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Emmes Supports Groundbreaking Anal Cancer Study Sponsored by the National Cancer Institute

Treatment of Precursor Lesions Was Found to Significantly Reduce the Risk of Progression to Anal Cancer, with Study Results Highlighted in the New England Journal of Medicine

Rockville, MD – June 16, 2022 – Emmes, a global, full-service clinical research organization (CRO) dedicated to supporting the advancement of public health and biopharmaceutical innovation, today announced that a team of its researchers contributed to a successful AIDS Malignancy Consortium (AMC) study. Results of the <u>study</u>, which demonstrated that treating and removing anal cancer precursor lesions reduced the cancer risk for HIV-infected men and women, were published in the *New England Journal of Medicine*. The Phase 3 trial results included 4,446 participants at 21 clinical sites across the U.S. and Puerto Rico.

The study enrolled people living with HIV aged 35 years and older who had at least one precursor lesion for anal cancer, called high-grade squamous intraepithelial lesions (HSIL). Participants were randomized into two groups: those who received treatment for the lesion(s) and those who were actively monitored but did not receive treatment. Participants were re-evaluated every three to six months. Rates of progression to anal cancer were compared between the two groups. The findings showed that treating HSIL resulted in a nearly 60 percent reduction in anal cancer progression among people living with HIV.

Emmes' role was to coordinate the research, which included protocol development, electronic data capture, site monitoring, and regulatory compliance, along with general study management for the research team.

The National Cancer Institute's <u>Office of HIV and AIDS Malignancy</u> sponsored the current study through the <u>AMC</u>, which was led by Joel Palefsky, MD, of the <u>University of California San Francisco</u> (UCSF).

Don Vena, vice president and head of Emmes' oncology therapeutic research unit, said, "Dr. Palefsky facilitated collaboration among varied stakeholders – government, industry, labs, clinical sites and our team – to build the research infrastructure needed to run a landmark trial in the developing field of anal cancer prevention. Emmes is proud to have been a contributor and proud of our 18-year relationship with the AMC."

Dr. Palefsky, who created the world's first clinic devoted to anal cancer prevention at USCF in 1991, reported that the data from the <u>ANal Cancer/HSIL Outcomes Research</u> (ANCHOR) study show for the first time that anal cancer can be prevented in high-risk populations, such as people living with HIV. He shared that the results are likely relevant for other groups at high risk of anal cancer, such as people who are immunosuppressed for reasons other than HIV, and women with a history of cervical or vulvar cancer, even though the study focused exclusively on those with HIV.

He presented the study highlights on February 15 at the Conference on Retroviruses and Opportunistic Infections, a highly regarded event for HIV/AIDS research that attracts infectious disease scientists and professionals from around the world. He noted that office-based electrocautery not only resulted in the reduction in anal cancer incidence but that the treatment was well-tolerated.

According to Dr. Palefsky, "Anal cancer is the fourth most common cancer among people living with HIV. Primary prevention of this disease can occur in the long-term, for those with little or no history of sexual activity, with the use of the human papillomavirus (HPV) vaccine. Unfortunately, many people have already been exposed to HPV, are over the age of vaccination, or do not have access to the vaccine. For these individuals, the ANCHOR study shows for the first time that secondary prevention of anal cancer is possible through treatment of anal HSIL. We expect that the results of the ANCHOR study will lead to adoption of screening and treatment of anal HSIL in people living with HIV as the standard of care."

Dr. Palefsky added, "The Emmes team played a key role in the success of the study through its diligent oversight and implementation of the many components of such a complex trial."

Dr. Christine Dingivan, Chief Executive Officer of Emmes, commented, "We are extremely pleased that the ANCHOR study showed that HSIL treatment is effective in reducing anal cancer risk, and it ultimately will have a profound effect on patients' quality of life. This project reflects how client tenure and close collaboration can make a big difference in public health – for people with HIV or at highest risk of anal cancer and for others in the future."

About the Research

This project has been funded with federal funds from the National Cancer Institute's Office of HIV and AIDS Malignancy under Grant No. #UM1CA121947.

About Emmes

Founded in 1977, Emmes is a global, full-service CRO dedicated to excellence in supporting the advancement of public health and biopharmaceutical innovation. The company's clients include numerous agencies and institutes of the U.S. federal government and a wide range of biotechnology, pharmaceutical and medical device companies throughout the world. To learn more about how our research is making a positive impact on human health, go to the Emmes website at www.emmes.com.