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JanOne Successfully Begins Production of JAN101 cGMP Batch for Phase 2b Peripheral Artery Disease (PAD) Trial and Potential Covid-19 Study

Company continues to make progress on its potential treatment for PAD, a disease affecting 200 million people worldwide

LAS VEGAS, Sept. 24, 2020 /PRNewswire/ -- JanOne Inc. (Nasdaq: JAN), a company focused on developing treatments for conditions that cause severe pain and drugs with non-addictive, pain-relieving properties, today announced that the Company has started production of JAN101 under Current Good Manufacturing Practices (cGMP) for the company's anticipated Phase 2b trials to treat Peripheral Artery Disease (PAD) and as a potential treatment for Covid-19 vascular complications.

This development follows the successful completion of the JAN101 prototype and engineering batches and positive stability data. The initial production batch will be 250,000 sustained release tablets and matching placebos. The Phase 2b trial is expected to begin in early 2021. PAD presents a large market opportunity as there currently are no effective treatments for the disease.

"The initiation of this batch is a major milestone for the Company, as it demonstrates that we now have the ability to economically scale up production of JAN101," said Tony Isaac, President and Chief Executive Officer of JanOne. "This cGMP batch will help set the stage for our anticipated Phase 2b PAD trial, as well as the exploration of JAN101 as a treatment for vascular complications caused by Covid-19, with additional product available for collaborations with independent investigators on other indications."

JAN101 is a patented sustained release form of sodium nitrite aimed at improving vascular function, reducing neuropathic pain and other conditions resulting from poor blood flow. It is highly selective, acting only in damaged tissue. In animal studies, sodium nitrite has been shown to promote blood vessel growth and function, prevents tissue inflammation and necrosis, and prevents diabetic nephropathy, a leading cause of death in diabetics. Additionally, three human clinical studies have found that sodium nitrite significantly reduces pain.

About JanOne
JanOne (NASDAQ: JAN) is focused on developing treatments for diseases that cause severe pain. By alleviating pain at the source, JanOne aims to reduce the need for opioid prescriptions to treat disease associated pain that can lead to opioid abuse. The company is also exploring solutions for non-addictive pain medications. Its lead candidate JAN101 is for treating peripheral artery disease (PAD), a condition that affects over 8.5 million Americans.

JAN101 demonstrated positive results in a Phase 2a clinical trial, and Phase 2b trials are expected to begin in early 2021. JanOne is dedicated to funding resources toward innovation, technology, and education for PAD, associated vascular conditions and neuropathic pain. JanOne continues to operate its legacy businesses under their current brand names, which are undergoing review to determine appropriate strategic alternatives. For more information, visit janone.com

Forward-Looking and Cautionary Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In accordance with the safe harbor provisions of this Act, statements contained herein that look forward in time that include everything other than historical information, including statements relating to (i) whether JAN101 can treat vascular complications in Covid-19 patients, (ii) whether the company can obtain FDA approval for its Covid-19 study, and (iii) if and when the Phase 2b trials for PAD will commence. These forward-looking statements can be identified by terminology such as "will," "aims," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates" and similar statements. JanOne may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the "SEC") on Forms 10-K and 10-Q, Current Reports on Form 8-K, in its annual report to stockholders, in press releases, and other written materials and in oral statements made by its officers, directors or employees to third parties. There can be no assurance that such statements will prove to be accurate and there are a number of important factors that could cause actual results to differ materially from those expressed in any forward-looking statements made by the company, including, but not limited to, plans and objectives of management for future operations or products, the market acceptance or future success of our products, and our future financial performance. The company cautions that these forward-looking statements are further qualified by other factors including, but not limited to, those set forth in the company's Annual Report on Form 10-K for the fiscal year ended December 28, 2019 (available at http://www.sec.gov). JanOne undertakes no obligation to publicly update or revise any statements in this release, whether as a result of new information, future events, or otherwise.

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