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*****For Immediate Release*****

PMG Research of Charleston is Participating in a Phase III Trial of an Investigational Vaccine for the Prevention of *Clostridium difficile*

Volunteers Needed for Study of Vaccine to Prevent Leading Cause of Healthcare-Associated Infections

Charleston, SC – April 9, 2015 – *Clostridium difficile* (C. diff) is the most common infection in American hospitalsⁱ, yet most people are unfamiliar with the disease and its severe effects. While most types of healthcare-associated infections (HAIs) are declining, C. diff is emerging as a leading cause of life-threatening HAIs worldwide. Between 2000 and 2010 the number of C. diff infections more than doubledⁱⁱ, and the numbers are still rising. The infection poses the greatest danger for older adults in hospitals or long-term care facilities who take broad-spectrum antibiotics and about 80% of deaths caused by C. diff are in people 65 years of age and olderⁱ.

About C. diff

C. diff is a bacterium that causes inflammation of the colon, known as colitis. The bacteria that cause C. diff are found in the feces and are spread easily through primary or secondary contact. People receiving treatment for other conditions with antibiotics are at much higher risk for contracting C. diff because antibiotics kill off other intestinal bacteria that fight off *C. diff*. In fact, more than 50 percent of hospital patients test positive for colonized C. diff organisms but do not exhibit any clinical symptoms.ⁱⁱⁱ When antibiotics disrupt the gut's normal flora and a person has ingested C. diff spores, the C. diff bacteria multiplies and releases potent toxins that can damage a patient's intestinal lining and cause C. diff disease.^{iv} Approximately 20 to 30 percent of patients experience recurrences of C. diff infections, which result in re-hospitalizations and longer hospital stays.^v

About the Research Study

PMG Research of Charleston is currently participating in a clinical study to evaluate an investigational vaccine for the prevention of C. diff. More than 200 sites across 17 countries around the world are partaking in the [Cdiffense](#) clinical trial, a Phase III randomized, observer-blind, placebo-controlled study. Volunteers for the study should be age 50 or older and planning an upcoming hospitalization of more than 72 hours for a surgical procedure. People in this age group who have had at least two hospital stays, each lasting more than 24 hours, and have received systemic antibiotics in the past year are also eligible.

“With the emergence of difficult-to-manage strains of C. diff, CDI has become more frequent, more severe and more difficult to treat in recent years, raising concerns about how to control it and prevent transmission,” explained Richard Mills, MD, of PMG Research of Charleston. “Vaccination could be an efficacious, cost-effective and important public health measure to protect individuals from C. diff.”

In 2010, the U.S. Food and Drug Administration (FDA) granted fast-track designation to the investigational C. diff vaccine candidate being developed by Sanofi Pasteur. The fast-track program of the FDA is designed to facilitate the development and expedite the review of new investigational drugs and vaccines that are intended to treat or prevent serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

For more information about the **Cdiffense** Phase III clinical trial, please contact the PMG Research of Charleston study coordinator at (843) 849-1880 or visit www.Cdiffense.org.

About PMG Research of Charleston

Dr. Richard Mills is a Board Certified physician specializing in Internal Medicine. He has been practicing with PMG Research of Charleston for 10 years. Dr. Mills earned his degree from Harvard College and was trained at University of Miami.

The clinical trial facility is located at 180 Wingo Way, Suite 203, Mt. Pleasant, SC 29464. For more information, please call (843) 849-1880 or email Jessica Collins at jcollins@pmg-research.com.

ⁱ Neporent, N. 'Super Bug' Linked Antibiotic Kills 30,000 Yearly. ABC News. 26 February 2015. <http://abcnews.go.com/Health/super-bug-linked-antibiotic-kills-30000-yearly/story?id=29226704>. Accessed March 3, 2015

ⁱⁱ Szabo, L. Dangerous infections now spreading outside hospitals. USA Today. 25 February 2015. <http://www.usatoday.com/story/news/2015/02/25/clostridium-difficile-infections-grow/23942147/> Accessed March 3, 2015

ⁱⁱⁱ Cohen SH, Gerding DN, Johnson S, Kelly CP, Loo VG, McDonald LC, Pepin J and Wilcox MH. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol 2010;31:431-55

^{iv} Delmee M and Warny M. (1995). Clostridium difficile colitis: recent therapeutical and immunological considerations. Acta Gastroenterol Belg, 58 (3-4), p. 313-317.

^v Garey KW, et al. (2008) Meta-analysis to assess risk factors for recurrent Clostridium difficile infection. Journal Hospital Infection, 70, p. 298-304.