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JUPW Logo

JUPITER, FLORIDA, UNITED STATES, November 15, 2021 / EINPresswire.com/ -- NASDAQ Company Completes Pre-IND meeting with the U.S. Food & Drug Administration for JW-100 in the Treatment of Eczema (NASDAQ: JUPW) Jupiter Wellness

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>
> *Dr. Glynn Wilson, Chief Scientific Officer of Jupiter Wellness,*

Jupiter Wellness, Inc. (NASDAQ:JUPW), a clinical stage company developing cannabinoid receptor agonists for the treatment of eczema, actinic keratosis, burns, and herpes cold sores, announced that it has received an official written response from a Type B pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) for JW-100, a topical drug the treatment of eczema.

The main purpose of the pre-IND meeting was to evaluate the drug development plan for JW-100.

JUPW believes that the written response from the FDA supports the Company's approach and its overall drug development strategy to enable the filing of an IND for its clinical studies on JW-100.

Dr. Glynn Wilson, Chief Scientific Officer of Jupiter Wellness, stated, "The pre-IND meeting written

response marks an important milestone in the development of JW-100 for the treatment of eczema. We have obtained FDA concurrence and clear guidance on the proposed manufacturing, nonclinical pharmacology, and toxicology studies, and the Phase 1 clinical design."

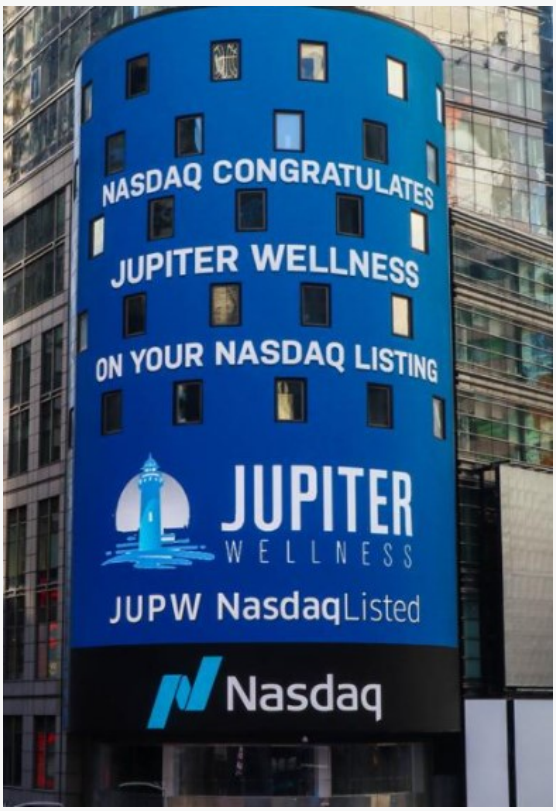
JW-100 met its primary endpoint in a recently completed Phase 1-equivalent international study in which Jupiter's topical formulation cleared or reduced eczema following two weeks of use. These results suggest JW-100 may potentially prove superior to existing prescription drugs for the treatment of eczema in future clinical trials. The global eczema treatment market is valued at $10 billion and expected to grow at a CAGR of 13% from 2020-2025.

-Developer of CBD Treatments for the Growing Global Skin Care Market.

-Multiple Clinical and Commercial Milestones Recently Achieved on the Company’s Proprietary Product Lines.

INSIDER	RELATION	LAST DATE	TRANSACTION	OWNER TYPE	SHARES TRADED	PRICE	SHARES HELD
JOHN BRIAN	Officer	08/16/2021	Acquisition (Non Open Market)	Direct	18,832	$0.00	2,720,750
MCKINNON DOUGLAS O	Officer	08/16/2021	Acquisition (Non Open Market)	Direct	14,124	$0.00	127,274
WILSON GLYNN	Officer	08/16/2021	Acquisition (Non Open Market)	Direct	14,124	$0.00	756,024
MILLER RICHARD A	Officer	08/16/2021	Acquisition (Non Open Market)	Direct	9,416	$0.00	986,316

