



NEWS RELEASE

# Intelligent Bio Solutions' FDA Clearance Process Remains on Track for 2025 U.S. Launch

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NEW YORK, March 25, 2025 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today provided shareholders with a status update on the FDA clearance process for its Intelligent Fingerprint Drug Screening System, which remains on track for launch in the U.S. in 2025 targeting its opiate test system for codeine, as validated in the Company's Pharmacokinetic (PK) study.

On December 18, 2024, the Company announced the submission of its 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for review and clearance of its Intelligent Fingerprinting Drug Screening System, which the FDA classified as a 21 CFR 862.3650, Opiate Test System, a Class II device requiring submission of a 510(k) premarket notification. This submission marked a critical milestone in the Company's efforts to enter the U.S. market with its drug testing system in 2025.

The Company's 510(k) submission included performance data and validation studies, including a method comparison study that demonstrated the system's 94.1% accuracy and a PK study that showed fingerprint sweat provides a reliable sample matrix for drug detection, with quantitative PK data closely aligned to blood, based on statistical comparisons made at the 95% confidence level. These findings highlight the system's accuracy, reliability, and usability, demonstrating its capacity to meet the growing demand for efficient, non-invasive testing solutions in the U.S. market.

INBS's 510(k) submission started the 90-day period within which the FDA is required to review and respond to 510(k) submissions. As expected, the FDA has reviewed and responded with questions by issuing an Additional Information (AI) request. When the FDA issues an AI request, the 90-day review clock is paused. The Company has reviewed the AI request and is in the process of responding so that the FDA can restart the review clock. As a result

of this process, although the FDA is required to review and respond in 90 days, it is not uncommon for the FDA clearance process to take three to six months or longer if additional data is required. As INBS awaits FDA clearance, it continues to develop its plans to enter the multi-billion-dollar U.S. market in 2025 and pursue FDA clearance for additional drug classes on its panel. The Company's full panel test is already widely adopted, with a presence in 19 countries and over 400 accounts globally.

"The submission of our 510(k) premarket notification to the FDA marked a pivotal step in the journey to bring our Intelligent Fingerprint Drug Screening System to the U.S. market," said Harry Simeonidis, President and CEO at INBS. "We appreciate the thoroughness of the FDA's process, which aligns with our expectations. As we await FDA clearance, we remain confident in the strength of our data, which demonstrates the accuracy, reliability, and usability of our technology. We are actively preparing for our planned U.S. launch in 2025, where we see significant opportunities to revolutionize drug screening with our non-invasive, rapid testing solution."

#### 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 U.S. 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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