NEWS RELEASE

Now ideas for wellness

meiji

Meiji Seika Pharma Co., Ltd.

February 5, 2024

Persistence of Immune Response of Kostaive™, Self-Amplifying mRNA Vaccine Against COVID-19, compared to COMIRNATY® was Published in *The Lancet Infectious Diseases*

- **GMTs against Wuhan-Hu-1 remained higher 6-months after Kostaive™ than those observed 1-month after COMIRNATY®.**
- **These results follow approval of Kostaive™, the world's first sa-mRNA COVID-19 vaccine for adults, by Japan Ministry of Health, Labor and Welfare in November 2023.**

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced today that persistence of immune responses of Kostaive™ (ARCT-154), self-amplifying mRNA vaccine against COVID-19, compared to COMIRNATY® (BNT162b2) were published in *The Lancet Infectious Diseases*.
(https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00060-4/fulltext)

Despite the high efficacies of conventional mRNA vaccines against Wuhan-Hu-1 strain and early SARS-CoV-2 variants, they elicit a relatively short duration of immunity. For example, the effectiveness those vaccines against omicron declined to below 20% within 6 months of vaccination[1]. The ongoing risk of COVID-19 outbreaks due to persistent viral circulation necessitates new vaccines to extend vaccine-induced immunity ideally for at least one year to meet new annual immunization recommendations[2].

In the reported study, Japanese adults who had been primed with two dose of mRNA vaccine and a booster dose of COMIRNATY® at least three months earlier were randomized equally to receive a second booster of either Kostaive™ (n=420) or COMIRNATY® (n=408)[3]. In this extension analysis, 332 and 313 participants, respectively, were left eligible for inclusion at the 6-month time point.

The authors previously reported that a booster dose of Kostaive™ induced superior immunogenicity

than COMIRNATY® one month after administration. As for the secondary-endpoint of this study, three-months post-booster, GMTs against Wuhan-Hu-1 in Kostaive™ and COMIRNATY® groups were 5928 and 2899, a higher GMT ratio of 2.04 (1.80-2.32). Six-months post-booster, GMTs were 4119 and 1861, respectively, maintaining a GMT ratio of 2.21 (1.91-2.57) between vaccine groups. GMTs against Wuhan-Hu-1 strain remained higher 180 days after Kostaive™ than those observed 1-month after the COMIRNATY® booster (Figure 1).

Kostaive™ is a vaccine against COVID-19 applying self-amplifying mRNA technology. It is designed to self-amplify* once delivered into cells, so that it generates a strong immune response and the potential for extended duration of protection while using lower doses of mRNA compared to existing mRNA vaccines. Meiji Seika Pharma is currently working for the vaccines against novel variants of COVID-19 virus, toward the goal of commercialization in 2024.

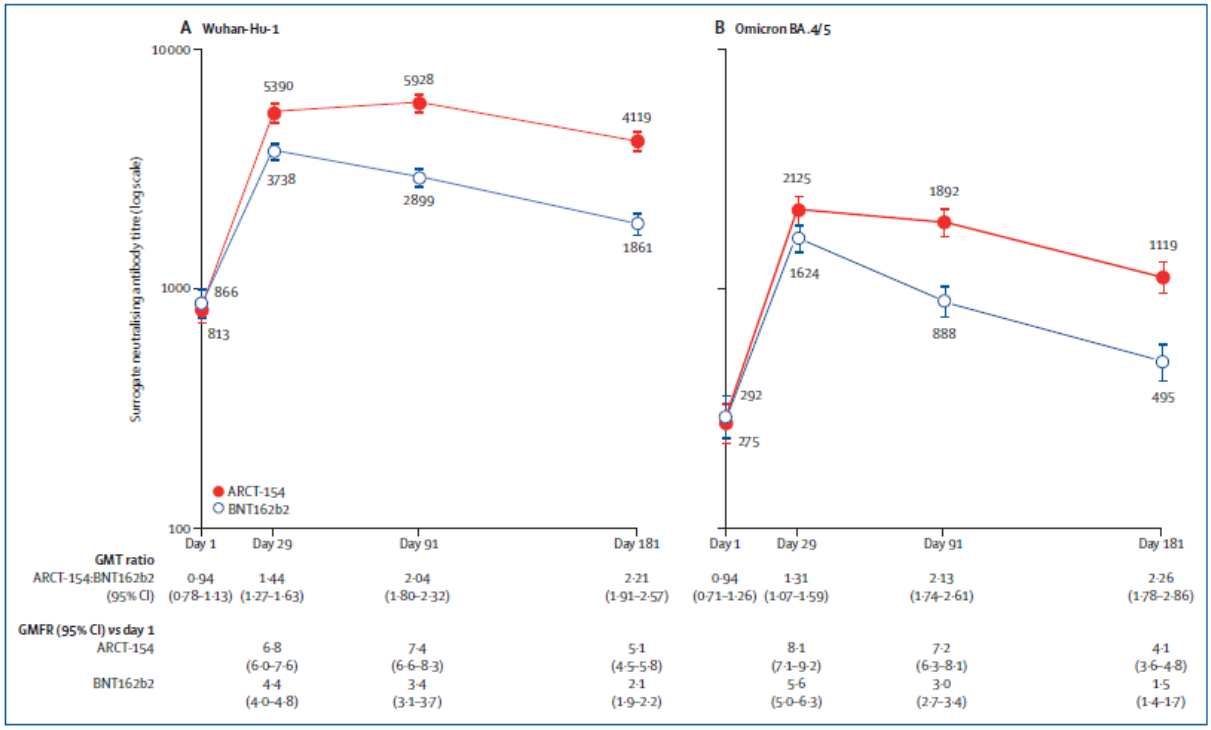

Figure: **Geometric mean titres (with 95% CIs) of surrogate neutralising antibodies against the SARS-CoV-2 Wuhan-Hu-1 (A) and Omicron BA.4/5 (B) strains up to 6 months after vaccination with one booster dose of either ARCT-154 or BNT162b2**

GMT ratios (95% CI) for ARCT-154:BNT162b2 are shown for days 1, 29, 91, and 181 and GMFR (95% CI) are shown for each group at days 29, 91 and 181. GMFR=geometric mean-fold rises over baseline. GMT=geometric mean titre.

(Oda Y et al. Lancet Infect Diseases; published online February 1, 2024)

References:

(1) Andrejko KL, Pry JM, Myers JF, et al. Waning of 2-dose BNT162b2 and mRNA-1273 vaccine effectiveness against symptomatic SARS-CoV-2 infection accounting for depletion-of-susceptibles bias. Am J Epidemiol2023; 192: 895–907.

(2) WHO. COVID-19 advice for the public: getting vaccinated. Dec 5, 2023. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice (accessed Jan 2, 2024).

(3) Oda Y, Kumagai Y, Kanai M, et al. Immunogenicity and safety of a booster dose of a self-amplifying RNA COVID-19 vaccine (ARCT-154) versus BNT162b2 mRNA COVID-19 vaccine: a double-blind, multicentre, randomised, controlled, phase 3, non-inferiority trial. Lancet Infect Dis 2023; published online Dec 20. https://doi.org/10.S1473-3099(23)00650-3.