

# Cardax Engages Industry Veteran Fred Sancilio, Ph.D., to Launch Orphan Drug Development Program

## INFLAMMATION'S MAJOR ROLE IN CHRONIC ORPHAN DISEASES SUPPORTS PROGRAM'S STRONG POTENTIAL

HONOLULU, June 13, 2018 /PRNewswire/ -- Cardax, Inc. (OTCQB: CDXI) announced today that it engaged industry veteran and orphan drug expert, Frederick D. Sancilio, Ph.D., to launch the Company's orphan drug development program. Dr. Sancilio has over 40 years of pharmaceutical industry experience, including founding and running a leading contract research organization that contributed to more than 2,000 drug product registrations in the U.S., Asia, and Europe.

Orphan drugs are defined by federal statute as treatments for diseases with fewer than 200,000 patients in the U.S. While clinical trials are required for the approval of an orphan drug, the U.S. Food and Drug Administration ("FDA") may designate an orphan drug candidate as a potential orphan drug early in the development process, often prior to initiation of clinical trials. Receipt of an "Orphan Drug Designation" from the FDA can be a significant factor in financing and/or partnership opportunities to support the development of an orphan drug candidate.

The major role of inflammation in chronic disease, including rare (orphan) diseases, supports the strong potential of safe anti-inflammatory treatments for orphan indications. Dr. Sancilio will focus first on obtaining an Orphan Drug Designation for a safe anti-inflammatory orphan drug candidate from the Company's astaxanthin platform.

Cardax believes an orphan drug development program provides an opportunity to address major unmet medical needs in underserved populations and typically offers a number of other benefits, including smaller, less costly clinical trials, leading to a more efficient regulatory path. In addition, potential tax credits and research grants may be available, and importantly, seven-year market exclusivity is granted by the FDA upon orphan drug approval.

"We feel the efficient, economical, and potentially rewarding orphan drug pathway makes a lot of sense for Cardax as a pharmaceutical development program," said Cardax President and CEO David G Watumull. "We are pleased and honored to be working with someone with Fred's background and experience to lead this important program."

"After reviewing the research on astaxanthin and Cardax's wealth of knowledge regarding astaxanthin's potential to treat several rare orphan diseases, I am delighted to join their team and launch this program," added Dr. Sancilio. "Having worked in both rare orphan disease research and inflammation medicaments, I look forward to continue helping patients who have limited or no pharmaceutical treatment options."

The Company plans to submit an orphan drug designation application to the FDA within twelve months. This application primarily focuses on providing evidence supporting the size of the orphan population and also includes a rationale for the drug's potential efficacy in the orphan indication. By statute the FDA has 90 days to respond to the application but may require additional data or reject the application outright.

#### **About Cardax**

Cardax devotes substantially all of its efforts to developing and commercializing dietary supplements and pharmaceuticals. Cardax is initially focusing on astaxanthin, which is a powerful and safe naturally occurring anti-inflammatory compound. The safety and efficacy of Cardax's products have not been directly evaluated in clinical trials or confirmed by the FDA.

#### **About Astaxanthin**

Astaxanthin is a clinically studied compound with safe anti-inflammatory activity supported by more than 1,600 peer-reviewed papers and more than fifty human proof-of-concept studies, including more than twenty randomized, double-blind, placebo-controlled clinical trials.

### **Media and Investors**

Janice Kam 1-808-457-1400 press@cardaxpharma.com

#### 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. Forwardlooking 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 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.



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