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UBI launches USA based Regulatory Clinical Trial for Xprecia Prime and recruits “First Patient”

Universal Biosensors, Inc. (ASX:UBI) is pleased to announce that on 25 October 2021, it successfully recruited the first patient into the clinical trial for UBI’s next generation hand-held coagulation analyzer, “Xprecia Prime”.

Data generated from the Clinical Study will be used to support an application for Xprecia Prime to be approved for sale in the USA (by the FDA) and by regulators in Europe and around the world.

Xprecia Prime is UBI’s next generation coagulation product and will ultimately replace Xprecia Stride which is already approved for sale in 67 countries throughout the world.

The Clinical Trial will be conducted under Good Clinical Practice protocols (GCP). The trial will take six months to recruit and will include more than 200 patients across multiple sites.

Regarding the clinical trial sites, UBI has entered into agreements with Excellence Medical Research and Lundquist UCLA Institute and is currently finalizing negotiation and clinical trial documentation with Loma Linda VARE. A fourth clinical trial site is expected to follow in the coming months.

John Sharman, CEO of UBI said; “UBI has invested millions of dollars developing this next generation product for coagulation and it is exciting to see the project entering the final stage. We expect the clinical trials will take six months to complete and for our submission to the FDA (510K) and other European regulatory bodies to be lodged during H1 2022”.

Mr Sharman said; “UBI has a large installed base for its existing Xprecia Stride coagulation product in Europe and a smaller presence in the USA. Our new Xprecia Prime device is a significant improvement from Xprecia Stride and we expect it to deliver market leading performance. We are excited for our new technology to come to market. We expect when Xprecia Prime is approved for sale in the USA and Europe, it will lead to a significant growth in sales of our coagulation monitoring platform.”

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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 wine testing platform Sentia is UBI's newest product which is being launched globally. For additional information regarding Universal Biosensors, Inc., refer to: <http://www.universalbiosensors.com>.

About Excellence Medical Research

Excellence Medical and Research (EMR) is comprised of doctors who specializes in palliative care, endocrinology (including diabetes and metabolism), ophthalmology, and internal medicine. EMR has 40+ years of collective experience in medical practice and clinical research. Prior research experience includes studies such as, but not limited to, COPD, Type II Diabetes, immunosuppressant therapy, cardiovascular comorbidities, herpetic neuralgia, COVID-19, gout, and more. EMR is conveniently located in South Florida, which comprises of large, diverse population. The team has been able to secure a subject list of 5,000 subjects strong who are available for clinical trials.

About Lundquist UCLA Institute

The Lundquist Institute for Biomedical Innovation is a 501(c)3 independent non-profit biomedical research organization that was founded in 1952. The Institute has more than 120 principal investigators and 400 researchers in total — MD's, MD/PhD's, and PhD's — working on 600 research studies. Their investigators are academically affiliated with UCLA and work in partnership with the Harbor-UCLA Medical Centre.

About Loma Linda VARE

LLVARE is not a governmental agency but is a large nonprofit research foundation who works with the Department of Veterans Affairs nationwide. LLVARE is a 501(c) (3) corporation located in Redlands, California. LLVARE was established in 1988 and serves the veteran population in the Inland Empire of Southern California. LLVARE has successfully carried out hundreds of research projects and is currently handling over 100 active medical research projects. LLVARE has a seven-person board of directors and is incorporated as a nonprofit charity.

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.