

OneWorld Health Launches Phase 4 Program of Paromomycin IM Injection in India

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Patna, Bihar, November 7, 2007 /[India PRwire](#)/ -- The Institute for OneWorld Health (iOWH), the US-based non-profit pharmaceutical company that develops drugs for people with infectious diseases in the developing world, today announced the initiation of a major Phase 4 pharmacovigilance and access program of Paromomycin IM Injection for the treatment of visceral leishmaniasis (VL) in India.

Working with the principal investigators who are experts in the treatment of kala-azar, and nongovernmental organization (NGO) partners, OneWorld Health's Phase 4 Program will investigate the safety and efficacy of treatment of VL with Paromomycin IM Injection in progressively more rural areas in Bihar State. Bihar is the epicenter of the disease in India, with an estimated 250,000 people infected there each year. The first module of the program will enroll approximately 500 patients to provide additional safety data on Paromomycin IM Injection. Over the course of the three-year program, up to 1500 additional patients will be included in two subsequent access modules that will extend the network of treatment facilities, providers, and related logistics systems into the most rural areas of Bihar. This is an innovative access model for administering Paromomycin IM Injection that uses an outpatient setting to diagnose and treat impoverished patients and advanced data transmission technologies in the remote areas where VL is endemic. It is hoped that this access model will be transferable to other infectious diseases in the developing world.

With approximately 500,000 new cases occurring annually, visceral leishmaniasis, also known as kala-azar, is the world's second most deadly parasitic disease, after malaria. VL primarily afflicts rural, resource-poor populations in India, Nepal, Bangladesh, Sudan and Brazil, and affordable therapies are needed.

The Phase 4 Program follows on the success of OneWorld Health's Phase 3 clinical study – the largest VL clinical study performed to date - that established Paromomycin IM Injection as safe, effective, and well-suited to treating VL in impoverished areas. The Drug Controller General of India (DCGI) approved Paromomycin IM Injection as a treatment for VL on August 31, 2006. The drug was subsequently added to the World Health Organization's Essential Medicines List, and the results of the Phase 3 clinical study were published in the [New England Journal of Medicine](#) in June 2007.

"Now that Paromomycin IM Injection has been confirmed as a safe, affordable, and effective treatment for VL, a major public health problem in India, we are excited to bring this additional data and access model to fruition," said Dr. Ahvie Herskowitz, OneWorld Health's co-founder and Chief Medical Officer. "Our ongoing research results underscore the potential of Paromomycin IM Injection to treat VL—and save lives—at very low cost and in safe and practical ways. We look forward to working with our partners and the government of India on this important Phase 4 Program."

Medical researchers from key local research centers, many internationally renowned for their work in VL, are participating in the Phase 4 Program, including: **Dr. C.P. Thakur**, Kalazar Research Centre, Patna,

Bihar; **Dr. T.K. Jha**, Kalazar Research Centre, Muzaffarpur, Bihar; **Dr. Shyam Sundar**, Kala-azar Medical Research Centre, Muzaffarpur, Bihar; **Dr. P. Das** and **Dr. P.K. Sinha**, Indian Council of Medical Research, Rajendra Memorial Research Institute of Medical Sciences, Patna, Bihar; **Dr. Devendra Nath**, Shrimati Hazari Maternity and Medical Care, Motihari, Bihar; **Dr. Supriyo Mukherjee**, Research Centre for Diabetes, Hypertension and Obesity, Samastipur, Bihar; and **Dr. Amerendra Kumar Aditya**, Dr. A.K. Aditya Clinic, Samastipur, Bihar.

The Hyderabad, India-based drug manufacturer Gland Pharma Limited, is the drug manufacturing partner who makes Paromomycin IM Injection available at cost, currently priced at \$10-15 USD per 21 day course. The clinical studies are supported with funding from the Bill & Melinda Gates Foundation.

Several other partners are engaged in the Phase 4 Program, including: Janani, incorporating VL treatment into their existing clinic referral and treatment network into the most rural areas of Bihar; John Snow, Inc., providing technical assistance on supply chain system management; Odyssey Research, providing clinical research management; Synteract, providing data analysis; and Voxiva, developing a data management system.

Notes to Editor

About Visceral Leishmaniasis

VL is a systemic infection caused by various species of Leishmania parasites. The infection is transmitted by sandflies and causes chronic fever, weight loss, splenomegaly, hepatomegaly and anemia. Left untreated, VL is nearly always fatal. VL currently occurs in 62 countries, primarily in the developing world. Of the approximately 500,000 new cases of VL occurring annually, 90% are found in just five countries: India, Bangladesh, Nepal, Sudan and Brazil. The Indian subcontinent carries 70% of all estimated new VL cases per year worldwide, with India alone carrying 50% percent of all new cases. The most affected state in India is Bihar, but VL is also endemic in the states of Jharkand, West Bengal, and Uttar Pradesh.

About Paromomycin IM Injection

An off-patent aminoglycoside antibiotic, paromomycin is an established drug with an extensive history of use and well-characterized safety profile. Paromomycin IM Injection is approved as a treatment for VL in India, and is administered as a once-a-day injection for 21 days. The cost of Paromomycin IM Injection is significantly lower than other currently approved VL therapies. In the Phase 3 study, the most common adverse reaction among patients treated with Paromomycin IM Injection was pain at the injection site (55%).

About the Institute for OneWorld Health

The Institute for OneWorld Health, the first US nonprofit pharmaceutical company, develops safe, effective and affordable new medicines for people with infectious diseases in the developing world. The Institute for OneWorld Health, headquartered in San Francisco, California, USA, is a tax-exempt 501 (c) (3) US corporation. (<http://www.oneworldhealth.org/>). Media resources are available at <http://www.oneworldhealth.org/media/index.php/>.

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