



Industry Updates

Meridian Life Science® Successfully Manufactures Second cGMP Production Campaign for a Novel RV3 Oral Rotavirus Vaccine Candidate

Source: *Biowire*

Meridian Life Science, Inc., (MLS) of Memphis, Tennessee, today announced the completion of a second clinical cGMP production lot of the live oral RV3 rotavirus vaccine candidate for the Murdoch Childrens Research Institute (MCRI). The cGMP vaccine manufacturing process at MLS was observed by representatives from MCRI, international nonprofit organization PATH, and Indonesian manufacturer BioFarma.

The RV3 strain was discovered in babies at a newborn nursery in Melbourne, Australia. Babies who were naturally infected with the RV3 strain had no symptoms and were protected from contracting rotavirus disease in the first three years of life. In 2009 (during a previous collaboration with MCRI and PATH) MLS successfully manufactured an initial clinical cGMP batch of

the RV3 vaccine candidate, which is currently undergoing clinical evaluation in Australia; first in adults, then children, and, in the final stage, infants. Rotavirus is the leading cause of severe dehydrating diarrheal illness and deaths in infants and young children. While rotavirus infection is a global health care issue affecting nearly every child by the age of three, it has the most impact in developing countries where nearly 90 percent of the 500,000 rotavirus-related deaths occur annually.

The RV3 vaccine candidate was manufactured using the Vero working cell bank and RV3 master virus bank previously produced at MLS in 2009. Once again, MLS was able to meet the required target titer ensuring sufficient materials for additional clinical studies. Release testing of the vaccine has been completed. A component of the program with MCRI was for MLS to provide onsite training to representatives of

BioFarma in the manufacture and analysis of the RV3 vaccine candidate for eventual transfer to them for commercial scale production. The products produced at MLS will be used in Phase I and II clinical trials in Australia, New Zealand, and Indonesia.

Dr. Victor Van Cleave, Vice President of Research and Development for MLS, stated, “We were extremely pleased that MCRI returned to MLS for the second cGMP manufacturing run of the RV3 vaccine candidate. Once again, representatives from MCRI, and also PATH and BioFarma, worked hand-in-hand with our scientists to ensure a successful production run. MLS has extensive experience in the production of live viral vaccines in Vero cells, thus, this project was an excellent fit for our capabilities in viral vaccine manufacturing. It is rewarding to be a part of this important clinical vaccine development program that could prevent

rotavirus infection in infants.”

Dr. Carl Kirkwood, joint head of the Rotavirus Research Group at MCRI, was “extremely pleased with the repeated success at MLS to manufacture the clinical lots at the titres required for the clinical trials.”

“The RV3 rotavirus vaccine is a highly promising candidate that is naturally adapted to grow in the intestine of newborn babies. Delivering a rotavirus vaccine at birth could have several advantages. It provides the earliest opportunity to protect babies from rotavirus gastroenteritis, as well as potential benefits to streamlining implementation programs, particularly in developing countries,” said Professor Julie Bines, of MRCL, the University of Melbourne and The Royal Children’s Hospital Melbourne.

ABOUT MERIDIAN LIFE SCIENCE:

Meridian Life Science, Inc. provides contract R&D, process development,

and clinical cGMP biomanufacturing of vaccines, viral challenge materials, gene therapies, virus-like particles, and recombinant proteins at its contract biopharmaceutical manufacturing facility in Memphis, TN. This business focuses on materials that will be used in Phase I-II clinical trials that are intended for use as "injectables." As such, they are produced under cGMP Regulations for Biologics and Human Drugs under the auspices of the FDA. With over 25 years of cell culture experience, virus production, purification, assay development and quality, MLS has become a leader and trusted partner for Phase I-II cGMP biomanufacturing solutions. MLS also supplies critical assay reagents, antigens, antibodies, and contract biological R&D and manufacturing services to the research, diagnostic, and biopharmaceutical markets. MLS services its customers from three primary manufacturing operations in Memphis (Tennessee), Saco (Maine),

and Boca Raton (Florida). The Company’s shares are traded through NASDAQ’s Global Select Market, symbol VIVO. MLS’s website address is www.meridianlifescience.com.

ABOUT MURDOCH CHILDRENS RESEARCH INSTITUTE:

Murdoch Childrens Research Institute is Australia’s largest and most prestigious child health institute. Its staff work side by side with the doctors and nurses at Melbourne’s Royal Children’s Hospital and have a unique opportunity to make discoveries and translate them into real benefits for children. The team of 1,100 passionate researchers conduct innovative, world class research into a wide range of conditions affecting children, including asthma, premature birth, cancer, depression, genetic conditions, obesity, and infectious diseases. For more information, please visit Murdoch Childrens Research Institute's website (www.mcri.edu.au). ■

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