Jupiter Wellness' Merger Partner Next Frontier Pharmaceuticals, Inc. Announces Plans for Oral Dronabinol Solution for the Treatment of Alzheimer's Disease Agitation

- ***Next Frontier Pharmaceuticals is pursuing FDA 505(b)(2) fast-track approval with its previously FDA approved oral dronabinol (THC) solution***
- ***Next Frontier Pharmaceuticals has completed a pre-IND meeting with the FDA, and intends to commence Phase II Clinical Trials in the 2H 2022; industry research and studies support targeted efficacy endpoints***
- ***Alzheimer's Disease Agitation (Agit-AD) is estimated to affect more than four million seniors in the U.S. with no current FDA approved pharmacotherapies available***

JUPITER, FL and ROUND ROCK, TX / ACCESSWIRE / February 1, 2022 / Jupiter Wellness, Inc. (NASDAQ:JUPW), today announces that its merger partner, Next Frontier Pharmaceuticals, Inc., a leading drug developer focused on pharmaceutical cannabinoid APIs, plans to pursue an IND for its oral dronabinol solution for the treatment of Alzheimer's Disease Agitation (Agit-AD). Next Frontier Pharmaceuticals' oral dronabinol solution CII is approved as SYNDROS® by the FDA for the treatment of chemotherapy-induced nausea and vomiting in cancer patients and loss of appetite in AIDS patients who have lost weight.

Alzheimer's Diseaseis the most common form of dementia and afflicts an estimated 6 million individuals in the U.S., which is estimated to grow to 14 million individuals by 2050.[1] Agit-AD is reported in 70% of patients with Alzheimer's Disease, and is characterized by emotional distress, aggressive behaviors, disruptive irritability, and disinhibition.[2] There are no current FDA approved pharmacotherapies for the treatment of Agit-AD, with current treatment consisting primarily of the use of antipsychotics and sedatives.

"We are thrilled to announce the potential for our oral dronabinol solution, specifically targeting the treatment of Alzheimer's Disease Agitation, which is a serious, prevalent, and debilitating condition for which there are currently no FDA-approved pharmacotherapies," said Shannon Soqui, Executive Chairman of Next Frontier Pharmaceuticals. "Given the large unmet need for a viable solution for Agit-AD, we are pursuing a fast-track FDA approval pathway for our oral dronabinol solution. We look forward to working with the FDA over the coming months as we advance development of our oral dronabinol solution for the treatment of Agit-AD."

Next Frontier Pharmaceuticals has completed its pre-IND meeting with the FDA, receiving feedback on endpoints and a proposed clinical protocol. The quality and safety aspects of its oral dronabinol solution have been completed and have met the FDA's required criteria at the proposed clinical dose. Next Frontier Pharmaceuticals is in the process of opening a formal IND application with the FDA and if successful, intends to launch a single-Phase II study in the second half of 2022 as part of its regulatory pathway to New Drug Approval (NDA). The proposed Phase II trial design is a 160-patient crossover trial using the Cohen-Mansfield Agitation Inventory (CMAI) as its primary endpoint. A positive signal would validate the efficacy of our oral dronabinol solutionon Agit-AD and guide sample size calculations for the pivotal Phase III studies.

About Jupiter Wellness

Jupiter Wellness, Inc. (NASDAQ:JUPW) is a leading developer of pharmaceutical cannabinoids focused on skincare therapeutics and treatments. The Company's product pipeline incorporates cannabidiol (CBD) to address indications including psoriasis, eczema, burns, herpes cold sores, and skin cancer. Jupiter generates revenue from a growing line

of proprietary over-the-counter skincare products and other wellness brands. For additional information, please visit www.jupiterwellness.com.

About Next Frontier Pharmaceuticals, Inc.

