

Emmaus Life Sciences Provides Operational Updates

TORRANCE, Calif., June 02, 2020 (GLOBE NEWSWIRE) -- Emmaus Life Sciences, Inc. (OTCQB: EMMA), a leader in sickle cell disease treatment, provided today operational updates in advance of the filing of its 10-K for the year ended December 31, 2019 and its 10-Q for the first quarter of 2020.

"We look forward to reporting our financial results for the full year 2019 in our Form 10-K upon the completion of our audit for the year-ended December 31, 2019 and for the first quarter of 2020 in our Form 10-Q, both filings planned for later in June," said Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer. "In the interim, Emmaus is pleased to share with our current and prospective stakeholders the significant progress it has made in several areas."

Sales Activity

For 2019, Emmaus shipped 24,072 boxes of Endari® to its U.S. customers (distributors and specialty pharmacies) compared to 16,304 boxes in 2018, a 48% increase. Emmaus had continuous sequential quarterly growth in boxes shipped in 2019. The shipments by quarter in 2019 were as follows:

| 2019 By Quarter: | | Q2 | Q3 | Q4 |
|--|-------|-------|-------|-------|
| Boxes of Endari® Shipped | 5,347 | 5,626 | 6,295 | 6,804 |
| Percentage Increase Over Prior Quarter | NA | 5% | 12% | 8% |

In accordance with U.S. GAAP, reported net revenue is determined by adjusting gross sales for shipments in transit, fees, discounts, rebates, other variable consideration, and adjustments to prior period estimates. The wholesale acquisition cost (WAC) per box was \$1,110 for Endari® in 2019. The cost to patients is reduced by any applicable discounts and eligibility for Emmaus' patient assistance program.

As of January 1, 2020, Emmaus switched from a contract sales organization to its own direct sales force and continues to build its internal sales and marketing capabilities. In the first quarter of 2020, Emmaus shipped to its U.S. customers 7,456 boxes of Endari®, a 10% increase over the preceding quarter and a 39% increase over the same quarter of the prior year. In the first quarter of 2020, the Company increased the WAC price per box to \$1,154.

Patient Compliance and COVID-19 Impact

Prescriptions from Emmaus' main specialty pharmacy partner increased in April and May of 2020 as compared to the average per month in the first quarter of 2020. While revenue is driven by sales to distributors and specialty pharmacies, Emmaus is encouraged that patient

compliance and health monitoring appear to be stronger in the wake of the COVID-19 pandemic. In addition, Emmaus has recently developed patient adherence programs in conjunction with several of its key customers. As previously stated, Emmaus has no supply chain issues regarding its prescription grade L-glutamine and has sufficient finished goods inventory of Endari® to support current and projected patient needs.

Research and Development

Emmaus' Pilot/Phase 1 study of the safety and efficacy of prescription grade L-glutamine oral powder in treating diverticulosis commenced in April 2019 is ongoing. The COVID-19 pandemic has slowed the progress of clinical trials in the pharmaceutical industry, in general, and patient enrollment at one of the three Emmaus trial sites was temporarily suspended. However, patient enrollment has now resumed, and Emmaus is confident that the study will ultimately evaluate the change in the number and size of colonic diverticula and assess safety in a total of up to 15 patients.

Emmaus is also exploring the possible investigational use of its prescription grade L-glutamine for those patients with COVID-19. It is looking into the possibility of providing its prescription grade L-glutamine as part of the therapy that some coronavirus patients might need to mitigate the impact of the coronavirus and assist them in their recovery.

Manufacturing

To meet the longer-term potential demand for prescription grade L-glutamine, in December 2019, a 40% owned investee of Emmaus purchased a manufacturing facility in Ube, Japan. This facility was formerly owned by Kyowa Hakko Bio Co. Ltd. and was used for the manufacture of prescription grade L-glutamine and other amino acids. Emmaus, its partners and contractors are beginning the process of establishing and obtaining regulatory approval and recertification for the production of prescription grade L-glutamine and anticipate that test production will commence in early 2021 with regulatory approval expected in 2022. Emmaus expects to fund the additional expenditures required for the restart and recertification of the plant.

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.emmausmedical.com.

About Endari® (prescription grade 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.

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, including statements regarding operating results, recent operational updates, and research and development activities. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to Emmaus' working capital and ability to carry on its existing operations and obtain needed financing and other factors previously 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.

Company Contact:

Emmaus Life Sciences, Inc. Joseph (Jay) C. Sherwood III Chief Financial Officer (310) 214-0065, Ext. 3005

Investor Relations Contact:

LifeSci Advisors Bruce Mackle (929) 469-3859

bmackle@lifesciadvisors.com

jsherwood@emmauslifesciences.com



Source: Emmaus Life Sciences