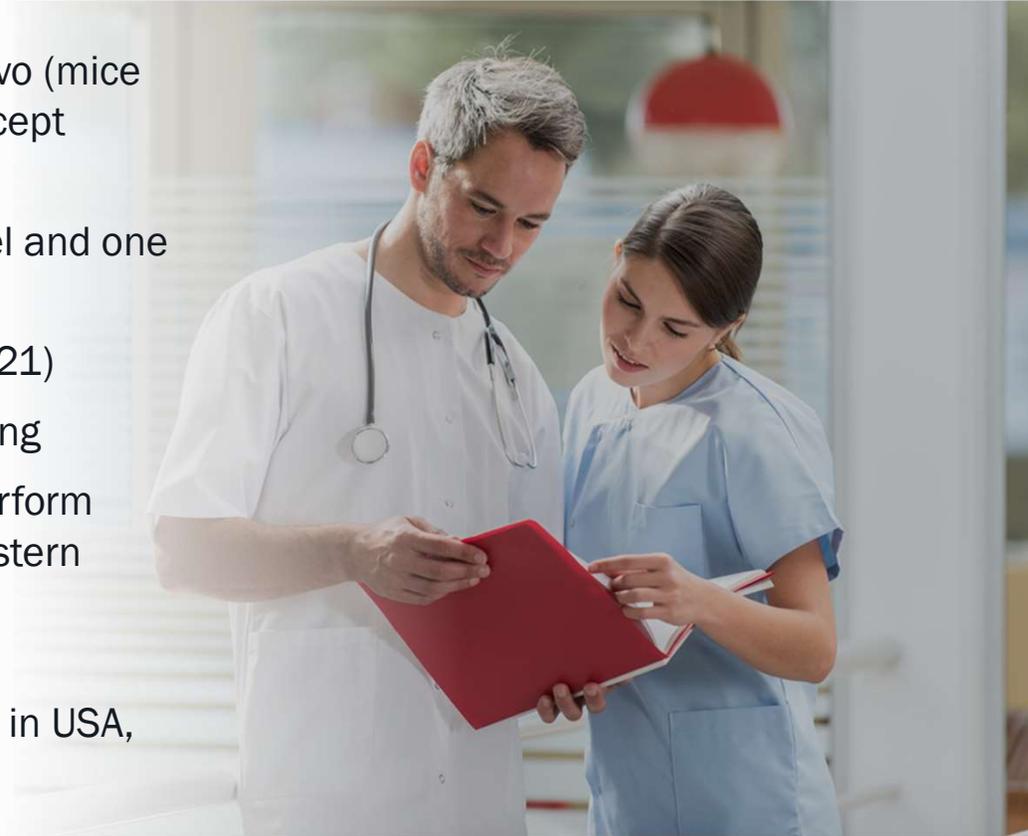


1. [www.healthcarefinancenews.com/news/average-cost-hospital-care-covid-19-ranges-51000-78000-based-age](http://www.healthcarefinancenews.com/news/average-cost-hospital-care-covid-19-ranges-51000-78000-based-age)

# MGC Pharma's Regulatory Strategy for CimetrA™



- Pre-clinical Studies according to the FDA requirements – In-Vivo (mice and rats) and In-Vitro (toxicity, safety, efficacy) – Proof of concept (performed in Israel, ended Sep 2020 and August 2021)
- Clinical – Phase II Study (performed in three hospitals in Israel and one hospital in India, ended Nov 2020)
- Clinical – Phase IIa Study (performed in India, ended June 2021)
- Clinical – Phase 3 Study started in Israel July 2021 and ongoing
- For later stage Clinical Trials, in addition to Israel, MGC will perform studies in other countries in South America, East Asia and Eastern Europe. Preliminary contacts have already been initiated
- **CimetrA™** is currently in early stages of approval as an IMP (Investigational Medicinal Product) and under Emergency Use in USA, India, and several Eastern European countries



