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**FDA CLEARS IND FOR FIRST CLINICAL TRIAL PROTOCOL DEVELOPED USING CROWDSOURCING**

***—Open Innovation Drug Developer Transparency Life Sciences Gains Clearance to Proceed with Phase II Trial of Lisinopril as Adjunctive Therapy in Multiple Sclerosis—***

***—Groundbreaking Crowdsourced Protocol Eliminates Most Study Visits by Using Telemonitoring to Assess Outcomes—***

**New York, NY — December 18, 2012** — Transparency Life Sciences, LLC (TLS), the world's first drug development company based on open innovation, today announced that its Investigational New Drug Application (IND) to assess lisinopril as an adjunctive therapy for multiple sclerosis (MS) has been cleared by the US Food and Drug Administration (FDA). This clearance is the first for a clinical trial protocol developed with the aid of crowdsourcing, and is among the first to make intensive use of telemonitoring and other remote methods for patient data collection.

"FDA clearance of our first crowdsourced protocol is a major milestone in our efforts to build a drug development company for the 21<sup>st</sup> century," said Tomasz Sablinski, MD PhD, founder and CEO of TLS. "In response to widespread recognition that the existing development model is unsustainable, TLS is pioneering a fresh approach that leverages advances in technology and communications. We look forward to working with the FDA and a growing community of contributors and partners to implement the lisinopril Phase II trial, as we also assess additional development candidates encompassing both new chemical entities (NCEs) and repurposed compounds."

A key element of TLS's approach is incorporating insights gathered from a global crowd into its clinical protocols using the company's Internet-based [Protocol Builder](#)<sup>™</sup>, an online tool that elicits input from patients, physicians and researchers to help design clinical trials more efficiently and with greater relevance to clinical practice and patients' needs.

Dr. Sablinski continued, "We spent much of this year refining our Protocol Builder tool and were able to use the responses we obtained from patients and healthcare experts to strengthen the lisinopril Phase II protocol. These included valuable insights on primary and secondary endpoints, inclusion/exclusion criteria and remote monitoring strategies. Going forward, we expect even more of the content of our protocols will be derived from curated crowd input."

A second TLS strategy is to dramatically reduce the cost and patient inconvenience of executing clinical trials by replacing patient site visits with telemonitoring and other measurements obtained from patients' homes. To achieve its goal of 50% or greater reduction in the cost of clinical trials, TLS is partnering with Advanced Monitored Caregiving (AMC Health), a comprehensive telehealth provider offering an array of easy-to-use in-home telemonitoring solutions. In the proposed twelve-month lisinopril study, patients will visit in-person with clinical trial staff at the start and end of the trial, and all other study data will be collected at home.

John Holland, Senior Vice President for Research and Business Development at AMC Health commented, "Based on our 10 years of successful operations, we know first-hand how effective at-home patient monitoring can be, providing significantly improved care at a much lower cost. FDA clearance of this lisinopril protocol, which primarily relies on telemonitoring-based patient assessments, is an encouraging breakthrough, and we look forward to working with TLS to ensure the success of this patient-centric approach to clinical research."

Multiple sclerosis expert Dr. Lawrence Steinman, the George A. Zimmermann Professor of Neurology and Neurological Sciences & Pediatrics at the Stanford School of Medicine and Chair of the TLS Scientific Advisory Board, presented preclinical data on the potential of lisinopril in multiple sclerosis at a Gordon Conference earlier this year.

Professor Steinman noted, "Our preclinical data confirms the role of the angiotensin system in the pathology of MS and provides evidence that the ACE inhibitor lisinopril can modulate those effects in target-specific ways. We are delighted that this novel clinical trial protocol has been cleared by the FDA, enabling us to test whether these preclinical findings can translate into a safe and affordable new therapeutic option for MS patients."

The work of Dr. Steinman and others has demonstrated that angiotensin receptors and an angiotensin-producing enzyme are abundant at sites of disease and inflammation in brains affected by multiple sclerosis. In animal models of MS, studies have shown that blockade of these receptors with lisinopril reduces the areas affected by pathology and may provide significant clinical benefits, including reduction in paralysis and improved mobility.

TLS has posted the FDA-cleared [lisinopril protocol](#) on its website and welcomes further input from patients, clinicians and researchers on details of the design, especially concerning the telemonitoring and statistical analysis aspects of the plan. TLS is also seeking input to its Protocol Builders for [low-dose naltrexone](#) as a potential treatment for Crohn's disease, and the PPAR activator [pioglitazone](#) as a possible new therapy for Parkinson's disease. In addition, the company's [Indication Finder](#) offers the opportunity to consider promising new indications for existing drug candidates. For more information on Transparency Life Sciences, visit: [www.transparencyls.com](http://www.transparencyls.com).

For more information about AMC Health, visit [www.amchealth.com](http://www.amchealth.com).

#### **About Transparency Life Sciences**

Transparency Life Sciences (TLS) is the world's first drug development company based on open innovation. TLS acquires promising new chemical entities (NCE's) and repurposed generics addressing significant unmet medical needs and tests them in clinical trials that leverage crowdsourcing methods, advances in telemedicine and full data transparency. The company expects to realize significantly reduced costs and clinical timelines.