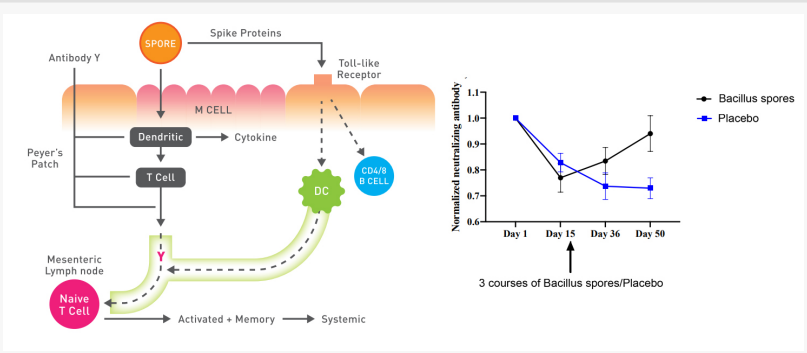
Inactivated Bacillus subtilis Spores Generate Effective Immune Response Against COVID-19

Safety and Immunogenicity Results for Covid-19 Vaccines in Humans with Heterologous Antibody Booster



Neutralizing Antibodies increased 20% after administered with Bacillus spores

Dr. Keith Kwong from DreamTec Research and Dr. Dominic Man Kit Lam, Former Professor in Harvard University and Texas Medical Center

HONG KONG, June 29, 2022 /EINPresswire.com/ -- DreamTec Research Limited today announces the results of an ongoing investigator-initiated trial who demonstrated an increase in SARS-CoV-2 neutralizing antibodies after receiving a DreamTec antibody booster. These results, described in a research article published in Vaccines on June 24, Safety and Immunogenicity of Inactivated Bacillus subtilis Spores as a Heterologous Antibody Booster for Covid-19 Vaccines, provide a foundation for further clinical data needed to demonstrate the safety and efficacy of utilizing recombinant Bacillus subtilis spores as effective heterologous (different variants) boosters for SARS-CoV-2 vaccinated individuals.

“We collaborated with Macao Greater Bay Area Association of Healthcare Providers to conduct a clinical trial in Macau,” says DreamTec’s Executive Director and Chief Scientific Officer, Dr. Keith Wai-Yeung Kwong, “with 16 people who were vaccinated with two shots of the Pfizer or Sinovac Covid-19 vaccines over a six-month period. Each individual was assayed for neutralizing antibodies against the SARS-CoV-2 spike protein after administered with Bacillus spores or placebo. Our team and collaborators reported last week that neutralizing antibodies against the spike protein dropped

over time in individuals taking placebo, while those who received a probiotic consisting of inactivated Bacillus subtilis spores increased their neutralizing antibodies by an average increase of 20%."

Dr. Kwong further explains that such a vaccination boosting approach has several advantages, including the ability to rapidly engineer SARS-CoV-2 spike variants to better reflect current variants, such as Omicron BA.1 and BA.2. He states that Bacillus subtilis spores displaying SARS-CoV-2 can be easily constructed, stored, and delivered to people as a probiotic that does not require cold-storage conditions.

In recent years, research findings have indicated that Bacillus subtilis, which is regarded by the FDA as Generally Recognized As Safe (GRAS) in specific probiotic conditions, has characteristics and properties that are ideal as oral vaccines consumed as a probiotic. Oral vaccines made with engineered Bacillus subtilis spores expressing antigens are known to stimulate systemic and localized immune responses with expected antibody production.

Miss Vick Lam, Dr. Tomas Kuok and Miss Vian Leung from Macao Greater Bay Area Association of Healthcare Providers

Dr. Kwong, Dr. Dominic, Man Kit Lam, former professor at Harvard University and Texas Medical Center, pioneer of oral vaccine, and his colleagues have confidence their efforts with SARS-CoV-21, will similarly result in viable boosters and vaccines ideal for real-world conditions without the need for cold-chain storage. Previously, they provided detailed descriptions of their advanced oral vaccine technology in Vaccines and in the design of clinical trials. In addition, they reported that the expression of a SARS-CoV-2 spike protein receptor binding domain (sRBD) on the surface of Bacillus subtilis (B. Subtilis) spores with human volunteers generated an immune response and showed no adverse effects.

"With new SARS-CoV-2 variants appearing globally on a regular basis," says Dr. Kwong, "it is essential that we focus on effective Covid-19 immunity boosters with the best chance of making it to people worldwide."

Dr. Lam explains that more new variants are expected in the future, due to the genomic instability of SARS-CoV-2. The key to fighting this Covid-19 pandemic, He states, and other different pathogens likely to come, is from rapid responses including boosters that are tailor-made to target specific variants.

“I am glad of the progress we and our colleagues continue to develop oral vaccines and boosters,” they state. “Our next steps include making Bacillus subtilis spores displaying the Omicron SARS-CoV-2 variant. This will showcase how we can rapidly meet such variant challenges in a timely manner.”

1. Sung JC-C, Lai NC-Y, Wu K-C, Choi M-C, Ma CH-Y, Lin J, Kuok C-N, Leong W-L, Lam W-K, Hamied YK, Lam DM-K, Sze ET-P, Kwong KW-Y. Safety and Immunogenicity of Inactivated Bacillus subtilis Spores as a Heterologous Antibody Booster for COVID-19 Vaccines. Vaccines. 2022; 10(7):1014. https://doi.org/10.3390/vaccines10071014

2. Sung et al., Expression of SARS-CoV-2 Spike Protein Receptor Binding Domain on Recombinant B. subtilis on Spore Surface: A Potential COVID-19 Oral Vaccine Candidate (2021) Vaccines 10, 2 https://doi.org/10.3390/vaccines10010002

3. Amuguni et al., Fragment Modulates Immune Response Elicited by Recombinant Bacillus subtilis Spores Presenting an Antigen/Adjuvant Chimeric Protein. Mol. Biotechnology. 2018, 60, 810–819.

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