

Intelligent Bio Solutions Concludes In-Clinic Testing for Clinical Study Plan, Advancing Toward FDA 510(k) Submission

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NEW YORK, Sept. 27, 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 in-clinic testing proposed to the FDA earlier this year in the Company's clinical study plan. The clinical studies are a key element of the Company's 510(k) submission, designed to demonstrate the accuracy and reliability of its sweat-based testing method.

The studies included a pharmacokinetic (PK) study, which aimed to demonstrate that the measurement of drugs in fingerprint sweat delivers results comparable or superior to other specimen matrices, such as blood, saliva and urine. In addition to the PK study, a method comparison and usability study was conducted to validate the accuracy of the Company's fingerprint sweat drug screening method in the hands of intended users.

The clinical phase of the PK study concluded in June 2024, with all laboratory analyses completed and data currently under review. The method comparison and usability studies, carried out across three sites, involved 135 subjects who were randomly dosed with codeine and then tested using the Company's drug screening system. The accuracy of the screening system results will be assessed relative to a traceable, laboratory-based reference method. "Executing these clinical studies required diligence and collaboration across multiple functions within Intelligent Bio Solutions and our CRO partners, CenExel and Cliantha," said Daniel Brown, Head of Clinical Affairs at INBS.

"Completion of these in-clinic studies marks a significant achievement for our team and brings us closer to our goal of obtaining FDA 510(k) Notification clearance," said Harry Simeonidis, President and CEO at INBS. "The early feedback on results from these studies demonstrates the potential of our fingerprint-based testing method to

provide a non-invasive, reliable alternative to traditional drug testing methods and address the needs of diverse sectors, including workplaces and government agencies.”

With the in-clinic testing phase now complete, INBS is preparing for the next steps in its FDA submission process. Achieving FDA clearance will enable the Company to market its product as a clinically validated tool, paving the way for adoption in the US and potentially transforming the landscape of drug screening. The Company expects clinical data analysis to be completed in the fourth calendar quarter of 2024 and to submit the 510(k) package during the same quarter.

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.

Company Contact:

Intelligent Bio Solutions Inc.

info@ibs.inc

LinkedIn | Twitter

Investor & Media Contact:

Valter Pinto, Managing Director

KCSA Strategic Communications

PH: (212) 896-1254

INBS@kcsa.com