



21 April 2020

Company Announcements Office  
Australian Securities Exchange  
Exchange Centre  
20 Bridge Street  
Sydney, NSW 2000

Dear Sir/Madam

### **MEDLAB EXTENDS NANOCELLE™ PLATFORM TO ANTI-MALARIA DRUG AS PART OF COVID-19 RELATED RESEARCH**

- Medlab extends its NanoCelle™ delivery platform to include anti-malaria drug, Chloroquine (proof of concept) as part of its community based COVID-19 research contribution
- University of Sydney validates Medlab's NanoCelle™ Chloroquine (CQ) nanoparticle characteristics
- Medlab's core focus remains across the chronic illness sector, in particular NanaBis™ for cancer pain and NRGBiotic™ for treatment resistant depression.

Medlab Clinical Limited (ASX:MDC), as part of its community based COVID-19 research efforts is pleased to announce early drug design (also known as a Proof of Concept formulation) has completed the application of Medlab Clinical's delivery platform NanoCelle™ technology to develop a nanoparticle Chloroquine (CQ) spray delivered by the oro-buccal membrane.

Chloroquine (CQ) is a known anti-malaria drug currently under investigation for the treatment of patients infected with the COVID-19 virus. Chloroquine is registered in the Australia Register of Therapeutic Goods and marketed under the brand name Chlorquin.<sup>1</sup>

It is important to note, CQ is not approved for COVID-19 use outside investigative trials.

The International Journal of Antimicrobial Agents (MAR 2020)<sup>2</sup>, cites "... 20 clinical studies were launched in several Chinese hospitals. The first results obtained from more than 100 patients showed the superiority of chloroquine compared with treatment of the control group in terms of reduction of exacerbation of pneumonia, duration of symptoms and delay of viral clearance..." Funding for this Article "Chloroquine and Hydroxychloroquine as available weapons to fight COVID-19" was funded by the French Government.

Early studies have reported, some positive Coronavirus outcome treatments from the use of high oral dosing (500mg tablets once to twice daily for up to 10 consecutive days)<sup>3</sup> that resulted in small levels of the drug detected in plasma. This became of interest to MDC specifically potentiating the use of the NanoCelle™ delivery platform to provide for a more efficient (and potentially safer) means of delivering CQ.

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<sup>1</sup> <https://www.healthdirect.gov.au/medicines/brand/amt.35869011000036107/chlorquin>

<sup>2</sup> Colson P., et al (IJANTIMICAG 2020.105932) : "Chloroquine and hydroxychloroquine as available weapons to fight COVID-19"

<sup>3</sup> [AHSP \(APR 2020\), Assessment of Evidence for COVID-19-Related Treatments, COVID-19 Evidence Table](#)

The Therapeutic Goods Administration (TGA) cites the following contraindications/side effects for CQ<sup>4</sup> as it relates to the approved use for the treatment of malaria:

**Contraindications:**

- Retinal damage or impaired visual field
- Allergy to chloroquine/hydroxychloroquine

**Adverse effects:**

- Headache
- Skin eruptions/itch
- GI disturbance
- May worsen psoriasis
- Rare - psychotic episodes, anxiety, personality change, seizures, blood dyscrasias.

As research evolves, the literature (non-peer reviewed) also shows serious contraindication concerns, such as with the concomitant use of Metformin<sup>5</sup>, a common drug used to manage type 2 diabetes. Adding to concerns, a recent Brazilian Safety study of 440 COVID-19 patients<sup>6</sup>, terminated early due to lethality concerns using doses as high as 600 mg CQ twice per day.

Professor Luis Vitetta, Medlab’s Director of Medical Research, who undertook the project said “presently our findings for applying Medlab’s NanoCelle™ technology to formulate CQ has been initially validated by the University of Sydney’s, NanoScale Unit (headed by A/P Chrzanowski) confirming the submicron particle size and concentration (Figure 1) below of the medicine in a water-soluble formulation. This result makes CQ primed for delivery by the buccal membrane, like other MDC NanoCelle™ products (e.g., NanaBis™).”