# Pre-Clinical Study of CimetrA™



- Managed according to the FDA standards in GLP Science in Action Preclinical Lab, Ness Ziona, Israel
- Included three phases :
  - In Vitro PBMCs Viability Study
  - In Vitro Mechanism of Action Study on Cytokines induced tissue
  - In Vivo acute Tox Study (elevated dose, 4 study groups – 3 treatment doses and control)
  - Mice Cytokines Storm model



# Pre-Clinical Study: General Results



1

**CimetrA™** does not affect cell death rate in the PBMC culture

2

**CimetrA™** found to be effective in the prevention of the COVID-19 related Cytokines production in the induced tissue

3

In Vivo Acute Tox study showed no abnormalities in animals treated with **CimetrA™**



# Clinical Study of CimetrA™



Randomised Placebo-Controlled Clinical Trial



50 patients: 33 in treatment group; 17 in placebo group



COVID-19 positive hospitalised patients in moderate condition



14 days of follow up

## Study sites:

- Rambam Medical Center, Israel
- Hillel Yaffeh Medical Center, Israel
- EMMS Medical Center, Israel
- University of Mumbai Hospital, India



# Clinical Study: General Results



1

**Full recovery** of patients in Treatment group vs. very low progress in the Placebo group (**p<0.04**)

2

**Reduced** %, and duration in the need for supplemental oxygen in the Treatment group vs. Placebo group

3

No mortality in Treatment group vs one case in Placebo group

4

No ICU admission in Treatment group vs. two cases in Placebo group

5

No mechanical ventilation in Treatment group vs. two cases in Placebo group

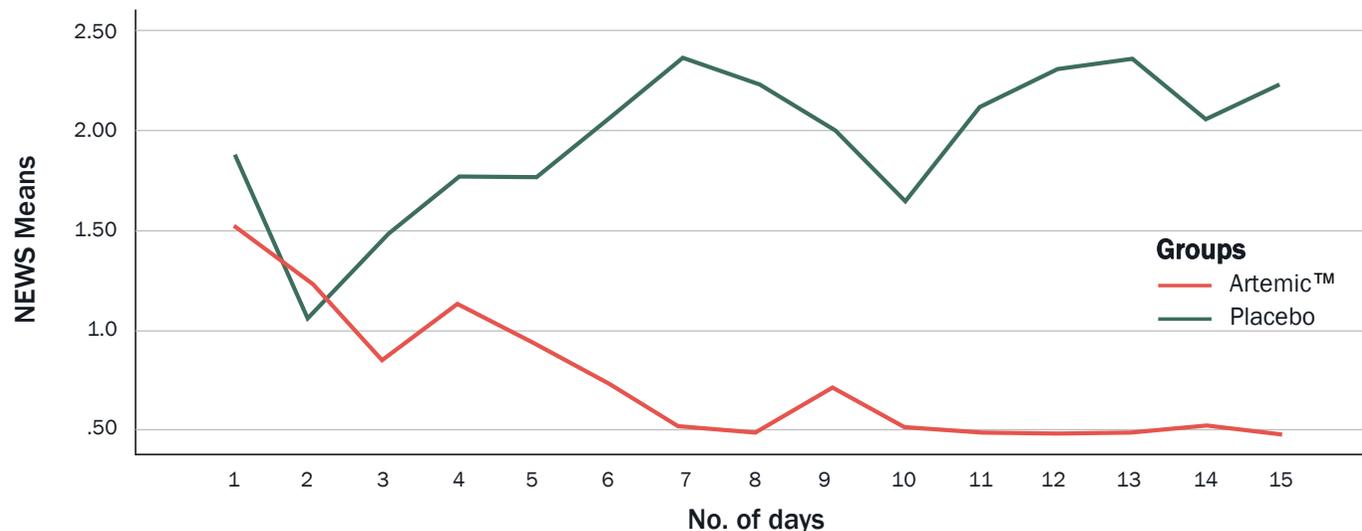
6

No **Cimetra™** related side effects

# Clinical Study: General Results



- **100% success** in “Time to clinical improvement” based on the national Early Warning Score 2 (NEWS2) of  $\leq 2$  Maintained for 24 hours in comparison to routine treatment
- NEWS Score 2 is the National Early Warning Score (NEWS), by the FDA, which advocates a system to standardise the assessment and response to acute illness



