



NEWS RELEASE

Intelligent Bio Solutions Initiates Additional Clinical Studies for FDA 510(k) Submission Supporting Planned Entry into Multi-Billion Dollar U.S. Market

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Clinical studies designed to support FDA clearance and planned commercial launch into the world's largest drug screening market

Company anticipates full data analysis by the end of March 2026; data to be incorporated into FDA 510(k) submission package

NEW YORK, Jan. 28, 2026 (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 commencement of its clinical study program to support its new FDA 510(k) submission for U.S. market clearance of its Intelligent Fingerprinting Drug Screening System for detection of the opiate codeine.

As part of its clinical study program, the Company has again partnered with Cliantha Research, a leading clinical research organization, leveraging its extensive regulatory and clinical trial expertise.

The first clinical study will assess codeine detection cut-off levels in 40 adults at a single site. The study will utilize the Intelligent Fingerprinting Drug Screening Cartridge with the DSR-Plus fluorescence reader, together forming the Company's non-invasive Intelligent Fingerprinting Drug Screening System. Participants will receive controlled doses of codeine, with sample collection and analysis conducted to establish and verify optimal detection cut-off levels. The study design includes direct comparisons with a predicate FDA-cleared device to support the 510(k) regulatory pathway. Results will be corroborated via a liquid chromatography-tandem mass spectrometry ("LC-MS/MS") analysis. This clinical approach is designed to support both the Company's U.S. regulatory pathway and commercial strategy to enter the U.S. market beyond the Forensic Use Only category.

The U.S. drug screening market represents a substantial commercial opportunity, generating several billions of dollars annually across workplace testing, criminal justice applications, pain management, and substance abuse treatment settings. The Company's non-invasive fingerprint-based technology offers significant advantages over traditional urine, oral fluid, and blood testing methods, including improved hygiene, ease of use, rapid results, and reduced collection costs.

"Obtaining FDA clearance for the U.S. market is a major opportunity for Intelligent Bio Solutions," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "The U.S. drug screening market is the largest and most sophisticated in the world, and our Intelligent Fingerprinting technology is uniquely positioned to address unmet needs across multiple high-value segments, including workplace testing, clinical settings, and law enforcement applications. Initiating our clinical studies marks a pivotal moment for our company and the customers we aim to serve. This milestone reflects years of rigorous scientific development and dedication from our team. It will further demonstrate the proven performance of our technology, with over 500,000 tests already sold and used outside the U.S. We look forward to completing these trials and compiling the results as part of our overall FDA submission."

Cliantha has initiated subject recruiting and screening, with the first testing cohort scheduled to begin on January 28, 2026, and full data analysis anticipated by the end of March 2026. The Company plans to incorporate this clinical data into its new FDA 510(k) submission package.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering intelligent, 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 U.S. include construction, manufacturing and engineering, transport and logistics firms, mining, drug treatment organizations, and coroners.

For more information, visit: <https://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, and involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, statements regarding Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefits from its partnerships and collaborations, and secure regulatory clearance or 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, actual results may differ materially from those expressed or implied by such 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," and "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, including those described in Intelligent Bio Solutions' public filings with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of the date of this release. 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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