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New Approaches to Pharmaceutical Development to Support a Nonprofit Model

The Institute for OneWorld Health (iOWH) is the first nonprofit pharmaceutical company in the US, formed to address the fact that only ten per cent of worldwide expenditure on health research and development is devoted to the problems that primarily affect the poorest 90 per cent of the world's population. Our mission is to develop safe, effective and affordable new medicines for people with infectious diseases in the developing world as well as provide affordable and accessible medicine to the affected populations in a manner which is sustainable.

OneWorld Health's core competencies lie in pharmaceutical product development. Our in-house teams identify development leads through partnerships with industry and universities. Together, iOWH works to optimize existing drug candidates, complete preclinical and clinical investigation needs, secure quality manufacturing of developed products, and obtain the necessary regulatory approvals to bring the product to the beneficiaries. Concurrently, iOWH collaborates to devise product delivery and access strategies with relevant stakeholders that include governments, donors, and international NGOs. These Public-Private-Partnerships (PPPs) allow for a more rapid development of new drugs by utilizing complementary skills and resources.

iOWH's current pipeline includes programs for visceral leishmaniasis (VL), malaria, and diarrheal disease. After the completion of a Phase III VL clinical trial in Bihar, India for paromomycin, iOWH submitted the dossier for regulatory approval in India, which was granted by the country last month. Commercial distribution of the drug is scheduled to begin shortly.

While the nonprofit model of pharmaceutical development defined at the iOWH is novel, many of the challenges are similar to those faced by traditional drug development professionals. This presentation will in part review the novel and traditional aspects of drug development at iOWH, and offer approaches that are broadly applicable for effective clinical development, partnership management, regulatory strategy, etcetera.

iOWH strives to provide a flexible and innovative vehicle to engage both the pharmaceutical and biotech industries, as well as public health organizations in global health product development. Through partnerships and collaborations, by adhering to the highest ethical standard for clinical research, and by utilizing the scientific and manufacturing capacity of the developing world, OneWorld Health hopes to deliver affordable and effective new medicines where they are needed most.

Kelly Oliver, Project Manager: Kelly is the project manager for the visceral leishmaniasis drug development project, which was just granted drug approval by Drug-Controller General of India (DCGI). She has several years of experience in drug development project management. Kelly received her Bachelor of Science in Biochemistry from San Francisco State University.

The target indication *Visceral leishmaniasis* (also known as kala-azar) is a deadly disease transmitted via the bite of an infected sand fly. Approximately 500,000 new cases of visceral leishmaniasis arise annually worldwide. Over 90% of visceral leishmaniasis cases occur in India, Bangladesh, Sudan, Brazil, and Nepal. DCGI's approval of Paromomycin IM Injection came less than three months after the submission of the drug's application, which was prepared by OneWorld Health in collaboration with the Hyderabad-based drug manufacturer Gland Pharma Limited. The application was based on data from a large Phase III multi-center, randomized and controlled clinical trial of 667 adult and pediatric patients conducted in Bihar State, India, which showed that nearly all patients (94.6%) treated with Paromomycin were cured of VL.

Blair Palmer, M.P.H., Research Analyst, Access Team: collaborates across project teams to facilitate the implementation of iOWH's drug development programs and gather stakeholder input to establish sustainable models for treatment delivery and drug access issues in developing countries. She recently worked with UCSF's Institute for Global Health and AIDS Policy Research Center, focusing on coordination of infectious disease research in sub-Saharan Africa, Latin America, and Asia. Blair received her M.P.H. from Yale University and a B.S. in Psychology and Neuroscience from Vanderbilt University.

Autumn Bill, Senior Project Manager, Malaria Program: Autumn is the project manager for the malaria development program. She has several years of biopharmaceutical project and partnership management experience including the management of infectious disease partnerships with the Naval Medical Research Center and the National Institutes of Health. Autumn received her B.S. in Molecular and Cellular Biology from the University of Arizona.

Malaria causes 300 -500 million acute illnesses and one - three million deaths annually, our goal is to produce a reliable supply of an essential component of the World Health Organizations recommended treatment for malaria—artemisinin combination therapies, or ACTs—at an affordable price.