

Universal Biosensors, Inc.  
ARBN 121 559 993

1 Corporate Avenue  
Rowville Victoria 3178  
Australia

Telephone +61 3 9213 9000  
Facsimile +61 3 9213 9099  
Email [info@universalbiosensors.com](mailto:info@universalbiosensors.com)  
[www.universalbiosensors.com](http://www.universalbiosensors.com)



23 January 2023

### **UBI completes Xprecia Prime clinical trial in USA**

Universal Biosensors, Inc. (ASX:UBI) is pleased to announce that it has recruited its last patient and completed enrolment for its 360-patient “Xprecia Prime” PT/INR blood coagulation clinical study. The clinical study protocol was discussed at a FDA Pre Submission meeting and patients were enrolled across the prescribed PT/INR measuring ranges. The study was conducted at five Clinical Sites in the USA.

The study is designed to provide clinical evidence as to the performance and safety of Xprecia Prime and will be used in UBI’s 510K submission to the FDA, which is expected to be lodged during Q1 2023.

Mr John Sharman, CEO of UBI said; “The completion of the clinical study in the USA is a key milestone for the future of UBI’s coagulation business. UBI has spent more than 10 years developing its Point of Care coagulation platform and the data generated by the clinical study is strong.”

Mr Sharman said; “UBI’s existing coagulation product (Xprecia Stride) has insignificant sales in the USA which represents about 50% of the estimated global US\$1 billion PT/INR market. We expect an approval to sell Xprecia Prime in the USA will add significant value to our coagulation business into the future.”

**End**

Enquiries:  
John Sharman  
Chief Executive Officer  
+61 (0) 414 440 680

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

**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.