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IDRI TO CONTINUE DEVELOPMENT OF INHALABLE TB DRUG CANDIDATE

Working with Hisun Pharmaceutical Co., Ltd., to Combat Drug-Resistant Tuberculosis

FOR IMMEDIATE RELEASE: SEATTLE, August 24, 2017: IDRI (Infectious Disease Research Institute), on behalf of the Lilly TB Drug Discovery Initiative, announces it has entered into an agreement with Zhejiang Hisun Pharmaceutical Co., Ltd., a China-based leading biopharmaceutical company, to continue development of inhalable CPZEN-45, a tuberculosis (TB) drug candidate that could potentially treat the growing problem of antibiotic-resistant TB. Burdening its victims with increased health concerns and a high cost of treatment, drug-resistant TB occurs when *Mycobacterium tuberculosis (Mtb)*, the bacterium that causes TB, becomes resistant to the drugs used to treat it, underscoring the need for the development of new drugs.

The Lilly TB Drug Discovery Initiative is a unique public-private partnership founded in 2007 by IDRI, Eli Lilly and Company and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Its focus is on the discovery of new anti-tuberculosis drugs.

Hisun and IDRI will work together to further develop CPZEN-45, an antibiotic that has a new mechanism of action that inhibits cell wall synthesis -- the 'Achilles Heel' of *Mtb* -- and has shown efficacy against both drug sensitive and multidrug (MDRTB) and extensively drug resistant (XDRTB) TB. CPZEN-45 was discovered by the Institute of Microbial Chemistry (IMC), a nonprofit research institute located in Tokyo, Japan.

"In 2003, when we were exploring derivatives of the caprazamycin family, which are liponucleoside antibiotics, we were surprised to find that the mode of action of CPZEN-45 was different from the parent compounds, and thus we were quite excited about this compound," said Masakatsu Shibasaki, Director of IMC and former President of the Pharmaceutical Society of Japan.

In 2008, IMC joined The Lilly TB Drug Discovery Initiative to collaborate on further studies for developing this candidate drug.

"Critical research and development milestones have already been achieved with CPZEN-45, making it a late-stage pre-clinical candidate with enormous potential, due to the outstanding expertise of our scientific colleagues at IMC and the Research Triangle Institute International (RTI) and resources provided by NIAID," said Steve Reed, President, CEO and Founder of IDRI.

“IMC has made important contributions to scale up the production of this molecule,” said Gail Cassell, Executive Vice President of TB Drug Development, IDRI. “Now, we are pleased to partner with Hisun, which is one of the few companies in the world that has the expertise to scale this drug to commercial level and provide us with GMP quality material for further development and clinical trials. The real value of this relationship is clinical data with the sought-after result being a validated drug that can improve health and stop the tide of drug-resistant TB.”

Bai Hua, Chairman of Hisun and Vice Chairman, China Pharmaceutical Industry Association, added, “We are excited to team up with world-class scientists to combat drug-resistant TB. I hope CPZEN-45 will soon be added to Hisun’s portfolio of other anti-TB drugs, including WHO approved capreomycin.”

Through its relationship with Hisun, IDRI will continue developing CPZEN-45 alone and in combination with capreomycin, a drug discovered in 1960 that is frequently used to treat TB infections.

“A combination of capreomycin and CPZEN-45 has been prepared as a spray dried powder for delivery as an aerosol using a commercially available device,” said Anthony Hickey, Distinguished Fellow of RTI International and an expert on delivery of inhaled pharmaceuticals. “The product is designed to meet regulatory standards to support a Phase I clinical trial. We believe that the use of aerosols offers a new and effective way of modifying the current approach to treat TB and can potentially shorten the time of treatment.”

In 2015, an estimated 10.4 million people worldwide developed TB and TB surpassed HIV as the leading infectious cause of death worldwide, with 1.8 million deaths, more than HIV/AIDS and malaria combined. MDR-TB as well as agrowing number of XDR-TB cases have been reported in nearly all countries. Worldwide emergence of MDR/XDR-TB threatens global eradication of TB.

About IDRI: As a nonprofit global health organization, IDRI (Infectious Disease Research Institute) takes a comprehensive approach to combat infectious diseases, combining the high-quality science of a research organization with the product development capabilities of a biotech company to create new diagnostics, drugs and vaccines. Founded in 1993, IDRI has 125 employees headquartered in Seattle with nearly 100 partners/collaborators around the world. For more information, visit www.idri.org .

