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JanOne Acquires Worldwide, Exclusive License for Promising Treatment of Peripheral Arterial Disease (PAD)

Phase 2b testing planned for PAD treatment and PAD-associated pain to address 8.5 million patient US market

LAS VEGAS, Nov. 25, 2019 /PRNewswire/ -- JanOne Inc. (NASDAQ: JAN), a company focused on reducing opioid addiction by finding treatments for conditions accompanied by pain and bringing to market drugs and therapies with nonaddictive pain-relieving properties, today announced a licensing agreement for TV1001SR, a treatment for Peripheral Artery Disease, commonly called PAD. The agreement with LSU Health Shreveport, UAB Research Foundation, and TheraVasc, Inc., gives JanOne a worldwide, exclusive license for TV1001SR along with a portfolio of 30 patents and other intellectual property relating to the sustained release of sodium nitrite.

The company anticipates TV1001SR will be a groundbreaking treatment for those with PAD, an often painful disease affecting more than 200 million people worldwide and 8.5 million in the United States[1]. There is no known efficacious single-drug treatment for PAD available[2]. Current treatments only mitigate the effects of PAD without treating the underlying cause – reduced ischemic tissue blood flow, which is a lack of blood flow to the extremities, and often leads to significant pain. As a result, according to a recent Stanford University[3] study, nearly 25% of patients with PAD are at increased risk of high opioid use.

TV1001SR was invented by Dr. Christopher Kevil, Professor of Pathology, Molecular and Cellular Physiology, and Cell Biology and Anatomy at LSU Health Shreveport. In initial research studies, the drug effectively restored ischemic tissue blood flow and was effective in a wide range of pathologies involving alterations of angiogenesis - development of new blood vessels - including diabetes, wound healing and tissue necrosis. Beneficial effects included enhancing angiogenesis, endothelial cell proliferation, and arteriogenesis.

"In our Phase 2a trials, we saw encouraging results in the participants. The compound not only improved vascular function, but patients also reported a significant reduction in their PAD-associated pain," said Tony Giordano, Ph.D., former CEO of Theravasc and JanOne scientific advisory board member. "During the trial, a number of patients reported that their long-term pain had subsided, which was a positive and unexpected development."

As a result of TV1001SR's promising clinical trial history, JanOne will begin planning a Phase 2b clinical protocol for PAD with an expectation to commence Phase 2b trials by the second half of 2020. In addition, the company intends to apply for the secondary indication of PAD-associated pain as part of its Phase 2b trails. To streamline development and FDA approval, the company expects to pursue FDA 505(b)(2) pathway for new drug approval, due to an already approved agent associated with TV1001SR.

"Developing a non-addictive drug to treat a major disease that causes pain normally managed with opioids is exactly the kind of imaginative thinking the opioid crisis demands," said Eric Bolling, JanOne's chairman and president. "By treating PAD, the root cause of the disease, we hope to also be preventing and treating pain."

"Partnering with JanOne to bring to market this important treatment for a significant health issue is extremely gratifying," said Dr. Kevil. "We know that by treating PAD we can improve outcomes, increase quality of life, and avoid opioid addiction for potentially millions of people. I'm excited to work with JanOne and to continue the ongoing development of this critical medication."

If the company is ultimately granted FDA market approval, it believes that TV1001SR would immediately disrupt the $4.37 billion a year PAD market in the United States[4].

"We are thrilled to fast-track this drug into Phase 2b clinical trials with the addition of treating pain associated with PAD. We believe that having a solution to a major cause of neuropathic pain while eliminating the dependence on opioids could be an effective game-changer, with even greater long-term implications," added Bolling.

Forward-Looking Statements

This press release contains statements that are forward-looking statements as defined within the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements relating to the fact that TV1001SR will treat PAD, the timing of the commencement of clinical trials, that the FDA will permit approval through a 505(b)(2) pathway, that upon approval TV1001SR will immediately disrupt the PAD market, and other statements including words such as "continue", "expect", "intend", "will", "hope" "should", "would", "may", "potential" and other similar expressions. Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us, are inherently subject to significant business, economic, competitive, political and social uncertainties, and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements described in this press release. Such factors could include, among others, those detailed in the Company's periodic reports filed with the Securities and Exchange Commission (the "SEC").

Should one or more of these risks or uncertainties materialize, or should the assumptions set out in the section entitled "Risk Factors" in our filings with the SEC underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this press release and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. We cannot assure you that such statements

will prove to be accurate as actual results and future events could differ materially from those anticipated in such statements. Investors are cautioned that forward-looking statements are not guarantees of future performance and accordingly investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein.

About JanOne

JanOne is a unique Nasdaq-listed company offering innovative, actionable solutions that it believes can help create an end to the opioid crisis. JanOne is dedicated to funding resources toward innovation, technology, and education to find a key resolution to the national opioid epidemic, which is one of the deadliest and widespread in the country's history. The company continues to operate its legacy businesses – ARCA Recycling and GeoTraq – under their current brand names. JanOne's subsidiary, ARCA Recycling, recycles household appliances by providing turnkey recycling and replacement services for utilities and other sponsors of energy efficiency programs. JanOne's subsidiary GeoTraq engages in the development, design and, ultimately, expected sale of Mobile IoT modules. Please visit www.janone.com for additional information.

About LSU Health Shreveport

LSU Health Shreveport is one of two Health Sciences Centers of the Louisiana State University (LSU) System and one of only 154 in the nation accredited by the Liaison Committee on Medical Education (LCME). LSU Health Shreveport is home to three professional schools (School of Medicine, School of Graduate Studies and School of Allied Health Professions), Graduate Medical Education (GME) and a robust research enterprise. At any one time, more than 900 students are enrolled in degree programs, and more than 560 residents and fellows are being trained at LSUHS partner teaching hospitals in North Louisiana. The primary mission of the LSU Health Shreveport is to teach, heal, and discover, in order to advance the well-being of the region and beyond. At the heart of LSU Health Shreveport is a strong faculty that includes a number of nationally and internationally acclaimed physicians and scientists. More than 600 strong, they lead research efforts, educate students, train residents and fellows, and provide primary and specialty care to patients throughout the region. LSU Health Shreveport has strong community support, fostering a culture of diversity and inclusion that promotes mutual respect for all. For more information visit www.lsuhs.edu.

(1) Diagnosis and Management of Peripheral Arterial Disease Debra Kohlman-Trigoboff, MS, ACNP-BC: 200 million people in the world suffer from PAD and 8.5 million of them reside in the US https://www.npjournal.org/article/S1555-4155(18)30645-7/fulltext

(2) https://www.nhlbi.nih.gov/health-topics/peripheral-artery-disease

(3) Dr. Itoga Department of Surgery Stanford University: 24.7% of PAD people with PAD are at increased risk of high opioid use https://www.jvascsurg.org/article/S0741-5214(19)30179-X/fulltext

(4) https://www.ncbi.nlm.nih.gov/pubmed/18687757#

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