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Cardax Releases White Paper on the Potential Role of Astaxanthin in the Treatment of Coronavirus Disease

Cardax seeking strategic collaborations to further develop astaxanthin for COVID-19

HONOLULU, March 20, 2020 /PRNewswire/ -- Cardax, Inc. (OTCQB:CDXI) today released a white paper outlining the potential role of astaxanthin in the treatment of coronavirus disease and is seeking strategic collaborations to further develop astaxanthin for COVID-19. The paper focuses on the scientific rationale of boosting the immune system and reducing the extreme inflammatory response that may lead to severe respiratory complications in subjects with COVID-19, the disease caused by the novel coronavirus (SARS-CoV-2). The paper is entitled "Astaxanthin: A safe, natural, and multi-faceted anti-inflammatory for maintaining lung health and possibly minimizing SARS-CoV-2 effects" and can be found at www.cardaxpharma.com/COVID-19. The paper was authored by Timothy J. King, Ph.D., M.S., Vice President, Research, Cardax, Inc. Astaxanthin is the exceptionally safe anti-inflammatory delivered by Cardax's lead pharmaceutical candidate, CDX-101, a proprietary astaxanthin prodrug.

Highlights:

Scientific Rationale: Immune Response, Inflammation, and COVID-19 The novel coronavirus (SARS-CoV-2) infection can induce COVID-19, an extreme immune response characterized by the overproduction of immune cells and the uncontrolled release of pro-inflammatory cytokines. Exceedingly high levels of the cytokines IL-1, IL-6, IL-8, TNF- α , and CRP result in overt inflammatory symptoms that include mild to severe respiratory disease, high fever, and cough. In progressed disease this "cytokine storm" will circulate throughout the body to trigger a surge of active immune cells into the lungs resulting in acute lung injury and acute respiratory distress syndrome (ARDS) and may be particularly severe in immune compromised subjects such as the elderly, diabetics, and those with cardiovascular disease.

This association between infection and progression of disease with inflammation suggests a strategy that would partner anti-infective agents, such as anti-virals and vaccines, with anti-inflammatory agents. An anti-inflammatory agent would be expected to mitigate symptoms including fever, pain, and swelling. Furthermore, an anti-inflammatory regimen initiated at a relatively early stage in disease progression might be expected to stem the immune over-response and to slow or even prevent progression of symptoms leading to lung injury and ARDS. Importantly, an appropriate anti-inflammatory intervention should not result in abnormal immune suppression but should target healthy immune homeostasis.

An anti-inflammatory treatment that resulted in the decrease of inflammatory cytokine

signaling would seem a promising approach. Chinese researchers have identified IL-6 as a main driver of immune overreaction in COVID-19 patients and have already included elevated IL-6 levels as a biomarker of disease worsening. China's National Health Commission has updated its treatment guidelines for COVID-19 to include Roche's injected biologic, Actemra (tocilizumab), an inhibitor of the IL-6 receptor. Actemra, first approved by the U.S. FDA in 2010 for rheumatoid arthritis, can now be used in China to treat serious coronavirus patients with lung damage.

The Potential Role of Astaxanthin. In pre-clinical and clinical studies, astaxanthin has demonstrated the ability to decrease levels of pro-inflammatory cytokines IL-1, IL-6, TNF- α , and CRP in multiple models of disease and in several patient populations. Furthermore, astaxanthin does not lead to abnormal immune suppression even at high doses and acts to restore healthy immune homeostasis. Astaxanthin has also demonstrated exceptional safety in multiple animal models, has been used extensively in humans for two decades as a dietary supplement, and is GRAS (Generally Recognized as Safe), according to FDA regulations.

Coronaviruses have been shown to induce lung damage by increasing inflammatory signaling pathways and cytokine production leading to elevated immune cell infiltration and macrophagic polarization shifts (M2 to M1). Astaxanthin has been shown to (i) significantly attenuate pathological elevation of critical inflammatory cell signaling pathways (NF- κ B), (ii) decrease the resulting elevated proinflammatory cytokine levels, (iii) reduce immune cell infiltration of the lung, and (iv) positively influence macrophage polarization in humans and animal models of disease. (Further discussion and references are provided in the [white paper.](#))

Results from the pre-specified interim review of the Company's ongoing CHASE (Cardiovascular Health Astaxanthin Supplement Evaluation) clinical trial demonstrated a statistically significant reduction in CRP (C-Reactive Protein, a measure of inflammatory health) in diabetics and a strong trend of CRP reduction in cardiovascular subjects. The CHASE clinical trial is a double-blind, randomized, placebo-controlled clinical trial evaluating the effect of the Company's synthetic astaxanthin dietary supplement ZanthoSyn®, on cardiovascular health, as measured by CRP levels over 12 weeks in up to 120 subjects with documented cardiovascular risk factors. Pre-specified secondary cardiovascular/inflammatory health markers, safety parameters, exploratory endpoints, and pre-specified sub-groups are also being assessed. The trial includes an optional open-label extension through 48 weeks.

Next Steps. Cardax is seeking strategic collaborations with appropriate academic, governmental, and/or commercial organizations to further develop astaxanthin for COVID-19. In addition, the Company filed a patent application yesterday related to the potential role of astaxanthin in the treatment of COVID-19.

About Cardax

Cardax is a development stage biopharmaceutical company primarily focused on the development of pharmaceuticals for chronic diseases driven by inflammation. The Company also has a commercial business unit that markets ZanthoSyn®, a physician recommended astaxanthin dietary supplement for inflammatory health.* CDX-101, the Company's astaxanthin pharmaceutical candidate, is being developed for cardiovascular inflammation and dyslipidemia, with a target initial indication of severe hypertriglyceridemia. CDX-301, the

Company's zeaxanthin pharmaceutical candidate, is being developed for macular degeneration, with a target initial indication of Stargardt disease. The Company's pharmaceutical candidates are currently in pre-clinical development, including the planning of IND enabling studies. The safety and efficacy of the Company's pharmaceutical candidates have not been directly evaluated in clinical trials or confirmed by the FDA.

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Safe Harbor

This release may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of our company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies, including the scientific rationale for the potential role of astaxanthin in the treatment of COVID-19, is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Some of the factors that could cause our actual results to differ from our expectations or beliefs include, without limitation, the risks discussed from time to time in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, we undertake no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.

* These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.



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