Kyntra Bio Presents New Roxadustat Data on Improvements in Transfusion Independence Regardless of Ring Sideroblast Status in Patients with Anemia due to Lower-Risk Myelodysplastic Syndromes

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- *In a post hoc analysis, patients treated with roxadustat showed a durable and clinically meaningful improvement in transfusion independence (TI) in patients with LR-MDS and high transfusion burden (HTB) compared to placebo*
- *Similar rates of TI for patients treated with roxadustat were observed in both ring sideroblast positive (RS+) and ring sideroblast negative (RS-) disease*
- *Pivotal Phase 3 trial protocol of roxadustat for the treatment of anemia in patients with LR-MDS and high transfusion burden is being finalized based on feedback received from the Food and Drug Administration (FDA)*

SAN FRANCISCO, June 11, 2026 (GLOBE NEWSWIRE) -- Kyntra Bio (Nasdaq: KYNB) today announced additional data from the Phase 3 MATTERHORN trial showing improvements in transfusion independence in patients with anemia associated with lower-risk myelodysplastic syndromes (LR-MDS) treated with roxadustat will be presented as a poster at the European Hematology Association (EHA) Congress 2026, taking place June 11-14, 2026 in Stockholm, Sweden.

“In addition to roxadustat demonstrating clinically meaningful efficacy in patients with lower-risk MDS and high transfusion burden, improvements in transfusion independence in both RS+ and RS- disease were also observed in this post-hoc analysis, which is an important finding given the limited effectiveness of currently available treatment options for patients with RS- disease,” said Thane Wettig, Chief Executive Officer of Kyntra Bio. “These findings underscore the potential of roxadustat to elevate the standard of care for patients with lower-risk MDS who are in need of additional treatment options. We are finalizing the protocol for the pivotal Phase 3 trial, which we expect to initiate in the second half of 2026, with the aim to build upon and confirm these findings in patients with lower-risk MDS and high transfusion burden, including both RS+ and RS- disease.”

“Through this novel MOA, stabilizing HIF1-α, thereby normalizing erythroid precursor development and improving hemoglobin production, these findings highlight the potential for roxadustat to address a significant unmet need, providing a convenient, well-tolerated and effective treatment option for anemia in patients with LR-MDS independent of RS histology,” said Amer Zeidan, MD, Professor of Medicine at Yale School of Medicine and Chief of the Division of Hematologic Malignancies at Yale Cancer Center. “This post-hoc analysis from the MATTERHORN trial shows clinically meaningful RBC transfusion independence among high transfusion burden patients, as well as clear evidence of hemoglobin increase among patients who received roxadustat compared to placebo. I am excited to be able to share this data with the MDS community at the EHA meeting and believe they provide strong rationale for the planned randomized Phase 3 trial in anemic patients with LR-MDS and high RBC transfusion burden,” concluded Dr. Zeidan, who is also the global principal investigator of the planned randomized Phase 3 trial.

As previously disclosed, the initial analysis with all of the patients who participated in the Phase 3 MATTERHORN trial showed that more patients receiving roxadustat achieved transfusion independence vs. placebo (48% vs. 33%; p=0.22). The presentation highlights data from a post hoc analysis of the entire trial population, demonstrating that roxadustat led to similar rates of transfusion independence in both RS+ and RS- patients. In RS- patients, which comprised 84 of the 140 patients enrolled in the trial, treatment with roxadustat led to transfusion independence for ≥8 weeks over 28 weeks in 48% of patients vs. 28% for placebo.

The presentation at EHA also provides additional details on the subgroup of patients (n=37) who met the criteria of HTB (≥ 4 units pRBCs per 8-week period for 2 consecutive 8-week periods) per IWG-2018, where roxadustat achieved clinically meaningful efficacy in patients with LR-MDS and HTB with higher rates of ≥8-, 12-, 16-week RBC TI vs placebo. TEAEs were generally lower grade and managed medically with no new safety signals.

The poster presentation, titled “Roxadustat improves transfusion independence in LR-MDS patients with anemia and high transfusion burden and in ring sideroblast positive and negative disease: post-hoc analysis of MATTERHORN study” is scheduled for the poster session taking place on June 12, 2026 at 18:45 CEST.

The pivotal Phase 3 trial protocol of roxadustat for the treatment of anemia in patients with LR-MDS and high transfusion burden is being finalized based on feedback received from the FDA.

About Myelodysplastic Syndromes Anemia

Myelodysplastic syndromes (MDS) are a group of disorders characterized by dysfunctional progenitor blood cells and stem cells, resulting in chronic anemia in most patients. Annual incidence rates of MDS are estimated to be 4.9/100,000 adults in the U.S., thereof 77% are considered lower-risk MDS. Approximately 80% of patients with MDS have anemia at the time of diagnosis, and around 60% of patients with MDS will experience severe anemia (hemoglobin <8 g/dL) at some point during the course of their disease. Anemia in patients with MDS is associated with increased risk of cardiovascular complications and the need for blood transfusion. Approximately 50% of patients with MDS require regular red blood cell transfusions. Transfusion dependent MDS patients suffer higher rates of cardiac events, infections, and iron overload with the related complications. In addition, anemia frequently leads to significant fatigue, cognitive dysfunction, and decreased quality of life. Today, patients are routinely treated with erythropoiesis-stimulating agents (ESAs), luspatercept, imetelstat, or lenalidomide in lower-risk MDS with isolated del(5q), and hypomethylating agents (HMAs) in higher-risk disease. Only 35-40% of patients respond to current treatments and the durability of response is short. Moreover, these treatments are challenging to dose-calibrate and can only be administered via subcutaneous injection or through IV infusion. There remains a high unmet need for the treatment of anemia associated with MDS, and new strategies that provide durable response and the convenience of oral administration are highly desired in managing patients with MDS.

About Roxadustat
Roxadustat, an oral medication, is the first in a new class of medicines comprising HIF-PH inhibitors that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin, improved iron absorption and mobilization, and downregulation of hepcidin.

Roxadustat is approved in Europe, Japan, and numerous other countries for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Kyntra Bio has the sole rights to roxadustat in the United States, Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas. Astellas and Kyntra Bio are collaborating on the commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, Turkey, Russia, and the Commonwealth of Independent States, the Middle East, and South Africa.

About Kyntra Bio
Kyntra Bio is a biopharmaceutical company focused on development of novel therapies in oncology and rare disease. Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in Europe, Japan, China, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. The Company continues to evaluate the development plan for the Phase 3 trial of roxadustat in anemia associated with lower-risk myelodysplastic syndromes (LR-MDS) in the U.S. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46, is in Phase 2 development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of FG-3180, an associated CD46-targeted PET biomarker. For more information, please visit www.kyntrabio.com.

Note: Amer Zeidan's views are his own personal views and do not necessarily represent his employer's views. He has also consulted and received honoraria and travel support from Kyntra Bio.

Forward-Looking Statements
This release contains forward-looking statements regarding Kyntra Bio's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs . These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of Kyntra Bio products and product candidates, and statements about Kyntra Bio's plans and objectives. These forward-looking statements are typically identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Kyntra Bio's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in Kyntra Bio's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, each as filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Kyntra Bio undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

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