



Zydus and IDRI sign agreement for the development of IDRI's Vaccine Candidate for Visceral Leishmaniasis (Kala-Azar)

Ahmedabad, 25 July 2013

In a unique partnership, Zydus, India's fourth largest healthcare group and an innovation-led global healthcare provider and IDRI, a Seattle-based non-profit research and product development organization, announced today that they are collaborating on the production and clinical development of IDRI's visceral leishmaniasis (VL) vaccine candidate, designed to prevent the deadly parasitic disease.

Known as Kala-Azar in India, VL is transmitted by the bite of an infected sand fly. There are over 500,000 new VL cases and 50,000 associated deaths each year. VL is the most severe form of leishmaniasis, affecting vital organs, and, if left untreated, the disease can be fatal. A vaccine is considered essential to control and eliminate the disease. Currently, leishmaniasis occurs in four continents and is considered to be endemic in 88 countries; 72 of those are developing countries, with the disease being most common in India, Nepal, Bangladesh, Sudan and Brazil. While there are drugs to treat the disease, they are expensive and often toxic. To date, a safe and efficacious vaccine to prevent this disease does not exist.

Zydus & IDRI will collaborate to conduct clinical development activities in India with the goal of developing, registering and marketing this vaccine candidate for the prevention of VL, which will achieve the objective of global access – that is, ensuring the vaccine is affordable to and accessible by all people in need. Conducting trials in India, where there are real-life situations of disease exposure, is critical to determining the effectiveness of IDRI's VL vaccine candidate and ensuring it is approved and available within endemic countries.

IDRI's VL vaccine candidate, LEISH-F3+GLA-SE, is the product of more than 20 years of research and development supported by the U.S. National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation. The defined, purified, recombinant vaccine comprises two fused *Leishmania* parasite proteins and an adjuvant to stimulate a protective immune response against the parasite. After completion of a Phase 1 clinical trial of 36 U.S. adult volunteers to test safety and immunogenicity, the vaccine was shown to be safe and to induce potent immune responses in healthy volunteers.

Speaking on the development, Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus group said, "Zydus has always been committed to working with partners and collaborating to bridge unmet healthcare needs. By partnering with IDRI on this very important mission, we will be taking an all important step to eradicate visceral leishmaniasis which is a huge healthcare burden."

Dr. Steven G. Reed, IDRI Founder and President added, “Zydus’ expertise and breadth of development and commercialization experience will be instrumental in getting IDRI’s VL vaccine to the people who need it most. We are appreciative of Zydus’ commitment to this program. This is an excellent example of cooperating to help combat a devastating disease without consideration for a profit motive. IDRI could not ask for a better partner in this endeavor.”

About Zydus:

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. From a turnover of Rs. 250 crore in 1995, the group posted revenues of over Rs. 6300 crore in FY2013. The group employs over 15,000 people worldwide and is dedicated to creating healthier communities globally. Zydus is the only Indian pharma company to launch its own patented NCE – Lipaglyn, the world’s first drug to be approved for the treatment of diabetic dyslipidemia. It aims to be a leading global healthcare provider with a robust product pipeline; achieve sales of over \$3 billion by 2015 and be a research-based pharmaceutical company by 2020.

Vaccine Technology Centre (VTC) is the Vaccine division of the Zydus Group. VTC has two state-of-the-art R & D Centers, one located in Catania, Italy; and the other in Ahmedabad, in the western part of India. Zydus Vaccine division has indigenously developed, manufactured and launched India’s first vaccine against H1N1 (Vaxiflu-S). The Vaccine Division’s Rabies Vaccine Manufacturing facility has received WHO pre-qualification, and is one of the largest Rabies manufacturing facilities in India. The current programmes under development include vaccine candidates designed to address infectious diseases like next-generation Influenza, Measles-Mumps-Rubella-Varicella, Typhoid, DPT-HiB, Hepatitis-B, Hepatitis-A, Hepatitis-E, Japanese Encephalitis, HPV and combination vaccines. Research is also focused on developing a Malaria vaccine.

www.zyduscadila.com

Media Contact: Sujatha Rajesh (sujatha.rajesh@zyduscadila.com)

About IDRI:

As a non-profit 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. IDRI combines passion for improving human health with the understanding that it is not just what our scientists know about disease, but what we do to change its course that will have the greatest impact. Founded in 1993, IDRI has 125 employees headquartered in Seattle with more than 50 partners/collaborators around the world. For more information, visit www.idri.org.

Media Contact: Lee Schoentrup: 206.858.6064 (lee.schoentrup@idri.org)