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UBI submits Xprecia Prime 510K Application to US Food & Drug Administration

Universal Biosensors, Inc. (ASX:UBI) is pleased to announce that it has submitted its 510K application to the US Food & Drug Administration (FDA) to have Xprecia Prime approved for sale in the USA.

The centrepiece of the 510K application is the 360 patient study (completed 23 January, 2023) conducted over 4 sites in the USA which is designed to provide clinical evidence as to the performance and safety of Xprecia Prime.

Mr John Sharman, CEO of UBI said; "UBI has spent more than 10 years developing its Point-of-Care coagulation platform and the submission of our 510K application is an important step towards building Xprecia Prime into a meaningful business."

Mr Sharman said; "UBI's existing coagulation product (Xprecia Stride) has insignificant sales in the USA. The USA coagulation market represents about 50% of the estimated global US$1 billon 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

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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.