ASX Announcement

19 March 2024

FDA Approval for Xprecia Prime

Universal Biosensors, Inc. (ASX: UBI) is pleased to announce it has received FDA 510(k) and CLIA Waiver approval for its Xprecia Prime Coagulation Analyzer as a Class II device.

The approval:

- Allows for UBI to sell Xprecia Prime into health care professional settings (including CLIA waived facilities) such as hospitals, clinics & doctor's offices in the USA.
- Is for the full measuring range of 0.8 – 8.0 INR for both 510(k) & CLIA Waiver.

UBI CEO John Sharman said, "Approval to sell Xprecia Prime in the USA is a historic moment for UBI. It represents more than 10 years of research & development work and many millions of dollars of investment."

Mr Sharman said, "This is the first time the FDA have granted a CLIA Waiver by Application to any coagulation device, and it is testament to the performance of Xprecia Prime. The number of PT/INR tests performed in clinics is the largest part of the USA market so to have won unrestricted access to all clinics and hospitals across the USA is a major achievement."

Mr Sharman said, "There are more than 6 million patients who take warfarin (coumadin) in the USA[1] and more than 140 million[2] PT/INR test strips are sold each year. This FDA approval represents the first opportunity in UBI's history to access the lucrative (and fully reimbursed) USA market. Our expectation is Xprecia Prime will qualify under the existing reimbursement codes used by Medicare, Medicaid and USA Health insurers. UBI has a pipeline of sales and distribution contracts already in negotiation and now that we have FDA approval we expect to conclude some, if not all of these contracts, win market share and generate substantial revenue for the company.

End

Announcement authorised by the Board of Directors of Universal Biosensors, Inc.

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About Universal Biosensors
Universal Biosensors, founded in 2001, specialises in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), wine, food, and agriculture. UBI's ambition is to build a multi product stable of biosensors in large markets which generate ongoing revenue streams. For additional information regarding Universal Biosensors, Inc., refer to: http://www.universalbiosensors.com.

About Xprecia Prime™
The Xprecia Prime™ Coagulation Analyzer is Universal Biosensors second generation, new and improved coagulation monitoring device. Xprecia Prime™ fits into your palm; is portable, accurate and easy to use. The device is designed for fast and reliable prothrombin time (PT) results displayed in seconds and International Normalised Ratio (INR). It is used to monitor the dosage of vitamin K antagonists in patients to ensure its safety and efficacy. Dangerous bleeding events can occur if the ideal dosage of the drug is exceeded, while if the dosage is lower than required the patient is at risk of thrombosis. The prothrombin time (PT) test allows physicians to appropriately adjust the patient's dose of the drug to compensate for any diet and lifestyle changes. Globally, approximately 10 million patients are taking warfarin, and over 300 million PT/INR tests are conducted annually to monitor the safe and effective dosage of anticoagulants, representing a major market opportunity for Xprecia Prime™. For additional information visit: https://www.universalbiosensors.com/products/xprecia/

What is CLIA Waiver
The Clinical Laboratory Improvement Amendments (CLIA) Waiver approval allows laboratories (which are not necessarily medical facilities) to undertake certain types of tests for patients approved by the FDA. By allowing laboratories to undertake certain tests, including for PT/INR it facilitates easy access for patients who may not be able to attend medical facilities. CLIA Waived facilities are the most used way for patients to test PT/INR in the USA.

What is a Dual Submission
The Dual Submission is a special procedure introduced by the FDA providing that both applications for 510(k) and CLIA Waiver by an Application, could be reviewed simultaneously in order to reduce the time spent on the authorization processes.

Forward-Looking Statements
The statements contained in this release that are not purely historical are forward-looking statements within the meaning of the US Securities Exchange Act of 1934. Forward-looking statements in this release include statements regarding our expectations, beliefs, hopes, intentions or strategies. All forward-looking statements included in this release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations. We cannot assure you when, if at all, the proposals outlined in this release will occur, and the terms of any such proposal are subject to change. Factors that could cause or contribute to such differences include, but are not limited to, factors and risks disclosed from time to time in reports filed with the SEC.

Sources
1. Medicare & Lincare.
2. Greystone Research & Global Data Reports.