juwp Insider



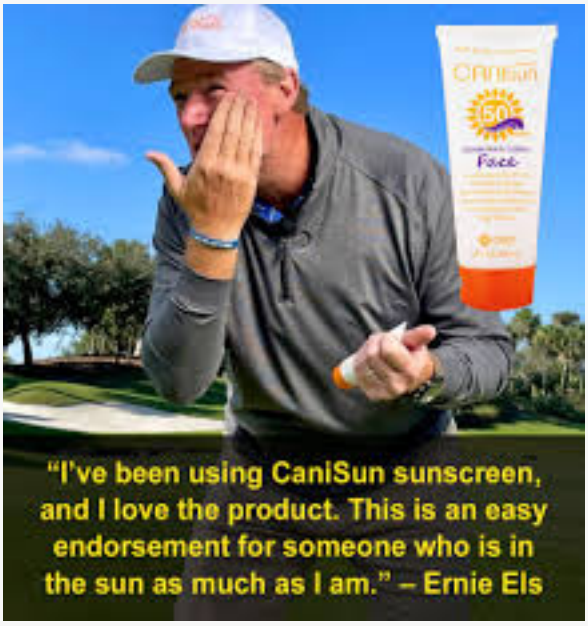
$JUPW Listed on the NASDAQ

-Pro Golf Hall of Fame Legend Ernie Els Extends Endorsement Deal.

-Submitted Pre-IND Meeting Request with US FDA for Proposed Clinical Program of JW-100 as a Treatment for Mild to Moderate Eczema.

Jupiter Wellness, Inc. (NASDAQ: JUPW) is a leading developer of cannabidiol (CBD) based medical therapeutics and wellness products. The JUPW clinical pipeline of prescription CBD-enhanced skin care therapeutics address indications including eczema, burns, herpes cold sores, and skin cancer. JUPW generates revenues from a growing line of proprietary over-the-counter skincare products including its flagship CaniSun™ sunscreen and other wellness brands sold through its robust distribution platform.

JUPW is NASDAQ listed and has an attractive share structure with only
22,927,465 shares currently outstanding.



Pro Golfer Ernie Els Endorses JUPW

-Shareholder Update on Multiple Clinical & Commercial Milestones Plus Upcoming Television Advertisement

On October 27th JUPW provided a comprehensive shareholder update on its advancing clinical programs and commercial progress. The updated included the following details:

Commercial:

The JUPW product Photocil™ ("Phototherapy in a bottle"), a patented topical Over-the-Counter drug for the treatment of psoriasis and vitiligo is expected to launch in Q1 2022. Photocil was licensed from Applied Biology. The clinical efficacy of Photocil™ in the treatment of psoriasis and vitiligo has been published in peer-reviewed medical journals. Photocil has been assigned the following NDC numbers by the FDA for each product:

-82301-001-001 (Atopic Dermatitis)

-82301-002-001 (Psoriasis)

-82301-003-001 (Vitiligo)

Clinical:

US FDA Filings for JW-100 as a Treatment of Eczema

JUPW recently submitted a pre-IND package for JW-100 as a prescription drug for the treatment of mild-to-moderate atopic dermatitis (eczema). JUPW anticipates a pre-Investigation New Drug (IND) meeting with the US FDA in Q4 2021. In a prior early study, JW-100 cleared or reduced eczema following 2 weeks of use, suggesting that through its unique mechanism of action it may potentially prove superior to existing prescription drugs for the treatment of eczema.

Phase III Head-to-Head Study of JW-100C in Eczema

A head-to-head Phase III double-blinded, placebo controlled clinical trial designed to evaluate superiority of JW-100 to Eucrisa (an FDA approved topical drug) in adult patients with mild-to-moderate eczema expects first patient enrolled in Q4 2021.

