GBT Takes Steps to Support Public Health Efforts to Address COVID-19 Pandemic

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SOUTH SAN FRANCISCO, Calif., March 17, 2020 (GLOBE NEWSWIRE) -- Global Blood Therapeutics, Inc. (GBT) (NASDAQ: GBT), which is focused on transforming the treatment and care of people living with sickle cell disease, today announced steps the company is taking to support public health efforts to address the COVID-19 pandemic. The company has instituted a number of proactive measures to reduce the risk of spreading the COVID-19 virus, and to ensure uninterrupted access of and support for patients who are prescribed Oxbryta® (voxelotor) tablets.

GBT supports and is aligned with public health strategies designed to stem the spread of COVID-19, including social distancing and other methods. With the health and safety of patients, healthcare professionals and employees as a top priority, GBT is temporarily suspending its field team from all in-person interactions, including visits to physician offices, clinics and hospitals as well as in-person meetings with payers. This temporary suspension will be in place until April 7, 2020, at which time GBT will reevaluate the situation. The company will continue to provide and scale up digital and internet-based education and outreach to healthcare professionals and payers. Additionally, in alignment with recent local public health directives, employees based at GBT's headquarters in South San Francisco, Calif., have been asked to work from home, with the exception of a limited number of employees who have critical needs to be in the facility.

"As a company focused on serving the needs of the sickle cell disease community, we believe that the we can help reduce the spread of COVID-19 transmission during this pandemic by limiting direct interactions and embracing virtual communications," said Ted W. Love, M.D., president and chief executive officer of GBT. "We are taking these steps in the interest of public health so that we can do our part to slow the trajectory of the illness. We appreciate and thank our nation's healthcare professionals, who are on the front lines and are continuing to provide quality care to our most vulnerable populations, including those with sickle cell disease."

GBT is committed to ensuring access for patients and is pleased to continue to meet the needs of the sickle cell disease community. GBT Source™, the company's support program for those prescribed Oxbryta, is fully functional and remains available to assist with new enrollments, reimbursement, financial and copay support, and adherence and refill support. In addition, GBT believes it currently has sufficient supply of Oxbryta to sustain patient need through the remainder of the year and into 2021.

About Sickle Cell Disease
Sickle cell disease (SCD) affects an estimated 100,000 people in the United States and millions of people throughout the world, particularly among those whose ancestors are from sub-Saharan Africa. It also affects people of Hispanic, South Asian, Southern European and Middle Eastern ancestry.[1] SCD is a lifelong inherited blood disorder that impacts hemoglobin, a protein carried by red blood cells that delivers oxygen to tissues and organs throughout the body.[2] Due to a genetic mutation, people with SCD form abnormal hemoglobin known as sickle hemoglobin. Through a process called hemoglobin polymerization, red blood cells become sickled – deoxygenated, crescent-shaped and rigid.[2-4] The sickling process causes hemolytic anemia (low hemoglobin due to red blood cell destruction) and blockages in capillaries and small blood vessels, which impede the flow of blood and oxygen throughout the body. The diminished oxygen delivery to tissues and organs can lead to life-threatening complications, including stroke and irreversible organ damage.[4-6]

About Oxbryta® (voxelotor) tablets
Oxbryta (voxelotor) is an oral, once-daily therapy for patients with sickle cell disease (SCD). Oxbryta works by increasing hemoglobin's affinity for oxygen. Since oxygenated sickle hemoglobin does not polymerize, GBT believes Oxbryta blocks polymerization and the resultant sickling and destruction of red blood cells. With the potential to improve hemolytic anemia and oxygen delivery, GBT believes that Oxbryta has the potential to modify the course of SCD. On November 25, 2019, Oxbryta received U.S. Food and Drug Administration (FDA) accelerated approval for the treatment of SCD in adults and children 12 years of age and older.[7] As a condition of accelerated approval, GBT will continue to study voxelotor in the HOPE-KIDS 2 Study, a post-approval confirmatory study using transcranial Doppler (TCD) flow velocity to assess the ability of Oxbryta to decrease stroke risk in children 2 to 15 years of age.

In recognition of the critical need for new SCD treatments, the FDA granted Oxbryta Breakthrough Therapy, Fast Track, Orphan Drug and Rare Pediatric Disease designations for the treatment of patients with SCD. The European Medicines Agency (EMA) has included voxelotor in its Priority Medicines (PRIME) program, and the European Commission (EC) has designated voxelotor as an orphan medicinal product for the treatment of patients with SCD.

Indication
Oxbryta is a prescription medicine used for the treatment of sickle cell disease in adults and children 12 years of age and older. It is not known if Oxbryta is safe and effective in children below 12 years of age.