Next Frontier Pharmaceuticals, Inc. is a leading drug developer focused on pharmaceutical cannabinoid APIs, and owns the FDA approved cannabinoid drug SYNDROS® (oral dronabinol solution CII). SYNDROS® is FDA approved as a prescription drug for the treatment of chemotherapy-induced nausea and vomiting in cancer patients and loss of appetite in AIDS patients who have lost weight. Next Frontier Pharmaceuticals is pursuing 505(b)(2) fast-track approval with the FDA for Investigational New Drugs (INDs) for its oral dronabinol solution, with a focus on large opportunities that have significant unmet needs with industry research and studies supporting targeted efficacy endpoints. Next Frontier Pharmaceuticals has a robust portfolio of patents and patents pending and pursues new intellectual properties for its drug products.

References:

1. Alzheimer's Association. 2020 Alzheimer's Disease Facts and Figures. Alzheimer's Dementia 2020;16(3):391+.
2. Tractenberg RE, Weiner MF, Thal LJ. Estimating the prevalence of agitation in community-dwelling persons with Alzheimer's disease. J Neuropsychiatry Clin Neurosci. 2002;14:11-18

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Forward Looking Statements

This communication contains forward-looking statements regarding Jupiter Wellness, including, but not limited to, statements related to the proposed acquisition of Next Frontier Pharmaceuticals and the anticipated timing, results and benefits thereof, including the potential for Jupiter Wellness to accelerate its growth and cannabinoid leadership, and for the acquisition to provide long-term growth opportunities to create shareholder value; and other statements that are not historical facts. You can generally identify forward-looking statements by the use of forward-looking terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "explore," "evaluate," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," or "will," or the negative thereof or other variations thereon or comparable terminology. These forward-looking statements are based on each of the companies' current plans, objectives, estimates, expectations, and intentions and inherently involve significant risks and uncertainties, many of which are beyond Jupiter Wellness' control. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: Jupiter Wellness' and Next Frontier Pharmaceuticals' ability to complete the acquisition on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to securing the necessary regulatory and shareholder approvals, and satisfaction of other closing conditions to consummate the acquisition; the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; risks related to diverting the attention of management from ongoing business operations; failure to realize the expected benefits of the acquisition; significant transaction costs and/or unknown or inestimable liabilities; the risk of shareholder litigation in connection with the proposed transaction, including resulting expense or delay; the risk that Next Frontier Pharmaceuticals' business will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; risks related to future opportunities and plans for the combined company, including the uncertainty of expected future regulatory filings, financial performance and results of the combined company following completion of the acquisition;

Next Frontier Pharmaceuticals' dependence on the successful commercialization of SYNDROS and the uncertain market potential of SYNDROS; pharmaceutical product development and the uncertainty of clinical success; the regulatory approval process, including the risks that the combined company may be unable to submit anticipated regulatory filings on the timeframe anticipated, or at all, or that the combined company may be unable to obtain regulatory approvals of any of its product candidates, and SYNDROS for additional indications, in a timely manner or at all; disruption from the proposed acquisition, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; effects relating to the announcement of the acquisition or any further announcements or the consummation of the acquisition on the market price of Jupiter Wellness' common stock; the possibility that, if Jupiter Wellness does not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Jupiter Wellness' common stock could decline; potential litigation associated with the possible acquisition; regulatory initiatives and changes in tax laws; market volatility; and other risks and uncertainties affecting Jupiter Wellness and Next Frontier Pharmaceuticals and, including those described from time to time under the caption "Risk Factors" and elsewhere in Jupiter Wellness' Securities and Exchange Commission (SEC) filings and reports, including Jupiter Wellness' Annual Report on Form 10-K for the year ended December 31, 2020 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and future filings and reports by Jupiter Wellness. In addition, the extent of the impact on the combined company's ability to generate sales of and revenues from its approved products, execute on new product launches, its clinical development and regulatory efforts, its corporate development objectives, and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Moreover, other risks and uncertainties of which the combined company is not currently aware may also affect each of the companies' forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. Investors are cautioned that forward-looking statements are not guarantees of future performance. The forward-looking statements made in this communication are made only as of the date hereof or as of the dates indicated in the forward-looking statements and reflect the views stated therein with respect to future events at such dates, even if they are subsequently made available by Jupiter Wellness on its website or otherwise. Jupiter Wellness undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

SOURCE: Jupiter Wellness, Inc.

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