



## **GBS Inc. Announces Application for FDA Breakthrough Device Designation to Fast Track Rapid Saliva Glucose Test**

December 13, 2021

NEW YORK, Dec. 13, 2021 (GLOBE NEWSWIRE) -- [GBS Inc.](#) (Nasdaq: GBS), a life sciences company developing non-invasive, real-time diagnostic testing for patients and their primary health practitioners at point-of-care, today announced that in collaboration with Life Science Biosensor Diagnostics Pty Ltd (LSBD), the licensor of the Rapid Saliva Glucose Test [that forms part of the Biosensor Platform licensed by GBS Inc. (GBS)], LSBD has filed an application with the U.S. Food and Drug Administration (FDA) for Breakthrough Device Designation.

The purpose of the application for the FDA Devices Breakthrough Program is to provide LSBD with an expedited path toward regulatory approval for its non-invasive, real-time Saliva Glucose test.

GBS is the licensee from LSBD for the Biosensor Platform for the Asia Pacific (APAC) Region. GBS also owns 50% of BiosensX (North America) Inc. which is the licensee for the North American Region. The Biosensor Platform includes the Rapid Saliva Glucose Tests and a suite of 150 potential different diagnostic point-of-care tests. The Biosensor is a small organic thin-film transistor diagnostic test, developed at Newcastle University, with the objective to enable accurate salivary glucose measurement in real-time at point-of-care.

"We believe that this technology will fill an important and urgent gap in improving the outcomes of the millions of people living with diabetes around the world. This gap is more evident in the midst of the COVID-19 pandemic as poor diabetes control increases morbidity and mortality from the infection," Interim GBS CEO and Chairman of the Board, Dr. Steven Boyages said.

The FDA's Breakthrough Devices Program allows expedited approval for medical devices and products that provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions, like diabetes. The Purpose of the Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review.

### **About GBS Inc.**

GBS Inc. is a life sciences company developing non-invasive, real-time monitoring and diagnostic tests for patients and their primary health practitioners. With the world-first Biosensor Platform, GBS Inc. is developing and launching diagnostic tests urgently needed to help people living with diabetes.

For more information, please visit [GBS.inc](#) or follow GBS Inc. on [Twitter](#) and [LinkedIn](#).

### **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, GBS Inc.'s ability to develop and commercialize its diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although GBS, 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. GBS 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 the Company's public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. We undertake 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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