

Large Agreement with SMI HealthCare to Manage Full Development and Sales of Patented Multiple Sclerosis Treatment: \$GSTC

SMI HealthCare to Manage Full Development and Sales of Patented Multiple Sclerosis Treatment in India, Southeast Asia, Africa, and Parts of The Middle East

RICHLAND, WASHINGTON, UNITED STATES, September 28, 2023 /EINPresswire.com/ -- Agreement with SMI HealthCare to Manage Full Development and Sales of Patented Multiple Sclerosis Treatment in India, Southeast Asia, Africa, and Parts of The Middle East: [GlobeStar Therapeutics Corporation \(Stock Symbol: GSTC\)](#)



□ Clinical-stage Pharmaceutical Company Focused on Transformative Therapies for Chronic Neurodegenerative Diseases including Multiple Sclerosis.



SMI HealthCare & its affiliates will collaborate closely with GlobeStar to advance our commercialization of Project Amethyst™. Our plan is to utilize the relationships and expertise of SMI HealthCare”
James C. Katzaroff CEO of GSTC

- Exclusive Global Licensee of the Multiple Sclerosis Project Amethyst™ Patents and Patent Applications.
- Agreement with SMI HealthCare for an Initial Clinical Trial, Regulatory Filings, Intellectual Property Rights, Manufacturing, Sales, and Distribution.
- Agreement Covers India, Southeast Asia, Africa, and Parts of the Middle East, Plus Private Aid Organizations.
- MS in the Middle East and Africa is Rapidly Growing, with

Treatments Expected to Grow from Approximately \$3.5 Billion in 2023 to \$4.5 Billion in 2032.

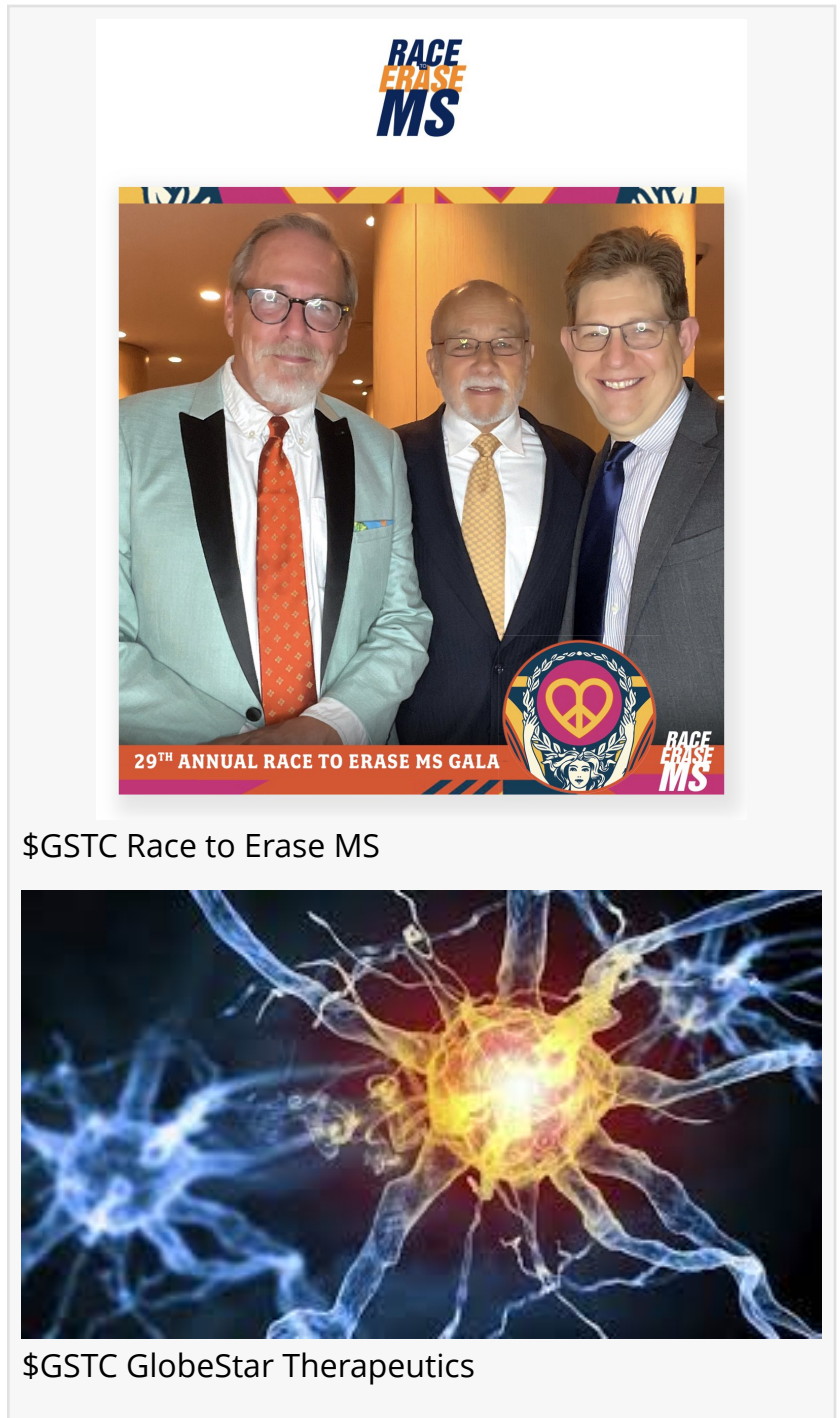
□ Within 5 Years After Launching Sales the GSTC Goal is to Capture from 20% to 50% of the

Market for MS Therapeutics in Each Country.

