

PATH, Clarus, and the Global Health Investment Fund Announce an Innovative \$25 Million Financing Arrangement to Improve Treatment of Intestinal Worms, Affecting More Than 1 Billion People Worldwide

PATH will lead a consortium of partners toward US FDA approval for tribendimidine and its inclusion in mass deworming campaigns

January 31, 2017 (SEATTLE): PATH is pleased to announce that, together with a consortium of government, nonprofit, and commercial partners, it intends to seek US Food and Drug Administration (FDA) approval for tribendimidine (TrBD) as a significantly improved treatment for hookworm infections. FDA approval is the initial step in a plan to incorporate TrBD in mass deworming campaigns in low-resource settings where soil-transmitted helminth (STH) infections cause significant morbidity. The \$25 million financing of PATH's TrBD program is being led by Clarus, a leading life sciences investment firm, alongside the Global Health Investment Fund (GHIF), an impact investment fund focused on neglected diseases and maternal/child health.

Supported by more than 20 years of clinical research and 10 years of approved use in China, TrBD is a widely studied anthelmintic drug that has demonstrated excellent efficacy against a variety of STH infections. With an estimated 1.5 billion people infected globally, STH is a widespread scourge in many poor countries, with disproportionate impact on pregnant women and young children. As a result, the World Health Organization (WHO) has recommended mass drug administration (MDA) of existing STH therapies in endemic areas since 2001. Emerging resistance to the drugs used in these treatment campaigns threatens their effectiveness, however, and there is an urgent need for new STH therapies to complement or replace currently used drugs. TrBD's unique mechanism of action, single-dose administration, and well-documented safety and efficacy make it an attractive next-generation therapy against STH, with the potential for enormous public health benefit.

This groundbreaking collaboration among diverse stakeholders has been made possible by the FDA's tropical disease priority review voucher (PRV) program. This program rewards the successful developers of drugs or vaccines for certain neglected diseases with a transferrable voucher that entitles the holder to an expedited FDA review of any subsequent application. PATH is pursuing a new drug application with the FDA for TrBD and will seek a PRV as part of the drug's approval. Any resulting PRV would then be monetized, with the proceeds to be shared among investors, PATH, and its consortium partners. Notably, a portion of PRV proceeds will be set aside to make TrBD available in low-income countries, and financial returns will also support additional public health research and development efforts among consortium partners.

"This financing is a terrific example of how for-profit investors with expertise in drug development can team up with sophisticated public health players such as PATH to 'do well by doing good,'" said Scott Requadt, managing director of Clarus. "We are very pleased to co-invest with GHIF on this financing, and look forward to working with PATH and its

consortium partners to make this important STH treatment available globally.”

“The launch of this collaboration is a major milestone for GHIF,” said Glenn Rockman, partner at the Global Health Investment Fund. “In addition to TrBD’s potential to treat hundreds of millions of vulnerable children for debilitating parasitic worm infections, this project also marks GHIF’s first direct investment in a nonprofit product development organization alongside a traditional American life sciences firm. Bringing all three organizations together around both social and commercial objectives validates the impact investment model on which GHIF was founded, with the expectation that profit and long-term public health improvements can be achieved with creativity and purposeful collaboration.”

“New tools to combat STH infection are urgently needed to prevent the emergence of drug-resistant parasites and to expand mass deworming programs, and TrBD has demonstrated excellent cure rates for hookworm and other helminths,” said David Shoultz, program leader for PATH’s Drug Development program. “Thanks to Clarus and GHIF, PATH and our partners now have the resources necessary to move forward with the remaining clinical, manufacturing, and regulatory work needed to expand access to TrBD in STH-endemic countries.”

To execute the project, PATH is leading a Tribendimidine Consortium that includes the National Institute of Parasitic Diseases at the Chinese Center for Disease Control and Prevention, which is credited with the development of TrBD in China; TrBD manufacturer Shandong Xinhua Pharmaceutical Company; and Swiss Tropical and Public Health Institute. Consortium members are committed to working together to ensure that TrBD is successfully integrated into safe and effective MDA programs.

Integration of TrBD into global deworming campaigns will require WHO endorsement, which PATH intends to pursue upon FDA approval and PRV monetization. Equally important, a portion of PRV monetization proceeds will be dedicated to ensuring affordable access to TrBD for these campaigns, including the donation of tens or hundreds of millions of TrBD tablets for public health programs. A portion of PRV proceeds has also been earmarked for additional neglected disease treatment and diagnostic research, including other potential uses for TrBD, such as the treatment of Asian liver fluke. The TrBD collaboration demonstrates that the PRV program can indeed catalyze high-impact investments in neglected disease research and development, in addition to ensuring that successfully developed products will be accessible to those who need them most.

About PATH: PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and

Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

About Clarus: Clarus is a leading global investment firm dedicated to life sciences. Founded in 2005 by a team of accomplished investment and operating professionals, Clarus manages over \$1.7 billion, which has been invested in more than 50 private and public companies in the biotechnology, medical device, and diagnostic spaces. In every investment, Clarus employs a hands-on philosophy and adheres to investment principles that are founded on core competencies in drug development, complex partnership structuring, and the ability to adapt to an ever-changing investment landscape. Clarus strives to generate outstanding returns for its investors by identifying and financing innovative medicines that improve people's lives. Clarus has offices in Cambridge, MA, and South San Francisco, CA. For more information, visit www.clarusfunds.com.

About the Global Health Investment Fund (GHIF): GHIF is an impact investment fund structured by JPMorgan Chase & Co. and the Bill & Melinda Gates Foundation. The fund received anchor support from Grand Challenges Canada (funded by the Government of Canada), the German Ministry for Economic Cooperation and Development (acting through KfW), the Swedish International Development Cooperation Agency, and the Children's Investment Fund Foundation. The fund's limited partners also include AXA, GlaxoSmithKline, International Finance Corporation, JPMorgan Chase & Co., Merck, the Pfizer Foundation, Storebrand, and individual investors.

With an emphasis on late-stage projects, GHIF finances the development of drugs, vaccines, and diagnostics for diseases that disproportionately burden low-income populations. Much like a traditional investment fund, GHIF searches for opportunities that will deliver compelling financial returns in developed markets and/or emerging markets. Of equal importance, each investment must also advance the fund's public health mission, which is to ensure that the innovations it supports are accessible to those who need them most in underserved markets. Key global health challenges targeted by the fund include malaria, tuberculosis, HIV/AIDS, cholera, and preventable causes of maternal and infant mortality, in addition to other neglected infectious diseases. GHIF's definition of success requires meaningful improvements in the lives of those afflicted by these challenges, and the fund forecasts and measures its progress against this objective alongside traditional financial return benchmarks. To learn more, visit www.ghif.com.