



*FOR RELEASE, November 29th, 2007*

## **Trinity Biotech Announces FDA Clearance of TRI♦stat™ Point-of-Care HbA1c Test**

**DUBLIN, Ireland November 29<sup>th</sup>, 2007** ... Trinity Biotech plc (NASDAQ: [TRIB](#)) a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced that the US Food and Drug Administration has given clearance to market the rapid, point-of-care TRI♦stat™ HbA1c system.

The TRI♦stat™ point-of-care platform is designed to measure HbA1c, also known as glycated hemoglobin, which is a measure of a patient's blood sugar control over the previous two to three months. The availability of the TRI♦stat™ system will improve overall efficiency of diabetes care by delivering HbA1c values during patient's visits to their physicians and outpatient clinics. Utilizing a patented Affinity Two-Phase Optical system, together with a simple, fully automated, or plug-and-play design, TRI♦stat™ offers highly accurate results within minutes while eliminating complex, hands-on operator requirements found with other point-of care technologies.

Diabetes is the fourth leading cause of death by disease in the world. According to the International Diabetes Federation, the number of people diagnosed with Type 2 diabetes worldwide has increased from 30 million to more than 246 million over the last two decades. This figure is projected to increase further to 380 million by 2025. In the USA, 20.8 million people (7 percent of the population) have the disease with a further 54 million considered to be pre-diabetic, according to the Centers for Disease Control and Prevention (CDC) and the American Diabetes Association (ADA).

The ADA strongly recommends that patients be tested for HbA1c at least 4 times a year. Testing should also be performed during treatment changes or after periods of elevated blood glucose levels. The ADA added a recommendation for point-of-care HbA1c monitoring to their 2006 professional practice guidelines emphasizing the importance of routine real-time HbA1c monitoring of persons with diabetes.

Commenting on the news, Brendan Farrell, CEO, said, "FDA Clearance of the TRI♦stat™ product is an extremely exciting development for Trinity Biotech and enables us to compete in the high growth point-of-care segment of the HbA1c market. As TRI♦stat™ provides test results within 10 minutes, patients will know their HbA1c status during their visit to their physician or diabetic clinic. This will assist the physician and patient to make immediate diabetes management decisions and ultimately improve outcomes".

"Our Ultra<sup>2</sup>™ and PDQ™ systems already address the \$700m clinical lab market for HbA1c and the launch of TRI♦stat™ means that Trinity will now have a presence in the point-of-care segment which is estimated at \$300m world wide. Discussions with distribution partners in the USA and Europe are well advanced and will be concluded shortly".

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 blood coagulation disorders, 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](http://www.trinitybiotech.com).

*Forward-looking statements in this release are made pursuant to the "safe harbor" provision of the Private Securities 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.*

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