

# Major Advancements in Combination Therapies to Treat for Multiple Sclerosis : GlobeStar: Stock Symbol GSTC

*Within 5 Years After Launching Sales the \$GSTC Goal is to Capture 20% - 50% of the Market for MS Therapeutics in Each Country: [www.globestartherapeutics.com](http://www.globestartherapeutics.com)*

RICHLAND, WASHINGTON, UNITED STATES, November 2, 2023 /EINPresswire.com/ -- Cutting Edge Advancements; Combination Therapies to Treat and Market for Multiple Sclerosis in India, Southeast Asia, Africa, and Parts of The Middle East: GlobeStar Therapeutics Corporation ([Stock Symbol: GSTC](http://www.globestartherapeutics.com))



For more information on \$GSTC visit: [www.globestartherapeutics.com](http://www.globestartherapeutics.com)

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I am pleased that GlobeStar and SMI Healthcare will receive advice and assistance from the superb team at AIP to further the growth of Project Amethyst. I have strong confidence in AIP”

*James C. Katzaroff, President and CEO of \$GSTC*

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

Exclusive Global Licensee of the Multiple Sclerosis Project Amethyst™ Patents and Patent Applications.

Definitive Agreement with Advanced Innovative Partners to Develop Clinical Studies and Strategies for Multiple Sclerosis Treatment

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](https://www.gstc.com)) 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.

Definitive Agreement with Advanced Innovative Partners to Develop Clinical Studies and Strategies for Multiple Sclerosis Treatment

On November 2nd GSTC announced building on its recent 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. GSTC



\$GSTC Race to Erase MS



\$GSTC GlobeStar Therapeutics

has also entered into a definitive agreement with Advanced Innovative Partners Inc. (AIP) for AIP to provide advice to GSTC and SMIHC on the global design, strategy, and execution of clinical trials, regulatory filings, intellectual property rights filings, and manufacturing for Project Amethyst™.

The GSTC Project Amethyst'M is a compound intended to treat neurodegeneration from multiple sclerosis (MS). GSTC is the exclusive worldwide licensee for Project Amethyst™, including all patents and patent applications relating thereto.

The GSTC-AIP agreement has been approved by the parties' respective boards and is immediately effective. AIP initially will advise GSTC and SMIHC on the design and launch of an initial clinical trial in India and the associated regulatory approvals in India for Project Amethyst'M. AIP will then focus on strategies to seek regulatory approvals for the GSTC MS products in North America and Europe.

According to the U.S. National Institutes of Health, between 2013 and 2020, the reported incidence of MS increased by 50% in the 81 most affected countries.

Pursuant to the parties' agreement, GSTC retains ownership of all intellectual property rights, and final approval of Project Amethyst'M, including the right to engage additional advisors and experts. For its consulting services, AIP will be paid a monthly consulting fee and bonuses, a portion of which will be deferred and will become payable only if GSTC secures FDA marketing approval. If AIP introduces GSTC or SMIHC to potential customers, investors, or strategic partners, subject to compliance with applicable law, AIP may also become entitled to receive commissions on certain revenues or profits derived from those relationships.

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](http://www.SMIGllc.com).

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.

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