This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Important Safety Information
Oxbryta should not be taken if the patient has had an allergic reaction to voxelotor or any of the ingredients in Oxbryta. See the end of the patient leaflet for a list of the ingredients in Oxbryta.

Oxbryta can cause serious side effects, including serious allergic reactions. Patients should tell their healthcare provider or get emergency medical help right away if they get rash, hives, shortness of breath or swelling of the face.

Patients receiving exchange transfusions should talk to their healthcare provider about possible difficulties with the interpretation of certain blood tests when taking Oxbryta.

The most common side effects of Oxbryta include headache, diarrhea, stomach (abdominal) pain, nausea, tiredness, rash and fever. These are not all the possible side effects of Oxbryta.
Before taking Oxbryta, patients should tell their healthcare provider about all medical conditions, including if they have liver problems; if they are pregnant or plan to become pregnant as it is not known if Oxbryta can harm an unborn baby; or if they are breastfeeding or plan to breastfeed as it is not known if Oxbryta can pass into breastmilk or if it can harm a baby. Patients should not breastfeed during treatment with Oxbryta and for at least 2 weeks after the last dose.

Patients should tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Some medicines may affect how Oxbryta works. Oxbryta may also affect how other medicines work.

Patients are advised to call their doctor for medical advice about side effects. Side effects can be reported to FDA at 1-800-FDA-1088. Side effects can also be reported to Global Blood Therapeutics at 1-833-428-4968 (1-833-GBT-4YOU).

Full Prescribing Information for Oxbryta is available at Oxbryta.com.

About Global Blood Therapeutics
Global Blood Therapeutics (GBT) is a biopharmaceutical company dedicated to the discovery, development and delivery of life-changing treatments that provide hope to underserved patient communities. Founded in 2011, GBT is delivering on its goal to transform the treatment and care of sickle cell disease (SCD), a lifelong, devastating inherited blood disorder. The company has introduced Oxbryta® (voxelotor), the first FDA-approved treatment that directly inhibits sickle hemoglobin polymerization, the root cause of SCD. GBT is also advancing its pipeline program in SCD with inclacumab, a p-selectin inhibitor in development to address pain crises associated with the disease. In addition, GBT's drug discovery teams are working on new targets to develop the next generation of treatments for SCD. To learn more, please visit www.gbt.com and follow the company on Twitter @GBT_news.

Forward-Looking Statements
Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including statements containing the words "will," "anticipates," "plans," "believes," "forecast," "estimates," "expects" and "intends," or similar expressions. These forward-looking statements are based on GBT's current expectations and actual results could differ materially. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. GBT intends these forward-looking statements, including statements regarding GBT's focus, priorities, goals and vision, reducing the risk of spreading the COVID-19 virus, slowing the trajectory of the illness, supporting public health efforts, SCD patients and healthcare professionals, the activities of GBT and its representatives and reevaluating such activities, digital and internet-based education and outreach, meeting the needs of the SCD community, the availability, use and functionality of GBT Source, having sufficient supply of Oxbryta to sustain patient need through the remainder of the year and into 2021, the safety, efficacy and mechanism of action of Oxbryta and other product characteristics, the availability, use, commercialization and commercial and medical potential of Oxbryta, the need for Oxbryta and other SCD treatments, transforming the treatment and care of SCD, and advancing GBT's pipeline and discovering, developing and delivering treatments, to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, and GBT makes this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect GBT's current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to the company and on assumptions the company has made. GBT can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved, and, furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond GBT's control including, without limitation, compliance with the funding and other obligations under the Pharmakon loan, the timing and progress of GBT's and Syros' research and development activities under their collaboration, the amount and timing of resources devoted by each of such parties to activities under the collaboration, the risks that GBT has only recently established its commercialization capabilities and may not be able to successfully commercialize Oxbryta, the impact of public health risks, such as the recent spread of the COVID-19 virus, risks associated with GBT's dependence on third parties for supply, development, manufacture and commercialization activities related to Oxbryta, government and third-party payor actions, including those relating to reimbursement and pricing, risks and uncertainties relating to competitive products and other changes that may limit demand for Oxbryta, the risks regulatory authorities may require additional studies or data to support continued commercialization of Oxbryta, the risks that drug-related adverse events may be observed during commercialization or clinical development, and data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, along with those risks set forth in GBT's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission, as well as discussions of potential risks, uncertainties and other important factors in GBT's subsequent filings with the U.S. Securities and Exchange Commission. Except as required by law, GBT assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

References

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