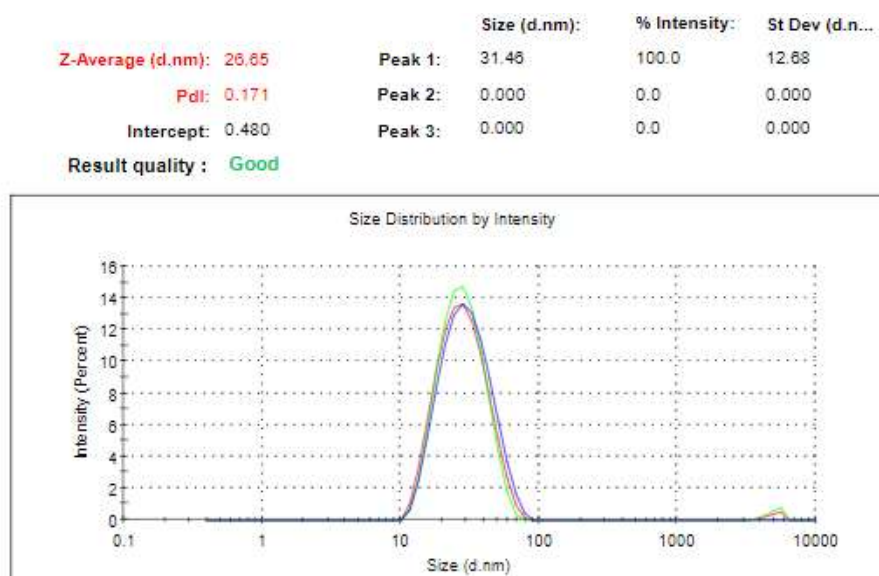


Figure 1: An example of size distribution of a sample of NanoCelle™ CQ with particle size peak of ~31.5nm

What this means is extremely small particles (consider a red blood cell to be 7000nm) of 31.5nm, optimised to cross the oro-buccal membrane thus bypassing known product degradation via first pass metabolism, allowing significantly lesser amounts of CQ to be used.

<sup>4</sup> <https://www.tga.gov.au/alert/new-restrictions-prescribing-hydroxychloroquine-covid-19>

<sup>5</sup> BioRxiv (MAR 2020), “Fatal toxicity of chloroquine or hydroxychloroquine with metformin in mice”

<sup>6</sup> Borba MGS, et al (APR 2020) “Chloroquine diphosphate in two different dosages as adjunctive therapy of hospitalized patients with severe respiratory syndrome in the context of coronavirus (SARS-CoV-2) infection: Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial (CloroCovid-19 Study)”

Professor Vitetta stated, “considering the clinical literature with regards to CQ, our focus is about the efficient and effective delivery of CQ that accesses the blood stream. Hopefully, this would translate to lesser side effects as cited in current literature. This is especially important considering literature regarding pharmacokinetic and pharmacodynamic data reports that up to 77% of oral ingested (600 mg tablet) CQ is excreted in urine<sup>7</sup>.”

NanoCelle™ is a patent protected, proprietary delivery platform used in both nutraceuticals and pharmaceuticals. NanoCelle™ allows for the creation of water solubilised nanoparticles of an API for fast and efficient utilisation by the human body. NanoCelle™ is most known for its use in the Cancer pain program, NanaBis™.

For and behalf of the Board.



Dr Sean Hall  
Managing Director

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**ABOUT MEDLAB** – [www.medlab.co](http://www.medlab.co)

Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and the United States. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, NanoCelle™, is being applied to its medicines, nutritional products and off-patent drugs like statins. Medlab has a growing patent portfolio.

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<sup>7</sup> Br. J. clin. Pharmac. (1987), 23, 295-301. Q Walker, et la. “The disposition of chloroquine in healthy Nigerians after single intravenous and oral doses”