GlobeStar Therapeutics Corporation (OTC PINK: GSTC) is a clinical-stage pharmaceutical company focused on advancing new therapies for Multiple Sclerosis (MS) and other neurological diseases. The GSTC mission is to pioneer biotechnology in transformative therapies for the management of chronic neurodegenerative diseases. In an initial study of Project Amethyst™ in Italy of 150 volunteers, 90 between 25 and 65 years of age with MS disease and 60 healthy volunteers, the average Expanded Disability Status Scale (EDSS) score for subjects with MS dropped by at least 1.3 points for pre-treatment and an average of 4.02 points after treatment. After 45 days of treatment, all subjects reported an improvement in balance and motor control of all extremities, and most reported an improvement in bladder control. GSTC is the exclusive global licensee of the Project Amethyst™ patents and patent applications.

Agreement with SMI Healthcare to Manage Clinical Trials, Regulatory Filings, Manufacturing, and Sales in MEA Region for Multiple Sclerosis Treatment

On September 28th GSTC announced that it has entered into a definitive agreement with SMI HealthCare LLC (SMIHC) to manage an initial clinical trial, regulatory filings, intellectual property rights filings, manufacturing, sales, and distribution in India, Southeast Asia, Africa, and the Middle East, excluding Israel and Iraq, and for government and private aid organizations, for the GSTC patented Multiple Sclerosis treatment. GSTC is the exclusive worldwide licensee for Project Amethyst™, including all patents and patent applications relating thereto, including U.S. Patent #10610592. For additional information about SMIHC visit: www.SMIGllc.com.



The image is a composite graphic. At the top, three men in suits are smiling. Below them is a graphic of a neuron with a glowing yellow nucleus and blue branching axons. At the bottom, there are logos for 'RACE TO ERASE MS' and '29th ANNUAL RACE TO ERASE MS GALA'.

\$GSTC Race to Erase MS

\$GSTC GlobeStar Therapeutics

SMI HealthCare LLC address can be found here: https://www.dnb.com/business-directory/company-profiles.smi_group_xii_llc.fcee5b80bb753910b2714caf1299f9ee.html

James C. Katzaroff, President and CEO of GSTC stated: "SMI HealthCare and its affiliates will collaborate closely with GlobeStar to advance our commercialization of Project Amethyst™. Our plan is to utilize the relationships and expertise of SMI HealthCare's professionals in the region to finalize arrangements locally for a clinical trial that meets the requirements for marketing approval by the Drug Controller General of India (DCGI). We then anticipate commencing sales in India and other countries in the region that accept DCGI approvals. Concurrently, we intend to arrange for additional clinical trials and begin the regulatory approval process in the United States, Europe, and elsewhere."

Shekar Tirumalai, Managing Director of Healthcare for SMI Group LLC added: "India has become a leading location for undertaking high quality clinical trials for the FDA and regulators in the UK and EU at a cost that is usually about half of a comparable trial undertaken in the United States. There are substantial opportunities for MS therapeutics and diagnostics in India, and throughout Southeast Asia, the Middle East and parts of Africa. Because of India's priorities for MS products, this is a particularly opportune time to commence an MS trial in India."

The GSTC agreement with SMIHC has been approved by the parties' respective boards and is immediately effective. Implementation of the first phase is subject to GSTC arranging financing. The first phase includes the formation of GSTC and SMIHC subsidiaries in India, the clinical trial, regulatory and intellectual property rights filings in India, identifying manufacturers, and planning for the commercial launch in India and countries in the region that accept DCGI approvals.

Implementation of the second phase is expected to commence approximately nine months later. The second phase may continue for the duration of patent validity, and consists initially of sales, marketing, and distribution in India and thereafter, countries in SMIHC's territory that will permit sales and distribution based upon DCGI approval. After proof of market in those countries, the intention is to seek regulatory approvals elsewhere in SMIHC's territory in order to expand the sales and distribution of GSTC MS products. Among other countries, SMIHC's territory includes India, Bangladesh, Indonesia, Saudi Arabia, Singapore, Thailand, the United Arab Emirates, Vietnam, and the members of the African Union.

According to the U.S. National Institutes of Health, between 2013 and 2020, the reported incidence of MS has increased by 50% in the 81 most affected countries. Although the market potential is uncertain in many of the developing countries in SMIHC's territory, in 2020, reported cases of MS in India reached 256,000, and the total reported cases in SMIHC's territory exceeded 600,000. According to multiple sources, the reported incidence of MS in the Middle East and Africa is rapidly growing, with treatments in the Middle East (excluding Israel) alone expected to grow from approximately \$3.5 billion in 2023 to \$4.5 billion in 2032. Within five years after launching sales in each country in which GSTC obtains regulatory approval, the GSTC goal is to

capture from 20% to 50% of the market for MS therapeutics in that country.

Pursuant to the parties' agreement, GSTC retains ownership of its intellectual property rights, regulatory filings, and approval of SMIHC's services regarding the foregoing, clinical trials, and manufacturing.

GSTC is discussing with Advanced Innovative Partners (AIP) the modification of their non-binding MOU announced on June 14, 2023, with the goal that AIP will focus on advising GSTC on opportunities in the United States and Europe and advising GSTC and SMIHC regarding potential clinical partners and design of the clinical trial in India.

For more information on \$GSTC visit: www.globestartherapeutics.com

For More information on

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SOURCE: CorporateAds.com

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