January 27, 2020

Emmaus Life Sciences Expresses Concerns Over Inaccuracies in Draft Report Issued by ICER (Institute for Clinical and Economic Review)

--To the Detriment of the Sickle Cell Disease Community, the Draft Report Does Not Accurately Reflect or Interpret the Original Clinical Data and Related Efficacy and Safety of L-Glutamine Validated and Approved by the FDA--

TORRANCE, Calif., Jan. 27, 2020 (GLOBE NEWSWIRE) -- **Emmaus Life Sciences, Inc. (OTCQB: EMMA)**, a leader in sickle cell disease treatment, responded today to the draft evidence report by ICER dated January 23, 2020 examining the effectiveness and value of Crizanlizumab, Voxelotor, and L-glutamine in treating sickle cell disease (SCD). After reviewing the draft report, Emmaus is very concerned about the negative impact the numerous inaccuracies and misinformation will have on the SCD community including patients, investigators and manufacturers.

The following table summarizes the results of Emmaus' Phase III clinical trial of Endari® (L-glutamine oral powder):

Descriptive Results	Sickle Cell Crises (median)	Acute Chest Syndrome (occurrence)	Hospitalizations (median)	Cumulative Days in Hospital (median)
L-glutamine	3	8.6%	2	6.5
Placebo	4	23.1%	3	11
Difference from placebo	25%	63%	33%	41%
P-value for between group difference	0.0052[a]	0.0028[a]	0.0045[a]	0.022[b]

a. Cochran Mantel Haenszel (CMH) with modified ridit scores b. Wilcoxon Rank Sum Test

The Phase III trial demonstrated relevant clinical impact by reducing the number of sickle cell crises, the frequency of hospitalizations, the length of hospitalizations and a dramatic reduction in acute chest syndrome – the leading cause of death in SCD patients. Based upon these results, the FDA approved Endari in July 2017 which marked the first approval of a therapy for SCD patients in nearly 20 years.

Although the ICER draft report appropriately cites the efficacy and safety data of Endari, the

draft report failed to accurately translate the data into an economic-based model due to its flawed and inaccurate assumptions. The Endari Phase III trial did not seek to measure all clinical syndromes and sequelae associated with SCD, nor did Emmaus attempt to directly quantify Endari's impact on quality of life as this is not only a highly complex outcome measure but also subject to bias, especially when used in the context of a clinical trial comprised of volunteers. The ICER draft report inexplicably suggests that reducing the incidence of acute chest syndrome does not have a meaningful beneficial effect on quality of life. This and other positive impact of Endari in improving the lives of patients with SCD has been well documented by patients in various forums.

The draft report does not explain why ICER simply dismissed the impact of Endari on meaningful clinical endpoints such as painful crisis, acute chest syndrome and hospitalizations in its economic modeling. Instead of acknowledging and accepting the peer-reviewed clinical data, ICER chose to minimize Endari's clinical impact on SCD and in most instances equated it to "optimal usual care" with minimal or no incremental benefit. Such an approach effectively ignores the clinical benefits of Endari and prejudices the large number of vulnerable and disadvantaged patients, families and communities who live with SCD.

Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus commented, "While the ICER report is in draft form only, we are concerned that the high degree of circulation and attention it is getting can negatively impact the efforts of Emmaus and the other companies covered by the draft report to improve the lives of SCD patients." Dr. Niihara further stated, "We are aware of no scientific or other justifiable basis for how ICER misused the original clinical data on treatment effect as reviewed by the FDA for approval and disregarded data in The New England Journal of Medicine. We sincerely hope ICER will listen to comments by Emmaus and others on its draft report and encourage the SCD community to hear the voices of patients whose lives have been improved by Endari."

Dr. Darrell Harrington, M.D., M.A.C.P., Chief Medical Officer of Emmaus added, "Emmaus is concerned that the ICER draft report contains some erroneous conclusions that could unfortunately restrict access to important sickle cell disease modifying therapeutics for one of the world's most underserved and neglected diseases."

About Emmaus Life Sciences
Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, including those in the rare and orphan disease categories. For more information, please visit www.emmauslifesciences.com.

About Endari® (L-glutamine oral powder)
Indication - Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Important Safety Information - The most common adverse reactions (incidence >10 percent) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremities, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

The safety and efficacy of Endari in pediatric patients with sickle cell disease younger than five years of age has not been established.

For more information, please see full Prescribing Information of Endari at: www.ENDARIrx.com/PI.

About Sickle Cell Disease

Sickle cell disease is an inherited blood disorder characterized by the production of an altered form of hemoglobin which polymerizes and becomes fibrous, causing red blood cells to become rigid and change form so that they appear sickle shaped instead of soft and rounded. Patients with sickle cell disease suffer from debilitating episodes of sickle cell crises, which occur when the rigid, adhesive and inflexible red blood cells occlude blood vessels. Sickle cell crises cause excruciating pain as a result of insufficient oxygen being delivered to tissue, referred to as tissue ischemia, and inflammation. These events may lead to organ damage, stroke, pulmonary complications, skin ulceration, infection and a variety of other adverse outcomes. Sickle cell disease is a significant unmet medical need, affecting approximately one hundred thousand patients in the U.S. and millions worldwide, the majority of which are of African descent. An estimated 1-in-365 African American children are born with sickle cell disease.

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Source: Emmaus Life Sciences