



Intelligent Bio Solutions Partners with Cliantha Research to Conduct Clinical Study as Part of FDA 510(k) Pathway

February 28, 2024

NEW YORK, Feb. 28, 2024 (GLOBE NEWSWIRE) -- [Intelligent Bio Solutions Inc.](#) ("INBS" or the "Company") (Nasdaq: INBS), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced its partnership with [Cliantha Research](#), a full-service Clinical Research Organization (CRO), to perform a pharmacokinetic (PK) study forming part of the Company's FDA 510(k) clinical study plan.

The Company's PK study will recruit 40 healthy adult subjects under an IRB/EC and regulatory approved protocol and compare the amounts of opiates in fingerprint sweat versus blood, oral fluid and urine specimens following the medically supervised administration of drugs. All fingerprint sweat, blood, oral fluid and urine specimens will be analyzed by a validated, traceable liquid chromatography mass spectrometry (LC-MS/MS) method, widely accepted as the gold standard for such studies. The fingerprint sweat specimen will be screened using INBS' [Intelligent Fingerprinting Drug Screening System](#) comprising the Intelligent Fingerprinting Drug Screening Cartridge and DSR-Plus fluorescence reader and compared to the LC-MS/MS results.

The start of the clinical study plan marks an exciting milestone for the Company as it advances on its 510(k) pathway. Harry Simeonidis, President and CEO at Intelligent Bio Solutions, commented, "We are pleased to share news of our partnership with Cliantha and progress on our 510(k) journey. Initiating our clinical studies plan represents a critical milestone for our organization. We have developed a detailed plan that we are committed to executing, and while there is considerable work ahead, we have taken the crucial first step in this process. Our focus is on ensuring we remain on track for our planned entry into the US market and expand access to our innovative screening solution." Dr Anne Marie Salapatek, Chief Scientific Officer and Executive Vice President at Cliantha Research, stated, "At Cliantha, we are excited to commence this rigorous and controlled clinical trial to test this innovative device with potential to provide rapid and non-invasive testing for opiates."

In June 2023, the Company announced it had received guidance from the FDA regarding the regulatory classification of its Intelligent Fingerprinting Drug Screening Cartridge. The FDA provisionally determined that the cartridge falls within 21 CFR 862.3650, Opiate Test System, a Class II type device that requires the submission of a pre-market notification 510(k) and the FDA's clearance prior to marketing.

The Company intends to demonstrate through the PK study that the fingerprint sweat measurement is a suitable proxy for measurements obtained from blood, oral fluid, or urine specimens to detect the presence of opiates. Recruitment and screening of subjects for the PK study are anticipated to take place in March and April 2024, with studies set to begin in May 2024. Sample analysis is projected to conclude by the end of June 2024.

About Cliantha

Cliantha Research Limited is a full-service, global Clinical Research Organization (CRO) providing comprehensive and integrated offerings in Clinical Endpoint Trials (Phase I – IV), Bioequivalence (BA/BE) Studies, Safety/Phase I/ FIM (SAD/MAD/POC) Studies, and those studies involving Personal Healthcare products. Cliantha specializes in Nutraceutical Products, Dermatology, Respiratory, Allergy, and Ocular trials. Cliantha also offers a state-of-the-art Bioanalytical Laboratory.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering innovative, rapid, non-invasive testing solutions. The Company believes that its Intelligent Fingerprinting Drug Screening System will revolutionize portable testing through fingerprint sweat analysis, which has the potential for broader applications in additional fields. Designed as a hygienic and cost-effective system, the test screens for recent use of drugs commonly found in the workplace, including opiates, cocaine, methamphetamine, and cannabis. With sample collection in seconds and results in under ten minutes, this technology would be a valuable tool for employers in safety-critical industries. Additionally, the Company's biosensor platform has the potential to test for up to 130 indications, ranging from glucose to immunological conditions and communicable diseases. The Company's current customer segments include construction, manufacturing and engineering, transport and logistics firms, drug treatment organizations, and coroners.

For more information, visit: <http://www.ibs.inc/>

Forward-Looking Statements:

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Intelligent Bio Solutions Inc. has attempted to identify forward-looking statements by terminology, including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, included in Intelligent Bio Solutions' public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. Intelligent Bio Solutions undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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