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Universal Biosensors

5 October 2016

Universal Biosensors welcomes FDA clearance for Xprecia Stride Analyzer

Melbourne, Australia: Universal Biosensors (ASX:UBI) today welcomes news that the US Food and Drug Administration (FDA) has cleared for sale in the US the Xprecia Stride Coagulation Analyzer which is produced by partner Siemens Healthineers and uses test strips developed and manufactured by UBI.

The Xprecia Stride analyzer is a handheld device which delivers Prothrombin Time International Normalized Ratio (PT/INR) testing for point-of-care monitoring and assessment of patients taking oral anticoagulation therapy warfarin.

Siemens announced that the FDA had granted 510(k) clearance for the device and a copy of their press release is attached.

The Xprecia Stride analyzer was commercially launched in Europe in May 2015 and has won a number of international design awards, including the Red Dot Award: Product Design for 2015 and the iFDesign Award. The device was designed specifically to meet the demand for fast and accurate analysers that can be used in clinics or doctors' offices where quick and informed decisions can be made about a patient's care.

UBI produces the test strips used in the Xprecia Stride analyzer at its Rowville facility in Victoria, Australia.

UBI Executive Chairman Andrew Denver said: "We are thrilled for Siemens that the Xprecia Stride analyzer has received clearance from the FDA and that patients and medical professionals in the US will now have access to this exceptional device. We look forward to working with Siemens to help establish its place in the US market."

The worldwide point-of-care market for coagulation testing was estimated to be worth about US\$1 billion in 2014 and is forecast to grow by 9% per annum to about US\$1.4 billion by 2018. The point-of-care coagulation testing market is dominated by PT/INR testing, which represents around 65% of this market.

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About Universal Biosensors

For additional information regarding Universal Biosensors, refer to: <http://www.universalbiosensors.com/>.

Universal Biosensors is a specialist medical diagnostics company, founded in 2001, that is focused on the development, manufacture and commercialisation of a range of in vitro diagnostic tests for point-of-care use. These tests capitalise on a technology platform which uses a novel electrochemical cell that can be adapted for multiple analytes and provide for enhanced measurements in whole blood.

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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.

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Siemens Receives FDA Clearance of the Xprecia Stride™ Coagulation Analyzer

- **The Xprecia Stride is a truly handheld portable analyzer for any professional point-of-care setting**
- **Features such as an integrated bar-code scanner, hands-free strip disposal and intuitive navigation promote safety, accuracy and ease of use**
- **The Xprecia Stride is the first POC PT/INR device cleared by FDA based on the new rules published in March 2016**

October 04, 2016 02:43 PM Eastern Daylight Time

TARRYTOWN, N.Y.--(BUSINESS WIRE)--Siemens Healthineers has more than 30 years of central lab hemostasis leadership. Building on to its portfolio, the company announced today FDA 510(k) clearance for a hand-held portable coagulation analyzer. The Xprecia Stride Coagulation Analyzer delivers fast, reliable Prothrombin Time International Normalized Ratio (PT/INR) testing for point-of-care monitoring and management of oral anticoagulation therapy with warfarin, a vitamin K antagonist.

Millions of PT/INR tests are administered world-wide each year as part of therapy monitoring for patients with a host of conditions, including atrial fibrillation, heart valve replacement surgery, deep vein thrombosis and congenital heart defects, among others. The Xprecia Stride Coagulation Analyzer was specifically designed to meet the growing demand for fast and reliable PT/INR results in physician offices and walk-in clinics to help healthcare professionals make informed decisions about patient care.

Winner of multiple international design awards such as the Red Dot Award: Product Design for 2015 and the iFDesign Award, the analyzer includes a number of innovations and features not found on most other point-of-care analyzers. No bigger than a smartphone and weighing just 10.5 oz, the Xprecia Stride Coagulation Analyzer can be held at virtually any angle and brought directly to the patient's finger for efficient and comfortable blood sample application.

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“Among the many challenges of point of care testing, accuracy and safety have become paramount to both the user and patient. With the Xprecia Stride analyzer, Siemens Healthineers delivers on the promise to bring a safe and lab-accurate test directly to the patient,” said Michael Sampson, Senior Vice President, Point of Care, Siemens Healthineers, North America. “The Xprecia Stride analyzer is designed to be safe, efficient and ergonomically friendly. By adding the Xprecia Stride analyzer to our existing product portfolio in the U.S., we now have the ability to cover the full range of hemostasis testing from the hospital lab to the physician’s office.”

Today’s busy healthcare professional is challenged by a complex work environment and heavy patient workflow. The Xprecia Stride analyzer was designed to address these concerns through an intuitive user interface and features such as an integrated barcode scanner to simplify data capture and improve patient workflow. To further enhance usability, the Xprecia Stride features simple icons and animation in a color display more commonly found in mobile devices than medical instruments.

The Xprecia Stride analyzer uses fresh capillary (fingerstick) whole blood and results are expressed as INR. It utilizes the same Dade® Innovin® reagent used by Siemens Healthineers central lab analyzers to minimize any potential for variability. Studies have shown the performance to be equivalent to a reference laboratory hemostasis system,¹ with results available within minutes.

Safety features include a first-of-its kind test strip eject button that allows the user to eject a used test strip and easily dispose of it without touching it, minimizing potential biohazard exposure.

When taken together, all of these innovations ultimately enable better patient care as point-of-care PT/INR testing becomes critical to healthcare providers managing the growing number of patients that require anticoagulation therapy.

¹ White Paper, Fernando R, Jacobson AK, Kennedy S, Lessard C, Olson K, Scribner A, “PT/INR Test Performance of the Xprecia Stride Coagulation Analyzer Demonstrates Equivalency with Established Laboratory Hemostasis and Point-of-care Methods”

For further information on the Xprecia Stride Coagulation Analyzer, please visit:

www.siemens.com/xprecia

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Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 165 years. The company is active in more than 200 countries, focusing on the areas of electrification, automation and digitalization. One of the world’s largest producers of energy-efficient, resource-saving technologies, Siemens is No. 1 in offshore wind turbine construction, a leading supplier of gas and steam turbines for power generation, a major provider of power transmission solutions and a pioneer in infrastructure solutions as well as automation, drive and software solutions for industry. The company is also a leading provider of medical imaging equipment – such as computed tomography and magnetic resonance imaging systems – and a leader in laboratory diagnostics as well as clinical IT. In fiscal 2015, which ended on September 30, 2015, Siemens generated revenue of €75.6 billion and net income of €7.4 billion. At the end of September 2015, the company had around 348,000 employees worldwide. Further information is available on the Internet at www.siemens.com.

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