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Trinity Biotech Announces CE Marking of New Meritas Heart Failure (BNP) Point-of-Care Test

DUBLIN, Ireland (September 25, 2014).... Trinity Biotech plc. (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced it has obtained the CE mark (i.e. European approval) for its Meritas point-of-care BNP test.

Heart failure, also referred to as chronic or congestive heart failure, is a complex progressive syndrome that impacts about 26 million people worldwide with almost 700,000 new cases diagnosed each year in the United States alone. Heart failure is a serious condition in which the heart cannot pump enough blood to meet the needs of the body. Although often life threatening, the typical symptoms of heart failure (breathlessness, fatigue and swelling of the limbs) are usually less dramatic than those associated with a heart attack. In economically developed countries, up to one in five people are expected to develop heart failure at some point in their life. As the symptoms of heart failure are variable and non-specific, blood-based biomarkers are frequently used to assist in the difficult diagnosis of heart failure.

Brain or B-type natriuretic peptide (BNP) levels in the bloodstream increase as the severity of heart disease proceeds. Thus, BNP has emerged as the principal biomarker in aiding the diagnosis of and determining the clinical severity of acute and chronic heart failure. In addition, BNP can be useful in a wide range of clinical applications including risk stratification and monitoring of patients with heart failure and heart attacks.

The Meritas BNP test demonstrates exceptional sensitivity and precision, which is at least comparable to much larger and far more expensive central laboratory systems, while delivering results in ten minutes, right at the point-of-care. Existing competitive BNP tests have certain limitations due to the effects of sample degradation. This makes those tests challenging to use in primary care and in retrospective studies, where sample degradation may falsely lower test results. Due to its design the new patented Meritas BNP test is not hindered by these limitations.

The worldwide point-of-care BNP market is estimated to be approximately \$300m p.a. with a growth rate of 12% p.a. With this European approval, we are now in a position to immediately enter the BNP market with a product that is at least as good as, if not better than, the current market leaders. However, of greater significance from a commercial perspective is that it will run side by side, on the same platform as Trinity's Troponin product for the detection of heart attacks. This test already demonstrates significantly superior performance to any point-of-care test currently on the Troponin market, which itself is worth \$350m p.a. at the point-of-care. Consequently, by having the highest quality combined product offering, Trinity is uniquely positioned to successfully target and achieve a significant share of the combined BNP and Troponin point-of-care market of \$650m.

Following the receipt of CE Marking, we will immediately commence our marketing efforts in Europe, whilst at the same time preparing for FDA submission. Given that most of the CE Mark data was already generated in the USA, it will now be augmented with additional USA trial data, with a view to submitting to the FDA by the end of quarter 1, 2015. BNP approval is anticipated during quarter 3, 2015 which is expected to coincide with FDA approval of our Troponin product, thus giving us the vital menu components for a product launch in the US, where the bulk of the cardiac point-of-care market resides.

Commenting on today's news, Ronan O'Caoimh, CEO of Trinity Biotech, said "We are pleased to expand the Meritas family of products, improve patient outcomes and resolve longstanding testing challenges. Trinity's best in class technology affords us many development possibilities. Our outstanding new Meritas BNP test is our second step into the point-of-care cardiac testing market following on from the launch of our Troponin test for detecting heart attacks. Collectively our Troponin and BNP tests will target point-of-care markets which are estimated to be US\$650m annually. In addition, and particularly in the case of Troponin, we will also be targeting the laboratory based markets for these products which have value of a further \$900m.

We are now committed to quickly expanding the Meritas menu further with the addition of a series of high value tests at the point-of-care. The next test is a D-dimer test for deep vein thrombosis, development of which is well underway and will further complement our testing panel".

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