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Trinity Biotech Announces European Approval of Guideline Compliant, Point-of-Care, High Sensitivity Troponin I Product

DUBLIN, Ireland (January 29, 2014).... Trinity Biotech plc. (Nasdaq: TRIB) today announced it has obtained the CE mark (i.e. European approval) for its Meritas, high sensitivity Troponin I (hsTnI) product. With its unrivalled precision, it is now the only point-of-care product capable of meeting all of the guidelines stipulated by the world's leading cardiac organisations for detection of heart attacks.

Troponin market

Troponin is the leading marker used in the detection of heart attacks or myocardial infarctions (MI). The worldwide market for Cardiac Troponin testing is estimated to be $1.2bn, growing at a rate of 12% per annum. Of this market, approximately $350m represents point-of-care testing carried out in the Emergency Room (ER) with the remainder being laboratory based testing. Historically, laboratory based testing has demonstrated significantly greater accuracy, albeit in a much slower timeframe. Typically, laboratory testing takes approximately 90 minutes versus the 15 minutes which can be achieved in the point-of-care environment. Speed is a crucial factor in the diagnosis and treatment of heart attack patients.

In 2007, a task force consisting of the ESC (European Society of Cardiology), ACCF (American College of Cardiology Foundation), AHA (American Heart Association) and WHF (World Heart Foundation) was convened to define MI and its diagnosis. Based on the recommendations of this task force, Troponin has been identified as the preferred biomarker to identify suspected heart attacks. A heart attack is diagnosed when Troponin levels in the blood exceed the 99th percentile reference limit of a normal healthy population whilst accompanied by one other clinical symptom. The task force further stipulated that high sensitivity Troponin assays should also demonstrate excellent precision at very low concentrations of Troponin, namely 10% or less variation at the 99th percentile value of the normal population. The current point-of-care market for Troponin is dominated by three participants, none of whose products come to near to meeting this guideline.

Since 2012, following its acquisition of Fiomi Diagnostics, Trinity has been developing a high sensitivity Troponin test capable of delivering laboratory based quality in the Emergency Room environment. The objective was to develop a test capable of meeting the 2007 guideline with a testing time of no more than 15 minutes. With the launch of the Meritas Troponin test these objectives have now been achieved. Trinity is thus in the unique position of being the first company to commercialise a fully guideline compliant product for use in the $350m Emergency Room market.

Meritas Troponin I Product

This Troponin test, which is the first test to be launched on Trinity's Meritas platform, has the following key characteristics:

- It demonstrates a limit of detection of 19pg/ml of whole blood and achieves a variation of 10% at 36pg/ml which corresponds to the 99th percentile of the reference population;
- Testing will be carried out in the Emergency Room with results available patient-side within 15 minutes;
- Tests will be run on the Meritas analyser, which is a cost efficient analyser approximately the size of a desk telephone. It has been specifically designed with ease of use in mind, using a single drop of whole blood in a one-step process.

In summary, this landmark test delivers unparalleled sensitivity and precision at the point-of-care, which allows doctors to evaluate whether or not patients are having a heart attack within a short time of admission.

Next Steps

With this CE mark, Trinity intends to immediately launch the product for sale in Europe and other selected markets through its specialist Cardiology Distributor network, which has been recruited over the past number of months.

However, CE marking of Meritas Troponin is only the first step in the commercialisation of Trinity's range of point-of-care cardiology products. Trinity will immediately commence US clinical trials and is confident that a product displaying such high clinical and current guideline compliant performance will meet and indeed exceed the very tight performance specifications necessary for FDA approval. Meanwhile, Trinity is in the process of developing products for the detection of BNP and D-dimer. The BNP product is already at an advanced stage with CE marking expected by mid-2014, to be followed by an FDA submission, thus leaving Trinity in a very strong position to take a very significant portion of the worldwide point-of-care cardiac diagnostic testing market in the years ahead.

Due to its unique technology the Meritas platform is eminently suitable for use in detecting conditions in a range of other diagnostic fields – particularly those requiring higher sensitivity. Following completion of its cardiac range of tests, Trinity will proceed to develop a range of other tests on this platform.

Comments

Dr. Frank Peacock, Professor of Emergency Medicine at Baylor College of Medicine, Houston, Texas stated "The Meritas Troponin test outperforms most historical central laboratory tests, is on par with some of the latest high sensitivity laboratory assays only available in Europe and does it all at the point-of-care in just 15 minutes. Its availability resolves a longstanding critical need and serves as an inflection/pivotal point in improving patient care."

Commenting on today's news, Ronan O'Caoimh CEO said "We are delighted to launch for the first time an Emergency Room Troponin test with superlative precision, which is in a category apart from its competitors. Until now, physicians haven't had a reliable tool to quickly and confidently test patients with chest pain at the point-of-care. As a result, patients needlessly waited hours to receive the treatment they needed and were often misdiagnosed, leading to poor outcomes. The Meritas Troponin test, now for the first time, provides physicians with an incredibly precise tool in the point-of-care setting to quickly and accurately test these patients in just 15 minutes from a drop of whole blood".

Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.

Trinity Biotech develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States, Germany, France and the U.K. and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information please see the Company's website: www.trinitybiotech.com