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JanOne Encouraged By Recent FDA Communications Regarding Phase 2B Clinical Trial Design of Lead Drug Candidate JAN101

JanOne's management is encouraged regarding Recent Discussions on Potential Phase 2b Trial Endpoints and Possible Regulatory Routes for JAN101 as Treatment for Peripheral Artery Disease (PAD)

LAS VEGAS, Sept. 28, 2021 /PRNewswire/ -- JanOne Inc. (Nasdaq: JAN), a company that focuses on the development of treatments for conditions that cause severe pain – in conjunction with its continuing focus on the development of drugs with non-addictive, pain-relieving properties – today announced that it is revising its development strategy based on recent communications with the U.S. Food and Drug administration (FDA) for its upcoming clinical trial of lead drug candidate JAN101 as a treatment for Peripheral Artery Disease (PAD). JanOne previously submitted data from the product's Phase 1 and Phase 2a studies showing improved vascular function and a reduction in pain, which was integrated into its Phase 2b protocols and primary and secondary endpoints. The FDA reviewed the data and it provided recommendations and comments on the planned clinical trial to JanOne.

"JanOne is grateful for the recommendations and comments provided by the FDA in response to our pre-Phase 2 submission," said Tony Isaac, President and Chief Executive Officer of JanOne. "Typically, it is in the best interest of the drug sponsor – and useful to the FDA – to conduct pre-Phase 2 meetings because early interactions between the two parties can lead to the efficient and effective application of directives in the trials and potentially reduce the number of review cycles between trial phases in the drug development process. We appreciate the FDA's interest and willingness to discuss our clinical plans in advance of our upcoming submission."

Tony Giordano, Ph.D., Chief Scientific Officer of JanOne commented, "We are very happy with the thorough review of our pre-Phase 2b briefing materials from the FDA. We are working now with our partners to incorporate all the recommendations and comments provided by the FDA into our Phase 2b protocol and supporting documents and we feel that this will result in a much stronger study. Our desire is to get a drug to market as soon as reasonably possible to start treating patients with PAD and to provide them with a

therapeutic benefit not available to them with current treatments."

PAD is a chronic disorder that reduces blood flow to the extremities, which results in severe pain, limited mobility, and in some cases, death. In the United States, estimates are that PAD affects over 8.5 million people with an annual cost of care at $10+ billion annually. When being treated for PAD-associated pain, 25% of patients are at risk for opioid prescriptions. By treating PAD at the source, the need for pain relieving medications, which are often dangerous and highly addictive opioids, is removed.

JAN101 is a twice-daily orally-dosed slow-release formulation of the FDA-approved compound therapeutic sodium nitrite. Results from Phase 2a clinical trials of JAN101 support the use of sodium nitrite for the treatment and prevention of PAD. An unexpected outcome of the Company's earlier studies was that some patients reported a significant reduction in PAD-associated pain. This led to JanOne's development of clinical protocols for PAD and PAD-associated pain for Phase 2b trials.

About JanOne

JanOne (Nasdaq: JAN) focuses on the development of 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. JanOne is exploring solutions for non-addictive pain medications. Its lead candidate, JAN101, is for potentially 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 the Company is currently in preparations for Phase 2b trials. JanOne is dedicated to funding resources toward innovation, technology, and education for PAD, associated vascular conditions, and neuropathic pain. For more information, visit www.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 whether the FDA will approve the Company's upcoming Phase 2b submission. These forward-looking statements can be identified by terminology such as "will," "aims," "upcoming," "may," "expects," "expected," "potential," "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 January 2, 2021 and other SEC filings (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.

Investor Relations & Media Contact
IR@Janone.com
1 (800) 400-2247

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