



Development of intranasal live attenuated SARS-CoV-2 vaccine

Nobuyoshi Hasebe/

The Research Foundation for Microbial Diseases of Osaka University

Background

COVID-19, first identified in 2019, remains an infectious disease that requires continued prevention and treatment measures. This is clearly demonstrated by the fact that the number of deaths attributable to COVID-19 in Japan exceeded 30,000 even in 2024. Although currently available mRNA vaccines made a major contribution to controlling the pandemic, several issues have become clear, including adverse reactions such as fever and pain, as well as the relatively short duration of protection. These issues remain to be addressed, and there is an unmet need for next-generation vaccine modalities that can provide improved safety, long-lasting protection, and broader protection against a wide range of viral variants.

BK2102, which is currently under development, is an intranasally administered live attenuated vaccine against COVID-19 and is a novel vaccine modality that has not yet been put into practical use for this disease. In contrast to existing injectable vaccines, including mRNA vaccines, BK2102 is expected to cause fewer adverse reactions and to prevent infection through the induction of mucosal immunity. Moreover, non-clinical study results indicate that BK2102 has an acceptable safety profile and may provide longer-lasting immune responses and broader protective efficacy.

Therefore, the development of BK2102 is expected not only to address some of the issues associated with existing vaccines but also to contribute to improving vaccination coverage.

Objective

The primary objective of this project is to evaluate the safety of BK2102 in humans through a Phase I clinical trial. In addition, as an exploratory objective, the project aims to obtain indicators of effectiveness to support the design and conduct of a subsequent Phase II clinical trial.

Through these efforts, the project aims to accelerate the clinical development of a novel intranasally administered live attenuated vaccine, thereby providing a new vaccine modality for COVID-19 and contributing to readiness for future emerging respiratory infectious diseases.