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Emmaus Life Sciences Advances Middle East Strategy with Real-World Evidence Initiatives and Expansion into Africa

Gulf observational studies and Saudi institutional access initiatives aim to generate region-specific evidence on Endari® in sickle cell disease

Marketing authorizations across five Middle Eastern markets and new Libya partnership further strengthen international commercial presence

TORRANCE, Calif.--(BUSINESS WIRE)-- Emmaus Life Sciences, Inc. (OTCQB: EMMA), a commercial-stage biopharmaceutical company focused on sickle cell disease (SCD), today announced the advancement of two real-world evidence (RWE) initiatives across the Gulf Cooperation Council (GCC) region and the signing of an exclusive distribution agreement in Libya, marking the company's entry into North Africa.

The initiatives are intended to generate additional real-world evidence on the use of Endari® (prescription L-glutamine oral powder) in routine clinical practice while supporting Emmaus' broader international growth strategy.

These initiatives build upon an expanding body of international real-world evidence from the United States, France, Egypt, and elsewhere, where Endari has been associated with consistent improvements in key clinical and patient-centered outcomes. Across these reports, patients receiving Endari experienced reductions in VOC frequency, hospitalizations, transfusion burden, and other disease-related complications, together with improvements in patient-reported outcomes and quality of life measures. Favorable changes in hemoglobin levels and other hematologic parameters have also been observed. Collectively, these findings, reported across both short-term and long-term follow-up periods, provide important context for evaluating treatment outcomes in routine clinical practice.

The RWE program includes an ongoing up to 240-patient Gulf observational study across the United Arab Emirates (UAE), Oman, Bahrain, and Kuwait, together with clinical outcomes data generation activities across participating military healthcare institutions in Saudi Arabia. The initiatives are designed to evaluate treatment outcomes and patterns of care among patients receiving Endari in real-world clinical settings.

Primary and secondary endpoints include annual rates of vaso-occlusive crises (VOCs), hospitalization frequency and duration, incidence of acute chest syndrome (ACS), and blood transfusion requirements. The studies are expected to be completed over approximately two years, with findings evaluated following data collection and analysis.

Sickle cell disease remains a significant public health burden across the Gulf region,

particularly in Saudi Arabia, Bahrain, and Oman. Despite advances in patient care, recurrent VOCs, hospitalizations, and long-term complications continue to impact patients, caregivers, and healthcare systems. Published studies have also highlighted variability in disease prevalence, clinical characteristics, and treatment practices across the region, underscoring the need for additional locally generated evidence.

By evaluating Endari in routine clinical practice, the initiatives aim to provide healthcare professionals and decision-makers with region-specific insights into treatment utilization and clinical outcomes, complementing data from randomized clinical trials.

"Real-world evidence plays an increasingly important role in understanding how therapies perform in routine clinical practice," said Willis Lee, Chief Executive Officer of Emmaus Life Sciences. "Through collaboration with healthcare institutions across the Gulf region, these initiatives are intended to generate meaningful regional data on treatment patterns and clinical outcomes in patients with sickle cell disease while supporting our broader international growth strategy."

Locally generated evidence from governmental and military healthcare settings may help inform Pharmacy and Therapeutics (P&T) committee evaluations, reimbursement assessments, physician education efforts, and broader patient access discussions.

In parallel with its clinical research initiatives, Emmaus continues to expand its commercial footprint across the Middle East and North Africa.

The company has obtained marketing authorization for Endari in the UAE, Qatar, Kuwait, Bahrain, and Oman. In Saudi Arabia, Endari has secured institutional formulary inclusion at several major military medical centers involved in the management of sickle cell disease, supporting access through established hospital procurement and P&T pathways.

Emmaus has also entered into an exclusive distribution agreement in Libya with Al Wataniya Aldawliya, a member of Assada Company for Medical Equipment and Medicine (ACMEM), to support Ministry of Health tender participation and site registration activities, establishing the company's first commercial presence in North Africa.

"Clinicians across the Gulf region have emphasized the importance of locally generated evidence in sickle cell disease," said JB Choi, General Manager, Middle East and Africa, Emmaus Life Sciences. "These initiatives are intended to contribute meaningful real-world insights from routine clinical practice while reinforcing our commitment to patients, healthcare professionals, and healthcare systems throughout the region. At the same time, our expansion into Libya represents an important step in extending Emmaus' international presence."

About Endari®

Endari® (L-glutamine oral powder) is approved in the United States to reduce acute complications of sickle cell disease in adult and pediatric patients five years of age and older. Endari is currently marketed in multiple international territories through Emmaus Life Sciences and its distribution partners.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company focused on the treatment and management of rare and orphan diseases, including sickle cell disease. The company markets Endari® and continues to evaluate opportunities to expand patient access in the United States and internationally.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended, regarding the potential efficacy of L-glutamine for the treatment of sickle cell disease based upon clinical observations. These forward-looking statements are subject to numerous assumptions, risks, and uncertainties that change over time, including the risks that observed clinical outcomes will be positive and that any positive outcomes observed cannot be replicated in large patient populations or will translate into improved sales of Endari® (L-glutamine oral powder), and the other risks and uncertainties disclosed in the company's reports filed with the Securities and Exchange Commission, and actual results may differ materially. Such forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update them, except as may be required by law.

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Company Contact:
Emmaus Life Sciences, Inc.,
pr@emmauslifesciences.com

Media Contact
Alexander Petti
Alexander@TakeOncommunications.com
201-978-4882

Source: Emmaus Life Sciences, Inc.