

March 14, 2022



# **Wesana Health Announces Positive Feedback From Pre-IND Meeting With FDA on SANA-013**

## **Pre-IND Meeting is a Significant Milestone in the Clinical Development of SANA-013, Defining the Pathway to Initiate in-Human Clinical Trials in Q4 2022**

CHICAGO and TORONTO, March 14, 2022 (GLOBE NEWSWIRE) -- **Wesana Health Holdings Inc. ("Wesana" or the "Company") (CSE: WESA; OTCQB: WSNAF)**, a data-driven life sciences company focused on developing the novel therapies of tomorrow and delivering new care paradigms today, announced that they have received a full written response from the Food and Drug Administration (FDA) regarding their pre-Investigational New Drug (IND) meeting for the novel therapy and proprietary protocol of SANA-013 for the treatment of Traumatic Brain Injury (TBI) related major depressive disorder (MDD).

The Company received positive written responses from the FDA on March 11<sup>th</sup> outlining the requirements to open the IND and commence with clinical studies for SANA-013. The Company believes the written response provides a path to agreements on IND-enabling studies and validates the team's effort and accomplishments over the past year. Wesana intends to initiate its in-human clinical study program in late 2022. The FDA response also provided important insights pertaining to advancing SANA-013 as a potential treatment for TBI-related MDD.

Mark A. Wingertzahn, Wesana's Chief Scientific Officer said, "We are highly appreciative of the clear direction FDA has given us in terms of what will be required to advance SANA-013. We look forward to commencing our clinical development program with their feedback in mind and in full compliance with FDA drug development guidelines."

SANA-013 is covered under patent applications owned by Wesana and directed to novel composition and novel methods of use. Patent applications detail the use of a loading dose of psilocybin and a maintenance dose of psilocybin given concomitantly with a dose of cannabidiol ("CBD"). This novel combination therapy has demonstrated effectiveness through different and potentially complementary pharmacologic pathways. Unlike therapist assisted, single dose therapy, where a large dose of psilocybin is administered in clinic, which has exhibited poor durability and waning effects beginning as early as a few weeks post administration, SANA-013 is being developed to utilize a loading dose of psilocybin followed by self-administered maintenance doses of psilocybin and CBD to provide more sustained effects and benefit over time.

"We were pleased with the feedback from the FDA regarding SANA-013," said Wesana founder and CEO, Daniel Carcillo. "This is the most important work of my lifetime, and I'm truly excited about the successful completion of this engagement and the clarity of guidance

provided by the FDA as we move toward our next phase of development for SANA-013.”

Please refer to the Company’s management’s discussion and analysis dated November 29, 2021, available on the Company’s profile on [www.sedar.com](http://www.sedar.com) for additional information as to the Company’s drug development program and the steps required to be completed for the Company to be able to commence phase I clinical trials.

### **About Wesana Health**

Wesana Health helps people transcend barriers in mental health and performance. We innovate in care development through our therapies and proprietary protocols, and in care delivery through activating a new multidisciplinary, technology-supported clinical model. Learn more at [www.wesanahealth.com](http://www.wesanahealth.com).

### **Cautionary Note Regarding Forward-Looking Information**

This press release contains “forward-looking information” within the meaning of applicable securities laws with respect to the Company, including, but not limited to: the initiation of Phase I clinical trials in late 2022, the patentability of the Company’s therapies or protocols and any other statement that may predict, forecast, indicate or imply future plans, intentions, levels of activity, results, financial position, operational or financial performance or achievements. Often, but not always, forward-looking information can be identified by the use of words such as “plans”, “expects”, “is expected”, “budget”, “scheduled”, “estimates”, “forecasts”, “intends”, “anticipates”, “will”, “projects”, or “believes” or variations (including negative variations) of such words and phrases, or statements that certain actions, events, results or conditions “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved. Except for statements of historical fact, information contained herein constitutes forward-looking information. Forward-looking information is not a guarantee of future performance and is based upon a number of estimates and assumptions of management at the date the statements are made.

Certain factors that influence successfully initiating its clinical development program in late 2022 include: (i) the Company has retained industry leading experts/consultant to assist with strategy, drafting and submission of pre-IND meeting Package; (ii) preparation of materials and internal discussions with consultants have been ongoing, productive and in line with timeline expectations; (iii) the pre-IND meeting was completed and provided the Company with the requisite guidance as to whether the protocols for the IND enabling studies are sufficient.

Certain assumptions that influence successfully initiating its clinical development program in late 2022 include: (i) third parties who assisted the Company with the pre-IND submissions will continue to satisfy deadlines on deliverables within anticipated timeframes; (ii) the pre-IND guidance will continue to support that a drug development plan and future clinical trials are going to be acceptable to the FDA; (iii) the Company and its consultants can efficiently and timely address any additional correspondence, submission of additional materials or information pursuant to any ongoing requests as they may arise during the course of their review following the filing of submissions; (iv) additional pre-clinical studies will be commenced and completed on a timely basis and results will be supportive and as anticipated; (v) the Company’s pre-clinical studies (animal pharmacology and toxicology testing) generate data and analyses to support an FDA decision that it is safe to proceed

with human trials of the Company's formulation; and (vi) the Company is able to maintain a GMP supply source necessary to conduct in-human clinical trials.

Any patent efforts of the Company remain at the application stage and there is no assurance that the Company will file additional patent applications or in what jurisdictions they may be filed, if any. Furthermore, while the PCT application has been filed, there is no assurance that a patent(s) will be granted or will be granted in a form that will be sufficient to protect the Company's proprietary therapies or protocols or enable it to gain or keep any competitive advantage that it may have.

Although management believes that the anticipated future results, performance or achievements expressed or implied by the forward-looking statements are based upon reasonable assumptions and expectations, the reader should not place undue reliance on forward-looking statements because they involve assumptions, known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to differ materially from anticipated future results, performance or achievements expressed or implied by such forward-looking statements. Certain risk factors include but are not limited to the ability of the Company to protect its intellectual property, changes to patent law, requirements to share intellectual property with service providers, general economic, market and business conditions and other risk factors including those found in the Company's annual information form dated September 3, 2021 filed on the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com) and discussed in the Company's other public filings available on SEDAR.

Forward-looking information is provided and made as of the date of this news release and the Company does not undertake any obligation to revise or update any forward-looking information other than as required by applicable law.

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Source: Wesana Health