



Intelligent Bio Solutions Achieves 94.1% Accuracy in Method Comparison Study, Following Positive PK Study Results

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Intelligent Fingerprinting Drug Screening System on path to FDA 510(k) submission, expected in the fourth calendar quarter of 2024

INBS will include data from recent PK study alongside results of method comparison study in 510(k) submission

NEW YORK, Nov. 26, 2024 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced the successful completion of its method comparison study (the "Method Study") on its Intelligent Fingerprinting Drug Screening System (the "System"). The Method Study confirmed the sensitivity, specificity, accuracy, and usability of the System, validating its potential for use in workplace drug testing and other applications. This milestone follows INBS' recently announced strong initial results from its Pharmacokinetic (PK) study, both of which are key achievements on the path to the Company's FDA 510(k) submission.

The Method Study was conducted in collaboration with CenExel, a nationwide clinical research site network. It adhered to clinical research standards, including Good Clinical Practice (GCP) guidelines. The Method Study's primary objective was to compare the results of fingerprint sweat opiate screening tests with those obtained using a validated, traceable liquid chromatography-mass spectrometry (LC-MS/MS) method in a laboratory. With a diverse group of 135 healthy donors and nine system operators, the Method Study demonstrated 82.2% sensitivity, 100% specificity, and 94.1% accuracy for the Intelligent Fingerprinting Drug Screening System. Operators found the System easy to use, with no usage errors generated during the course of the study.

"The results of our Method Study reaffirm the accuracy and reliability of our fingerprint-based drug screening system," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "By establishing alignment with laboratory-confirmed results through rigorous testing, we have solidified our drug screening system's credibility for use in safety-critical industries and beyond. This accomplishment is a significant step on our journey toward transforming drug testing with non-invasive technology."

The Method Study evaluated the System's three core components: the Drug Screening Cartridge, the Drug Screening Reader and the Fingerprint Collection Kit for laboratory analysis. Subjects were randomized and administered codeine doses, then provided fingerprint sweat specimens to assess the System's ability to detect and quantify drug use accurately. The Method Study's outcomes highlight the System's reliability, reinforcing its suitability for pre-employment and workplace drug testing applications.

If FDA 510(k) clearance were obtained, INBS believes that this would pave the way for the Company to introduce its innovative fingerprint sweat-based drug screening technology to the US market in 2025. As part of the Company's 510(k) submission, which is expected in the fourth calendar quarter of this year, INBS will include data from its recently concluded PK study alongside the results of its Method Study. The Company's clinical study achievements show the accuracy, reliability, and usability of its technology and reinforce the Company's readiness to address the growing demand for drug testing in the US across safety-critical industries such as construction, mining, and transportation, as well as in the law enforcement, drug rehabilitation, and forensic sectors.

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 the 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. The Company's current customer segments outside the US 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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