

Preventive Cancer Vaccine Trial Releases Two-Year Safety Evaluation

PHOENIX--([BUSINESS WIRE](#))--The Vaccine Against Canine Cancer Study (VACCS) trial (www.vaccs.org) reported its formal two-year evaluation of the safety of a vaccine to prevent cancer in healthy dogs. The largest interventional trial in dogs, it is sponsored by the Open Philanthropy Project, with additional support from Calviri, Inc., a biotech spinout from Arizona State University.

“This is an important milestone toward developing a preventive vaccine,
”

[Tweet this](#)

The VACCS trial intends to enroll up to 800 dogs in an equal arm, double-blind study of the vaccine versus mock inoculation. The Data Safety Monitoring Board (DSMB) for the VACCS trial is headed by Dr. Rod Page, director of the Flint Animal Cancer Center at Colorado State University. The DSMB evaluated the clinical records of over 600 dogs in the trial at the two-year mark, 300 of which had received the vaccine with yearly boosters. The DSMB concluded that there were no serious adverse events associated with the vaccination protocol in either arm of the study.

"This is an important milestone toward developing a preventive vaccine," said Stephen Albert Johnston, co-inventor of the vaccine and founding CEO of Calviri. "One of the criticisms of this vaccine effort, besides the unlikelihood of it working, has been that it might induce autoimmune responses. The DSMB concludes that for the over 300 dogs vaccinated there is so far no reason for such concern."

"The VACCS trial is collecting extensive clinical data on the enrolled dogs. Two independent veterinary oncologists and I reviewed the data and found no signs of a safety concern. The dogs in the trial are 6-11 years old when enrolled, so many may eventually develop aging-related conditions of different sorts, but there was no evidence of serious effects associated with the vaccine," said Page.

"This trial, besides testing the vaccine, is providing a wealth of other information," said Dr. Douglas Thamm, clinical director of the trial, and Professor of Oncology at the CSU Flint Animal Cancer Center. "For example, we are seeing a higher percentage of dogs with early-stage rather than late-stage tumors than observed in normal practice. We think this may be due in part to the regular, six-month exams the dogs receive."

The trial is expected to complete enrollment by the end of the year. The safety and efficacy will be evaluated each year. "Because of the latency period for tumor detection, we do not expect to see a decrease in tumor incidence, the primary clinical endpoint, until after year two, if the vaccine is working preventatively. We continue to be excited about this trial in our mission to end deaths from cancer. We

thank the dogs and the owner participants in this breakthrough clinical trial," said Marc Wolff, CEO of Calviri, Inc.

About Flint Animal Cancer Center

Flint Animal Cancer Center's mission is to improve the prevention, diagnosis, and treatment of cancer in pet animals, translating research and knowledge also to benefit people with cancer. The center offers the latest and most advanced diagnostics and treatments in surgery, chemotherapy, and radiation therapy. It attains its mission through an innovative study of cancer, thoughtful and compassionate care, specialized treatment options, and procedures. The Flint Animal Cancer Center continues to pursue a cure for cancer through its clinical oncology service, clinical trials, advanced clinical and research training for veterinarians, innovative research, and specialized consultation service available for clients and referring veterinarians. For more information, visit www.csuanimalcancercenter.org.

About Calviri, Inc

Calviri is a fully integrated healthcare company whose mission is to provide a broad spectrum of fundamentally different vaccines and companion diagnostics that prevent and treat cancer for those either at risk or diagnosed. Calviri is focused on using frameshift neoantigens derived from errors in RNA processing to provide pioneering products against cancer. The company is a spin out of the Biodesign Institute, Arizona State University. For more information, please visit www.calviri.com.