AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.
SUPPLEMENTARY INFORMATION: Technology description follows.

Human and Veterinary Cancer Therapeutic Agent Utilizing Anthrax Toxin-Based Technology

Description of Technology:

Due to the disorganized nature of blood vessels that run through tumors, chemotherapeutic agents often fail to penetrate tumors and kill cancer cells at the tumor’s center. This can lead to ineffective chemotherapeutic treatments, because tumors can quickly grow back if the entire tumor is not destroyed. NIH researchers have developed a therapeutic agent that solves this problem facing current chemotherapy treatments. By elegantly exploiting cell surface proteases present at high levels in tumors, they have developed a tumor-targeted anthrax based toxin that inactivates the blood vessels within tumors. While in some cases cancer cells are also killed by the tumor-targeted toxin, the primary mechanism of action is thought to be a decrease in blood flow to the center of tumors, causing cancer cell death and tumor necrosis. Preliminary and on-going studies have demonstrated that the targeted toxins have antitumor effects on melanomas, lung cancers and colon cancer in mouse models, and on feline and canine oral tumors. Interestingly, this therapy does not target a specific type of cancer cell, rather it targets the vasculature in and around tumors. Therefore, it has great potential to treat a wide range of solid tumors. Additionally, because few non-surgical treatments are available to treat many human and veterinary solid tumors, this technology would fill an unmet need in cancer therapy.
This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

**Potential Commercial Applications:**

Therapeutic agent for a wide range of human and veterinary solid tumors, including:

- Melanomas
- Lung and colon cancers
- Oral squamous carcinomas

**Competitive Advantages:**

- Proven effective in a variety of models, including models of important veterinary cancers
- Agent is only active in tumor micro-environments, resulting in low toxicity to healthy tissue
- Cancer cells are not directly targeted, so this agent can be used to treat a broad spectrum of solid tumors and resistance is unlikely to arise
- Fills an unmet need in cancer therapy, because few non-surgical treatments exist

**Development Stage:**

- *in vitro* data available
- *in vivo* data available (animal)
- prototype

**Inventors:**

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**Intellectual Property:**


**Licensing Contact:**

Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov

**Collaborative Research Opportunity:** The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize anthrax toxin-based
cancer therapeutics. For collaboration opportunities, please contact Dr. Natalie Greco, 301-761-7898; Natalie.Greco@nih.gov.

Dated: June 1, 2017.

**Suzanne Frisbie,**

*Deputy Director,*

*Technology Transfer and Intellectual Property Office,*

*National Institute of Allergy and Infectious Diseases.*

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