Trinity Biotech Announces That It Has Received 510(k) Clearance From The U.S. Food and Drug Administration for the Premier Resolution System

DUBLIN, Ireland, Aug. 07, 2023 — Trinity Biotech has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the Premier Resolution System, an automated analyzer for the accurate & precise quantification of hemoglobins F and A2, and the detection of >200 hemoglobin variants. The Premier Resolution System is now cleared for sale in the United States.

The Premier Resolution System is a lab-based hemoglobin diagnostic system consisting of a high-performance liquid chromatographic analyzer, reagents, analytical column, and software which allows for the fractionation and quantitation of fetal hemoglobin (Hb F), and hemoglobin A2 (Hb A2), and with fractionation and presumptive identification of abnormal hemoglobin variants. This is accomplished using the principles of ion-exchange (IEX) high performance liquid chromatography (HPLC). The Premier Resolution System is a modern successor to Trinity Biotech's Ultra System that held a leading position in the US hemoglobin variant diagnostic market.

The hemoglobin variants detected by the Premier Resolution can cause a range of medical conditions, including thalassemias and Sickle Cell Disease, which significantly impact the ability of red blood cells to efficiently transport oxygen. The incidence of these variant conditions has been steadily growing worldwide as global migration increases, and with this increase the need for accurate diagnostic methods has become ever more important. The Premier Resolution gives laboratories the tools to easily identify clinically important variants.

Comments

Commenting, Aris Kekedjian, Chairman and Chief Executive Officer of Trinity Biotech stated, "We welcome the news that our Premier Resolution has received 510(k) clearance from the FDA. Our intention is to regain our market leading position in hemoglobin variant detection with a modern successor to the highly regarded Ultra platform. The Premier Resolution System builds on our Ion Exchange technology reputation for excellence in the separation and identification of a broad range of rare hemoglobin variants. It features a high degree of advanced feature flexibility and a market leading combination of accuracy, speed and value. We also expect this important 510(k) clearance from the FDA to drive further penetration of the Premier Resolution System in key global markets, including Brazil, and allow us to begin the regulatory process for the Chinese market.

"This is an important milestone in the transformation of Trinity Biotech, which is anchored by the expansion of our hemoglobin and diabetes franchises. The Premier Resolution represents the first in a number of expected product roll-outs and investments in this space, with further product upgrades in our core diabetes HbA1c platform expected to follow in the new year."

Premier Resolution System sales enquiries for the US market should be sent to louis.pastors@trinitybiotech.com

Forward Looking Statements

Certain statements made in this release that are not historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "estimate", "project", "intend", "expect", "believe" and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties. Many factors could cause the actual results, performance or achievements of Trinity Biotech to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, but not limited to, the results of research and development efforts, risks associated with the outbreak and global spread of the coronavirus (COVID-19), the effect of regulation by the U.S. Food and Drug Administration and other agencies, the impact of competitive products, product development commercialization and technological difficulties. For additional information regarding these and other risks and uncertainties associated with Trinity Biotech's business, reference is made to our reports filed from time to time with the U.S. Securities and Exchange Commission.

About Trinity Biotech

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 Hemoglobin 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.

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