JW-200 Clinical Study in Actinic Keratosis to Complete Enrollment Q1 2022

An investigational clinical study with a protocol similar to an FDA Phase I is enrolling 115 adults diagnosed with actinic keratosis. Enrollment is expected to be completed by the beginning of 2022 and data will be used in preparation for an FDA IND filing.

JW-300 Clinical Study in Burns to Complete Enrollment Q4 2021

A double-blinded, placebo controlled investigational study in Europe and Asia with a protocol similar to an FDA Phase I is enrolling 50 patients with newly diagnosed first degree burns. Resulting data will be used in preparation for an FDA IND filing. Enrollment is expected to be completed by the end of 2021.
"Based on our acquisition and development strategy. Jupiter Wellness has short-term product opportunities and an extensive clinical pipeline conducting double-blinded, placebo controlled clinical trials to unequivocally establish efficacy of our novel and proprietary products for both OTC and prescription drugs," stated Dr Glynn Wilson, Jupiter's Chief Scientific Officer. "Jupiter Wellness is committed to providing rapid and consistent relief for the majority of people suffering from a number of skin indications, including eczema, psoriasis, and vitiligo. Jupiter Wellness is also committed to developing approaches that measure individual gene expression that can be used to determine the most appropriate patients for treatment and the outcomes of therapies."

-Multi-Year Extension of Endorsement Agreement with Pro Golfer Ernie Els

On September 8th JUPW announced a multi-year extension of its endorsement agreement with PGA Golf Legend Ernie Els. Els, known as “The Big Easy”, will help promote the JUPW patent pending CaniSun Suncare Product Line for two additional years. The CaniSun product line offers the highest quality suncare products infused with CBD.

Pursuant to the agreement, JUPW will extend its agreement with renowned golfer Ernie Els, who will act as a brand ambassador of the JUPW unique, one-of-a-kind Suncare products. The campaign is seen as CaniSun partnering with one of the best and well-liked athletes in the sport of golf. The campaign focuses on providing premium suncare protection for everyone from elite athletes like Ernie Els to the everyday weekend warrior.

"Because I spend so much time in the sun, I always hit the golf course with CaniSun. I'm constantly looking for the most effective products, and CaniSun consistently works well for me, so it's my first choice," Els stated. "I've been using CaniSun sunscreen and I love the product. This is an easy endorsement for someone who is in the sun as much as I am. Extending the relationship made sense."

-Submitted a Pre-IND Meeting Request with the US FDA for its Proposed Clinical Program of JW-

100 as a Treatment for Mild to Moderate Eczema
On August 23rd JUPW announced it has submitted a pre-IND (Investigational New Drug) meeting request with the U.S. Food and Drug Administration (FDA) in support of its JW-100 drug development program the treatment of patients with mild to moderate Eczema .

The benefits of holding a pre-IND meeting are to receive early FDA feedback on proposed preclinical and clinical study plans confirming strategy for IND submission. The FDA's statistics show that this can significantly reduce overall development times which impacts time to market.

The Global Eczema (atopical dermatitis) treatment market is valued at $10 billion and expected to grow at a CAGR of 13% from 2020-2025. 31.6 million Americans or roughly 10% of the population suffer from Eczema. 86% are not satisfied with their current treatment.

Through the JUPW research and development program, it has shown that in a double-blinded, placebo controlled clinical trial, JW-100 significantly reduced ISGA scores in 50% of adult patients suffering from eczema and JW-100 cleared or reduced eczema following 2 weeks of use.

For additional information on Jupiter Wellness, Inc. (JUPW) visit www.jupiterwellnessinc.com.

All products mentioned in this article are THC-free and compliant with the 2018 farm Bill

failure to meet schedule or performance requirements of the companies' contracts, the companies' liquidity position, the companies' ability to obtain new contracts, the emergence of competitors with greater financial resources and the impact of competitive pricing. In the light of these uncertainties, the forward-looking events referred to in this release might not occur.

SOURCE: CorporateAds.com

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