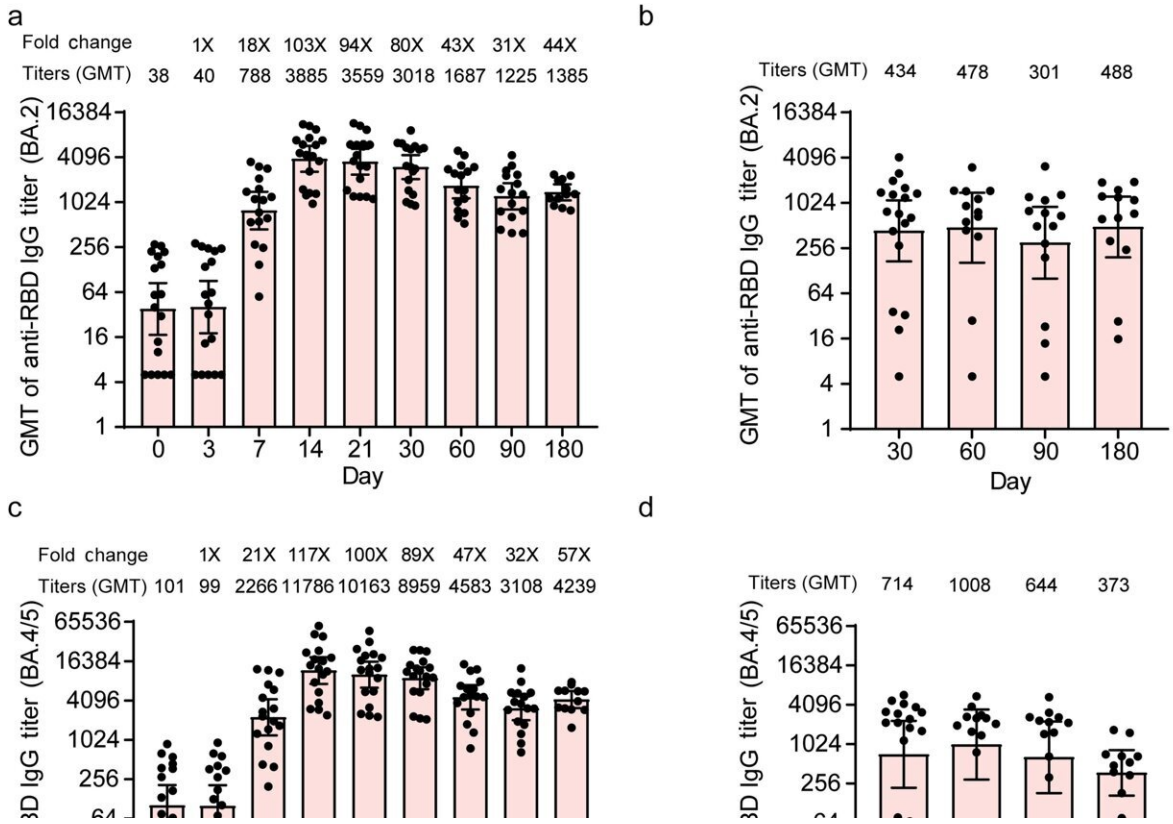
Safety and immunogenicity of COVID-19 mRNA vaccine SYS6006 evaluated in Phase 1 trial

June 30 2023



RBD-binding antibodies to omicron BA.2 and BA.4/5 of SARS-CoV-2. GMTs of RBD-binding IgG titers against omicron BA.2 in SYS6006 group (a) and convalescent group (b). GMTs of RBD-binding IgG titers against omicron BA.4/5 in SYS6006 group (c) and convalescent group (d). SCR of RBD-binding IgG titers against omicron BA.2 (e) and omicron BA.4/5 (f). Data are GMT (95% CI). Error bars indicate 95% CIs. RBD: receptor binding domain of spike

glycoprotein. Credit: *Life Metabolism* (2023). DOI: 10.1093/lifemeta/load019

The COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in more than 600 million confirmed cases and 6.5 million deaths worldwide. mRNA-based vaccines have emerged as a leading platform for COVID-19 protection and are extensively investigated in basic and clinical trials.

SYS6006 (CSPC Pharmaceutical Group) is a newly investigational COVID-19 mRNA vaccine encoding a full-length S protein sequence of the prototype SARS-CoV-2 strain and incorporating the key mutations of main epidemic variants. In March 2023, it was authorized for emergent use in China by the national medicinal product agency (NMPA) of China. Yet, the data from clinical trials have not yet been published. Moreover, the third dose of inactivated vaccine of COVID-19 has been proposed as the initial boosting regimen, and the second heterologous booster (the fourth dose of the vaccine) is worth investigating.

By enrolling eligible healthy subjects and convalescent COVID-19 patients, researchers from Shanghai Xuhui Central Hospital have worked to unveil the first clinical safety and efficacy profile of SYS6006. Eighteen eligible participants, who had completed three doses of inactivated COVID-19 vaccines, received a fourth boosting dose of SYS6006-20 μg. Eighteen convalescent COVID-19 patients were enrolled for the collection of serum samples as a comparator of immunogenicity. The incidence of adverse events within 30 days after the boosting was collected and reported.

The titers of anti-RBD antibodies of the omicron strain (BA.2 and BA.4/5) in serum and titers of neutralizing antibodies against

pseudovirus of the omicron strain (BA.2 and BA.4/5) were evaluated from baseline (day 0) until day 180 post-vaccination.

Additionally, specific T-cell responses against SARS-CoV-2 were measured by detecting the production of interferon gamma (IFN-γ) positive spots with ELISpot assay. This study entitled "Safety and immunogenicity of a modified COVID-19 mRNA vaccine, SYS6006, as a fourth-dose booster following three doses of inactivated vaccines in healthy adults: an open-labeled Phase 1 trial" is now published in the journal *Life Metabolism*.

In the study, no serious adverse events were reported within 30 days after vaccination. No Grade 3 fever or serious adverse event was reported in the SYS6006 group. Notably, SYS6006 elicited higher titers and longer increases in anti-RBD antibodies and neutralizing antibodies (>90 days) compared with the convalescent group (P