UNIVERSITY OF GEORGIA
Center for Vaccines And Immunology

Prevention and Treatment of *Pneumocystis* Pneumonia and other Fungal Pathogens

INVENTION: University of Georgia investigators have produced vaccines for the prevention of *Pneumocystis* pneumonia (PCP) and other fungal infections that affect immunocompromised individuals, such as HIV-infected individuals and those receiving immunosuppressive therapies.

Pneumocystis pneumonia (PCP) is the most common opportunistic infection of individuals with HIV infection, with an estimated 20% of all HIV patients at risk of infection. PCP is also a life-threatening complication of immunocompromised individuals and those on immunosuppressive chemotherapeutic regimens. The vaccine would be useful for the prevention of *Pneumocystis* pneumonia and broadly protective against other fungal infections in early stage HIV-infected persons, as well as in individuals planning to undergo immunosuppressive therapies, such as organ transplant recipients and individuals on anti-inflammatory therapies. In addition to the vaccine for the prevention of PCP, related vaccines for other medically relevant fungal infections caused by *Aspergillus sp., Candida, sp.* and *Cryptococcus neoformans* are in development. The pan-fungal vaccine would have the combined effect of preventing life-threatening PCP as well as other fungal infections that are often the most serious and intractable infections of chronically ill patients.

Additionally, the vaccines and therapeutics developed here may be effective in preventing or ameliorating *Pneumocystis*-associated Chronic Obstructive Pulmonary Disease (COPD).

APPLICATIONS:

- Prevention of PCP by immunization of healthy individuals (prophylactic vaccination) prior to immunosuppression (*e.g.* prior to initiation of immunosuppressive therapy for transplantation/cancer treatment or early stage HIV infection)
- Therapeutic vaccination using T-helper cell-independent immunization strategies for use in immunocompromised individuals.
- Pan-fungal vaccines for the prevention of infections including *Pneumocystis* pneumonia, Aspergillosis, Candidiasis and Cryptococcosis.
- Diagnostic reagents for fungal infections
- Immuno-therapeutic, monoclonal antibodies for treatment of acute PCP.

ADVANTAGES:

- The *Pneumocystis* vaccine candidate is highly immunogenic and conserved among medically relevant fungal opportunistic pathogens.
- Sero-prevalence to the vaccine protein is high among adults due to natural environmental exposure to *Pneumocystis*, thus immunization significantly boosts pre-existing memory responses resulting in the rapid development of protective humoral responses.
- Protective immunity can be elicited in immune-competent hosts prior to scheduled immunosuppressive therapeutic regimens, such as for organ transplantation, thus minimizing the risk of subsequent fungal infections.

STAGE OF DEVELOPMENT: Completion of pre-clinical, non-human primate studies (Kling, et al 2016, J. Infect. Dis.)

BACKGROUND: Fungal diseases are an increasing clinical burden, particularly among immunocompromised patients and there are presently no anti-fungal vaccines approved for clinical use. With increases in immunocompromised patient population, the risk of serious fungal infections and their complications will continue to rise. In these populations, infection with the opportunistic pulmonary pathogen *Pneumocystis jirovecii* remains an important cause of morbidity and mortality. We have developed protein-based vaccine against *Pneumocystis* infection that is protective in a pre-clinical, non-human primate model of HIV-*Pneumocystis* co-infection.

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In addition to causing life-threatening pneumonia, *Pneumocystis* infection is a co-factor associated with the development of **Chronic Obstructive Pulmonary Disease (COPD),** also known as emphysema and chronic bronchitis. COPD is the fourth leading cause of death worldwide with over 3 million deaths per year and is linked to cigarette smoking, air pollution and HIV infection. We have reported that *Pneumocystis* colonization is an independent predictor of COPD in HIV infected individuals and smokers and that persistent colonization with *Pneumocystis* leads to the development of COPD. The vaccines developed here may be effective in preventing or ameliorating *Pneumocystis*-associated COPD.

The *Pneumocystis* vaccine candidate is highly immunogenic and conserved among other fungal pathogens. Fungal cross-reactive peptide candidates are in development for use as a pan-fungal vaccine for the prevention of infections by other clinically relevant pathogens including ***Aspergillus, Cryptococcus* and *Candida spp.***

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PATENT STATUS: Pending and Issued US Patents: 9,181,538; 9,914,917

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