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## Regulatory Approval to sell Xprecia Prime™ in 32 countries in Europe

Universal Biosensors, Inc. (ASX:UBI) is pleased to announce it has been granted regulatory approval to sell its next generation handheld PT/INR coagulation testing platform, Xprecia Prime™, in 32 countries across Europe.

Xprecia Prime's approval comes via the granting of the appropriate CE Mark which means Xprecia Prime fully conforms with the European Directives for IVD Medical in Vitro Diagnostics (98/79/EC) and is now approved for sale and distribution throughout Europe.

The approval covers all components of the Xprecia Prime PT-INR Coagulation system including:

- Xprecia Prime Coagulation Analyzer;
- Xprecia Prime PT controls;
- Xprecia Prime PT-INR Test strips.

This approval is the second milestone in UBI's global growth strategy for PT/INR testing and follows the purchase of the global distribution network (more than 50 distribution relationships) from Siemens Healthineers. Work to migrate that existing distribution network to UBI began in H2 2021 and good progress is being made.

The annual market for PT/INR testing in Europe is estimated as \$370m p.a.<sup>[1,2,3,4,5]</sup>. UBI has more than 3,500 of its first generation Xprecia Stride Analyzers being used in 36 countries. Almost 2 million PT/INR biosensor test strips are manufactured and sold each year by UBI through its global distribution network. Because of the superior performance of Xprecia Prime, UBI expect to increase the installed base of Xprecia Analyzers in Europe and increase the number of test strips sold annually.

In addition, as part of UBI's global growth strategy we have commenced Xprecia Prime clinical trials in the USA that are designed to achieve FDA approval (and support ongoing approvals around the world). 53 patients have already been enrolled in a 360-patient trial which is expected to complete during H2 2022.

John Sharman, CEO of UBI said; "UBI has spent 7 years and tens of millions of dollars developing Xprecia Prime which we believe will prove itself as the best performing PT/INR Point of Care device available anywhere in the world. Our ambition is to develop a meaningful global market-share and grow sales."

Enquiries:

John Sharman  
Chief Executive Officer

*Announcement authorised 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. Our next generation PT/INR monitoring system, Xprecia Prime, is UBI’s newest product which is being launched globally. For additional information regarding Universal Biosensors, Inc., refer to: <http://www.universalbiosensors.com>.

### About Xprecia Prime

Xprecia Prime is UBI’s next generation PT/INR coagulation testing system.

A PT/INR test helps find out if your blood is clotting normally. It also checks to see if a medicine that prevents blood clots (warfarin) is working the way it should be. A prothrombin time (PT) test measures how long it takes for a clot to form in a blood sample. An INR (international normalized ratio) is a type of calculation based on PT test results. Prothrombin is a protein made by the liver. It is one of several substances known as clotting (coagulation) factors. When you get a cut or other injury that causes bleeding, your clotting factors work together to form a blood clot. Clotting factor levels that are too low can cause you to bleed too much after an injury. Levels that are too high can cause dangerous clots to form in your arteries or veins.

The market for PT/INR testing in Europe is estimated at \$370m p.a (global market \$1b p.a)<sup>[1,2,3,4,5]</sup> and UBI’s Xprecia Prime will be the most advanced Point of Care testing solution on the market. UBI expect Xprecia Prime to win significant market share over time since its performance is equal to or better than anything else on the market and will be offered at a very competitive price point.

	UBI: Xprecia Prime	iLine: MicroINR	Roche: CoaguChek Vantus	Roche: CoaguChek Plus	UBI estimate of potential global market share	Potential UBI Sales (\$AUD)
Sample Size (µL)	8 <input checked="" type="checkbox"/>	3	8	8	5%	21,296,773
Unit of Measure	INR & SEC	INR	INR	INR, SEC %Q	10%	42,593,546
Measuring Range	0.8 – 8.0 <input checked="" type="checkbox"/>	0.8 – 6.0	0.8 – 6.0	0.8 – 8.0	15%	63,890,319
Accuracy vs reference (slope, intercept, r <sup>2</sup> )	0.96, 0.09, 0.94 <input checked="" type="checkbox"/>	1.04, 0.03, 0.94	0.98, 0.1, 0.83	1.075, -0.1, 0.94	20%	85,187,092
Touchscreen	Y <input checked="" type="checkbox"/>	N	N	Y	25%	106,483,865
Data Communication	Wired / Wireless	Wired	Wired / Wireless	Wireless		
Power	Rechargeable	Rechargeable	4 AAA Batteries	Rechargeable		
Test Memory	2000 <input checked="" type="checkbox"/>	199	400	2000		
Price	<< \$650 <input checked="" type="checkbox"/>	\$650	\$650 - \$900	\$1050 - \$1550		

Figures: Xprecia Prime comparison to other products in market, potential UBI global market shares and potential UBI sales. UBI has used its own historical market information and public data to generate estimated potential sales based on share of global market. Sources include Greystone Research, Global Data, Siemens, Boston Biomedical Analysis and Lincare.

#### References

- [1] Greystone Research Market Report [2] Global Data Market Report [3] Siemens public data [4] Boston Biomedical Analysis public data [5] Lincare public data