

4 October 2023

## Xprecia Prime 4U approved for Patient Self-Testing in Europe

Universal Biosensors, Inc. (ASX: UBI) is pleased to announce it has received the approval required for the sale of “Xprecia Prime 4U” directly to patients for self-testing in Europe.

The approval is in the form of the **EU Technical Documentation Assessment Certificate (IVDR)** issued pursuant to Regulation (EU) 2017/746 on in vitro diagnostic medical devices (Class C) for Patient Self-Testing/near patient testing, issued by Notified Body -TÜV SÜD Product Service GmbH.

Mr John Sharman, CEO of UBI said; “We have been working on the development and approval of the new Xprecia Prime 4U device for more than 18 months and this approval is an important step towards building a meaningful Xprecia business in Europe.

“The Patient Self-Testing market is the fastest growing PT/INR market in Europe and when combined with the use of PT/INR devices and test strips in hospitals and clinic, we estimate the market is worth \$365m pa. More importantly, many of the hospitals and governments will only award tender ‘wins’ to products that have the approval for patients to take the device home and test themselves. This approval is therefore very important for the future sales growth of our Xprecia products in Europe.”

For further information please refer to the XPRECIA website (<https://www.universalbiosensors.com/products/xprecia/>).

**End**

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

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### **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/>

### **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>.

### **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.

### **Universal Biosensors Investor Hub**

Our investor hub delivers on our commitment to provide an enhanced shareholder experience. It is a dedicated channel where we can continue to interact regularly with shareholders and investors who wish to stay up-to-date and have their questions answered.

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