



Intelligent Bio Solutions Inc. Advances on FDA 510(k) Pathway with Biocompatibility Study Success

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NEW YORK, July 18, 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 biocompatibility testing of its Intelligent Fingerprinting Drug Screening System, a pivotal phase in the clinical study plan required for FDA 510(k) regulatory clearance.

The biocompatibility study, conducted in accordance with ISO 10993 standards, involved a thorough evaluation of the system's materials that come into contact with human skin. With the successful completion of the biocompatibility study, INBS has confirmed that all materials used in its system, including the Drug Screening Cartridge, Confirmatory Cartridge and the DSR-Plus Reader, are safe for use in medical devices.

Harry Simeonidis, President and CEO at INBS, commented, "This milestone is an important element of our FDA 510(k) pathway for regulatory clearance, and we are proud to announce its completion. Our development team continues to execute on our plan to meet FDA requirements for our Drug Screening System. We are now poised to move forward with the next stages of our clinical study plan and move closer to bringing our innovative technology to the market."

Rafael da Luz, Vice President of Regulatory Affairs for INBS, added, "The planned biocompatibility testing protocol included cytotoxicity, sensitization and irritation tests conducted on drug screening system materials and was presented to the FDA in November last year. Earlier this year, the FDA agreed that the proposed testing approach would be adequate for a future premarket 510(k) submission."

The Intelligent Fingerprinting Drug Screening System, which includes a drug screening cartridge, a DSR-Plus reader, and a collection kit for laboratory analysis, is at the forefront of non-invasive drug testing technology. The Company expects to submit the 510(k) package in the fourth calendar quarter of 2024, moving closer to its goal of bringing this innovative technology to the U.S. market in 2025.

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 various indications, ranging from immunological conditions to 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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