

# EMITBIO DEMONSTRATES STATISTICALLY SIGNIFICANT RESULTS IN CLINICAL TRIAL FOR COVID-19 TREATMENT

Investigational treatment reduces viral load leading to meaningful patient outcomes

**Durham, N.C.** (February 17, 2021) – EmitBio Inc., today announced statistically significant efficacy results from its randomized, placebo-controlled, double-blind Phase I/II clinical trial. The study was conducted with an investigational treatment device\* that directs precise wavelengths of safe, visible light targeted to the back of the throat and surrounding tissues. The device is designed for self-treatment of COVID-19 in an at-home setting. EmitBio™ achieved clinically and statistically significant results in both the reduction of SARS-CoV-2 viral load and accelerated time to symptom resolution in adults with COVID-19.

"The ability to show statistical significance on both viral load and symptom endpoints with this sample size is a direct illustration of just how powerful our light treatment device can be," stated Nate Stasko, PhD, Chief Scientific Officer at EmitBio.

The following clinical trial efficacy results were achieved in subjects who tested positive for SARS-CoV-2 in saliva at baseline:

- Coronavirus was eliminated faster with treatment An analysis of trend over time definitively showed that the treatment group had a significantly faster decline of SARS-CoV-2 viral load measured in saliva (p<0.05).</li>
- Reductions in viral load led to clearance of symptoms Treated subjects had a median time to sustained clearance of all COVID-19 related symptoms of 104 hours compared to 161 hours in sham controls, representing an accelerated time to symptom resolution of 57 hours (p<0.05).
- Over half the treated subjects had no virus remaining After seven days, the median log<sub>10</sub> viral load in saliva of treated subjects was 0.00 vs. 3.17 in placebo controls.
- On average treated subjects had 99.9% less virus after 1 week − The decrease from baseline to day eight in mean log<sub>10</sub> viral load for the treated group was −3.29 and for the placebo group was -1.81, resulting in a treatment superiority of -1.48 (p<0.05).</li>

Due to these statistically significant results and findings, the company concluded its Phase I/II <u>trial</u> early and initiated activities in preparation for additional COVID-19 trials in other populations.

"Saliva is highly biologically relevant for measuring SARS-CoV-2 viral load," continued Dr. Stasko. "In this trial, and in other studies, the quantity of virus and total body bio-burden were strongly correlated with disease outcomes. When you reduce the amount of virus in the body, people get better."

Researchers at Yale University and other major institutions recently published evidence that demonstrates a clear-cut relationship between SARS-CoV-2 viral load measured in saliva and COVID-19 symptom severity.<sup>1-4</sup> Salivary viral load is a powerful predictive indicator for disease progression to more severe manifestations of COVID-19.

"These clinical results provide evidence for our entire treatment approach," said Neal Hunter, Executive Chairman, EmitBio Inc. "We recognize that this new treatment paradigm takes a shift in how people think about treating respiratory infections but reducing viral load clearly correlates with reversal of COVID-19."

The clinical trial results along with the results from a Phase I safety study in healthy volunteers have been submitted as part of a comprehensive package to the FDA requesting Emergency Use Authorization (EUA).

## **About EmitBio Inc.**

EmitBio Inc. is a life science company using the precise delivery of safe, visible light to stimulate, heal and protect the body. EmitBio is comprised of a superior team of internationally recognized light science specialists merged with immunology and virology life science experts, prepared to react quickly to the pandemic and rapidly scale manufacturing for lifesaving medical breakthroughs. For more information, visit http://www.emitbio.com/.

EmitBio Inc. is headquartered in Durham, NC and is an operating subsidiary of KNOW Bio LLC.

\* The EmitBio device is investigational and is not yet available for sale in the United States.

#### References:

- 1. Silva et al. "Saliva viral load is a dynamic unifying correlate of COVID-19 severity and mortality," preprint, 2021. (https://www.medrxiv.org/content/10.1101/2021.01.04.21249236v2)
- 2. Wyllie et al. Saliva or nasopharyngeal swab specimens for detection of SARS-CoV-2. N Engl J Med. 2020; 383:1283-6. (https://www.nejm.org/doi/full/10.1056/NEJMc2016359)
- **3.** Huang et al. Integrated single-cell atlases reveal an oral SARS-CoV-2 infection and transmission axis, preprint, **2020.** (<a href="https://www.medrxiv.org/content/10.1101/2020.10.26.20219089v1">https://www.medrxiv.org/content/10.1101/2020.10.26.20219089v1</a>)
- **4.** To et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. **2020**; 20:565-74. (https://doi.org/10.1016/S1473-3099(20)30196-1)

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## Scientific Collaboration:

The team at EmitBio welcomes inquiries and offers of scientific collaboration from the global research community. Please direct communication to:

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