

DreamTec COVID-19 Oral Vaccine With SARS-CoV-2 Spike Protein Elicits Immune Response in Pilot Human Clinical Trial

Successful Achievement on the Development of a COVID19 Oral Vaccine Consisting of Bacillus Subtilis Spores by DreamTec

HONG KONG, CHINA, February 9, 2022 /EINPresswire.com/ -- DreamTec Research Limited today reports the completion of a clinical trial with Dr. Sahar Shojaei, of the National Institute of Genetic Engineering and Biotechnology & Middle East Cell and Gene Therapy. The preliminary results are promising in that over 60% of the volunteers acquired sera with antibodies against SARS-CoV-2 spike proteins, and will be published in a peer-reviewed journal in the near future.

DreamTec's Executive Director and Chief Scientific Officer, Dr. Keith WY KWONG, said, "This is an important development in our journey to develop an effective oral SARS-CoV-2 vaccine."

He states that DreamTec is meeting its milestones to conduct clinical trials in humans to demonstrate acquired immunity to SARS-CoV-2 via an oral vaccine and wants to share this update prior to publication.

In addition to the widely popular mRNA SARS-CoV-2 vaccines (Pfizer, Moderna) and related viral constructs (Janssen, Oxford-AstraZeneca), an oral SARS-CoV-2 vaccine offers additional advantages: stable storage at room temperature, easy to administer (probiotic capsule), cost-effective and no shots. These benefits are especially applicable for large populations in



MiCOVAC, a oral vaccine booster supplement developed by DreamTec



Dr. Keith Kwong from DreamTec Research

developing nations where cold storage and the need to administer shots in arms poses significant obstacles to vaccination.

“These are among the first clinical results of an oral SARS-CoV-2 vaccine in humans,” Dr. Kwong said. He states that 40 volunteers were administered an oral vaccine on days 1,14, and 28. On days 0, 21, and 42, blood samples were examined for neutralizing antibodies towards the SARS-CoV-2 spike protein, and over 60% taking the oral vaccine generated antibodies via a gut mucosal immune response.



GMP Pharmaceutical Production Facility in DreamTec HK

Previously, Dr. Kwong and his colleagues provided detailed descriptions of their advanced oral vaccine technology in Vaccines[1] and in the design of clinical trials[2,3]. Their research indicated 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 showed no adverse effects and, importantly, generated an immune response. As reported, the production of a Covid-19 oral vaccine and antibody booster utilizing *B. subtilis* spores is an industry breakthrough for oral vaccines.

“These clinical results with humans are showing the potential of our engineered *B. Subtilis* oral vaccine technology, which here includes SARS-CoV-2 spike protein expression, to result in an immune response by way of the human gut,” said Dr. Kwong.

“In this trial, human volunteers swallowed probiotic capsules containing *B. Subtilis*. The acidic conditions in the gut enable the *B. Subtilis* to release spores in the small intestine, expressing a SARS-CoV-2 spike Receptor Binding Domain (sRBD) on their surfaces. A mucosal immune response generated in the small intestine led over 60% of the volunteers to make antibodies towards this SARS-CoV-2 antigen, which is very encouraging.” He added that *B. Subtilis* has long been a favorable member of the human microbiome, and that the US Food & Drug Administration (FDA) views certain (*B. Subtilis*) strains as Generally Recognized As Safe (GRAS).

“At this time,” Dr. Kwong said, “DreamTec is focused on our *B. Subtilis* SARS-CoV-2 oral vaccine technology and our ongoing clinical trials to demonstrate efficacy. In the future, we envision additional applications with vaccines.

References:

1. 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>
2. The Development of a COVID-19 Oral Vaccine Consisting of Bacillus subtilis Spores.
<https://clinicaltrials.gov/ct2/show/NCT05057923>
3. Oral Neutralizing Antibody Booster for Post-vaccinated People With COVID-19 Vaccine.
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