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TRANSPARENCY LIFE SCIENCES AWARDED \$1.4 MILLION NCATS SBIR GRANT TO CONDUCT INNOVATIVE TRIAL OF LISINOPRIL IN MULTIPLE SCLEROSIS

—Phase 2a Trial is First to Use Crowdsourcing for Protocol Design and Telemonitoring for Patient Data Collection—

—AMC Health to Provide Telemedicine Technology and Video Study Visits—

New York, NY — September 8, 2014 — Transparency Life Sciences, LLC (TLS), the world's first clinical-stage drug development company based on open innovation, today announced that it has received a Small Business Innovation Research (SBIR) program grant to fund a Phase 2a proof-of-concept study testing the utility of the ACE inhibitor lisinopril as an adjunctive therapy for multiple sclerosis (MS). The \$1.4 million grant, *Repurposing a Generic ACE Inhibitor to Treat Multiple Sclerosis*, was awarded by the National Center for Advancing Translational Sciences (NCATS) of the U.S. National Institutes of Health (NIH).

Crowdsourcing and telemonitoring are key elements of TLS' clinical development strategy. TLS developed the clinical protocol for the lisinopril study with crowdsourced input from MS researchers, physicians and patients. The trial is also designed to minimize the need for patient site visits by relying primarily on telemonitoring and video interactions with subjects. An Investigational New Drug (IND) application for this novel approach has been cleared by the U.S. Food and Drug Administration (FDA).

TLS is partnering with [AMC Health](#), a comprehensive provider of telemedicine services, to conduct the study. AMC Health played a key role in designing and securing NIH funding for the lisinopril project, and will deploy its mobile technology to enable video study visits in patients' homes, collect biometric data and enable remote assessment of a primary multiple sclerosis endpoint.

"This project advances NCATS' mission to innovate in both the scientific and operational aspects of translation," said NCATS Director Christopher P. Austin, MD. "It aims to make drug repurposing more efficient and better measure patient-relevant clinical trial outcomes, all in the context of a company that operates in the new arena of open innovation drug development." [NCATS](#) was established to transform the translational science process so that new disease treatments and diagnostics can be delivered to patients faster.

"We are thrilled that NCATS is supporting this pioneering study designed to harness the wisdom of the crowd and the promise of telemonitoring technologies, with a goal of making clinical trials more patient-centric, more transparent and dramatically less costly," noted Tomasz Sablinski, MD, PhD, CEO of Transparency Life Sciences. "Our model is applicable to new chemical entities, as well as to repurposed drugs such as lisinopril, where safety is well documented, but low perceived return on investment has discouraged further clinical development. Using the cost-effective TLS approach to establish clinical proof-of-concept could make it possible to test many more repurposing candidates in the future."

The Icahn School of Medicine at Mount Sinai will conduct the lisinopril trial, with Fred D. Lublin, MD, the Saunders Family Professor of Neurology and the Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis, serving as Principal Investigator. Dr. Lublin noted, "Preclinical data suggest that lisinopril used as an adjunctive therapy may have the potential to improve the efficacy of current MS treatments while reducing costs. I welcome the opportunity to test this hypothesis, along with Transparency's innovative approach to conducting clinical trials."

Lisinopril is a widely used generic antihypertensive. TLS has an exclusive option from Stanford University to license its intellectual property (IP) covering the use of lisinopril as a treatment for multiple sclerosis. This IP is based on the work of MS expert Dr. Lawrence Steinman, the George A. Zimmermann Professor

of Neurology and Neurological Sciences & Pediatrics at the Stanford School of Medicine. Dr. Steinman is a co-founder of Transparency and Chair of TLS's Scientific Advisory Board.

For this project, TLS incorporated insights from a global crowd of researchers, physicians and patients using its [Protocol Builder™](#), a proprietary online tool that invites structured input to help design clinical trials more efficiently and with greater relevance to patient experience and clinical practice.

About Multiple Sclerosis

MS is a chronic autoimmune disease in which the body's immune system mounts recurring assaults on the myelin sheathing of nerve cells in the brain. This causes nerves to malfunction and can lead to paralysis, blindness and early death. Approximately 350,000 people in the US have been diagnosed with MS, and the disease affects an estimated three million people worldwide. A variety of new MS therapies have reached the market in recent years, but they are expensive and can carry risks of serious side effects.

About Transparency Life Sciences

Transparency Life Sciences (TLS) is the world's first clinical-stage drug development company based on open innovation. TLS acquires promising new chemical entities and repurposed compounds that address unmet medical needs and tests them in clinical trials that leverage crowdsourcing methods, advances in telemedicine and full data transparency. The company expects this innovative approach to result in significantly reduced costs and improved data quality. For more information, visit: www.transparencyls.com.