About The Lilly TB Drug Discovery Initiative: The Lilly TB Drug Discovery Initiative is a nonprofit, public-private collaboration launched by Eli Lilly and Company (Lilly) in 2007, with a mission to accelerate early-stage drug discovery for TB by bringing together the most outstanding scientists from around the world for the systematic exploration of vast, public and private molecular libraries. They come from government, academia, not-for-profit organizations and the pharmaceutical industry to create a truly “industrial strength” team. The Initiative’s founding members are Lilly, Infectious Disease Research Institute (IDRI), and National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). Lilly is the inventor

of capreomycin and cycloserine, two critical drugs for treating drug resistant TB, and in 2003 launched the MDR-TB Partnership (http://www.lillyglobalhealth.com/en/mdr-tb/index.aspx), a philanthropic initiative that now totals over $170 million. The Lilly TB Drug Discovery Initiative is housed within, led by, and "incubated" in IDRI whose operations are in Seattle, Washington. In November 2017, Lilly announced another $7.5 million in additional funding plus $7.5 million of in-kind services to IDRI over the next 5 years. Please review more detailed information about the contributions of each of the members at http://www.tbdrugdiscovery.org/**.**

About Eli Lilly and Company: Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels. C-LLY

About the National Institute of Allergy and Infectious Diseases: NIAID conducts and supports research-at the National Institutes of Health, throughout the United States, and worldwide-to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website at www.niaid.nih.gov.

About Zhejiang Hisun Pharmaceutical Co., Ltd: Founded in 1956, Hisun is China's major pharmaceutical company that conducts R&D, production and marketing of active pharmaceutical ingredients and pharmaceuticals such as anti-cancer drugs, cardiovascular, anti-infective, anti-parasitics, immunosuppressant, etc. The company exports its products to over 70 countries and regions around the world. Hisun has over 9,000 employees, of whom 900 are highly skilled researchers in R & D. In 2001, Hisun established its R&D Center, which focuses on innovations in synthetic chemistry, microbiological fermentation, biotechnology, plant chemistry and dosage formulation techniques. Hisun annually re-invests more than 8% of its total sales back into R&D. With respect to annual revenue, R&D expenditure as well as its Social Record, HISUN is definitely in the top 10 among the 7000 local Chinese Pharma**.** Hisun has received WHO regulatory approval for capreomycin for drug-resistant TB and is now the major supplier of capreomycin to the Global Fund; Hisun recently began manufacture of cycloserine, also a second-line TB drug. Importantly, Hisun is currently developing an aerosol therapy pipeline. To learn more about Zhejiang Hisun Pharmaceutical Co., Ltd go to www.hisunpharm.com .

About the Institute for Microbial Chemistry (IMC): The Microbial Chemistry Research Foundation (MCRF) was established in 1958, with funds raised from patent fees of the new antibiotic kanamycin, which remains today a critical drug for treating drug-resistant TB. Following authorization from the Prime Minister of Japan,

MCRF was reincorporated as a public interest foundation on April 1, 2011. The objectives of MCRF are to conduct microbial and microbiological research to discover beneficial substances to advance disease prevention and treatment. In 1962, MCRF established its Research Institute, IMC. The institute has since given rise to numerous beneficial pharmaceuticals, including kasugamycin, which is highly effective against rice blast, and bleomycin, which is the first target-specific anticancer antibiotic. The institute initiated the first research into the mechanism of resistance in TB strains resistant to aminoglycoside antibiotics such as streptomycin and kanamycin. This research initiative resulted in the successful synthesis of dibekacin and arbekacin, derivatives of kanamycin, which are effective against several strains of bacteria. This background has led to microbiology, medicine, and organic synthetic chemistry becoming the main pillars of the institute's research activities. CPZEN-45 is the first promising TB drug to arise at IMC. In 1982, MCRF revised its articles of association, adding "contribution to academic research" to its objectives www.bikaken.or.jp.

About RTI International: RTI International is an independent, nonprofit research institute dedicated to improving the human condition. Clients rely on us to answer questions that demand an objective and multidisciplinary approach—one that integrates expertise across the social and laboratory sciences, engineering, and international development. We believe in the promise of science, and we are inspired every day to deliver on that promise for the good of people, communities, and businesses around the world. For more information, visit **www.rti.org.**

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