Study Visit	Study Group	NEWS Score	P
Before Treatment	Artemic™	1.5152	0.54
	Placebo	1.8824	
Day 15	Artemic™	<b>0.5152</b>	<b>0.04</b>
	Placebo	<b>2.2353</b>	

# Benefits of Using CimetrA™ in Community



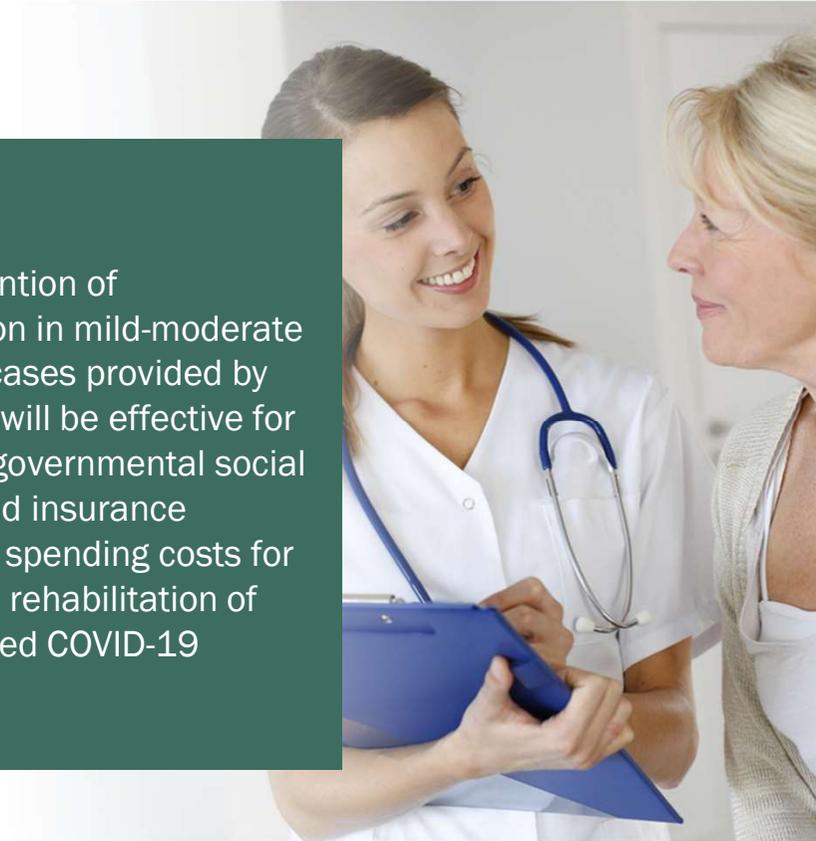
**CimetrA™** could be easily used in community clinics and by home-staying patients: oral spray administration does not require trained medical personnel or facilities



Use of **CimetrA™** on early stages in mild-moderate COVID-19 cases (home-staying patients) could save millions of dollars to healthcare providers by preventing multiple hospitalisations and ICU care spending costs and avoid healthcare system collapse



Early prevention of deterioration in mild-moderate COVID-19 cases provided by **CimetrA™** will be effective for savings in governmental social services and insurance companies spending costs for post-COVID rehabilitation of incapacitated COVID-19 survivors



# CimetrA™: Summary

- **CimetrA™** is affordable, safe and effective agent in mild and moderate COVID-19 cases in order to prevent clinical deterioration
- Simple Oral Administration: no medical personnel required
- Wide use in community and hospitals
- Cost-efficient solution for healthcare providers and governments
- Possible wide spectrum of further use in inflammatory conditions – GI diseases, chemotherapy treatment patients, autoimmune diseases, flu and pneumonia
- IP Protected by MGC Pharma SIPO P-202100096





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