Immunogenicity, reactogenicity, and safety of an mRNA-based seasonal influenza and SARS-CoV-2 multicomponent vaccine, mRNA-1083, in adults aged ≥50 years in Japan

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Disclosures and Acknowledgements

- Alexander Rumyantsev, Seun Osibajo, and Lusine Kostanyan are employees of Moderna, Inc., and may hold stock or stock options
- Osamu Kogawara and Koichi Hashizume are employees of Moderna Japan Co., Ltd. and may hold stock or stock options
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Background

- Influenza and COVID-19 remain major causes of morbidity worldwide and in Japan, particularly among older adults[1,2]
- Despite vaccine availability, uptake of influenza and COVID-19 vaccines remains below WHO-recommend levels[3-5]
- Viral evolution and seasonal circulation support the need for recurrent immunization strategies[6,7]
- mRNA-based vaccines are a well-established vaccine platform capable of inducing robust immune responses with favorable safety profiles, demonstrating effectiveness across diverse populations, including older adults[8]
- A combined influenza and COVID-19 vaccine could simplify vaccination within increasingly complex immunization schedules and improve vaccine coverage[9]
- In a phase 3 study in the United States(NCT06097273), mRNA-1083, an investigational multicomponent mRNA vaccine targeting seasonal influenza and SARS-CoV-2, met non-inferiority criteria; higher immune responses were induced with mRNA-1083 compared with recommended standard-of-care influenza and COVID-19 vaccines against SARS-CoV-2 and the 3 clinically relevant influenza strains in adults ≥50 years; mRNA-1083 also had an acceptable safety and tolerability profile[10]

Here, we present findings from Part 1 (Japan) of the APAC regional program phase 3 trial evaluating immunogenicity, reactogenicity, and safety of mRNA-1083 in adults aged ≥50 years

APAC, Asia-Pacific WHO, World Health Organization.

1. Arashiro T, et al. *Influenza Other Respir Viruses*. 2024;18(11):e70032. 2. WHO. WHO COVID-19 Dashboard. https://data.who.int/dashboards/covid19/cases?n=c. 3. WHO. Global COVID-19 vaccination strategy in a changing world: July 2022 update. https://www.who.int/publications/m/item/global-covid-19-vaccination-strategy-in-a-changing-world--july-2022-update 4. WHO. Understanding the drivers of influenza vaccine uptake. https://www.who.int/news-room/feature-stories/detail/understanding-drivers-of-influenza-vaccine-uptake 5. Goldin S, et al. Vaccine. 2024;42:126274. 6. Centers for Disease Control and Prevention. How Flu Viruses Can Change: "Drift" and "Shift". https://www.cdc.gov/flu/about/viruses/change.htm. 7. Yewdell, J.W. *Immunity*, 2021. 54(12):2681-2687. 8. Gote V, et al. *Int J Mol Sci.* 2023; 24: 2700. 9. Domnich A, et al. *Pharmaceuticals*. 2022;15:322. 10. Rudman Spergel AK, et al. *JAMA*. 2025;333(22):1977-1987.

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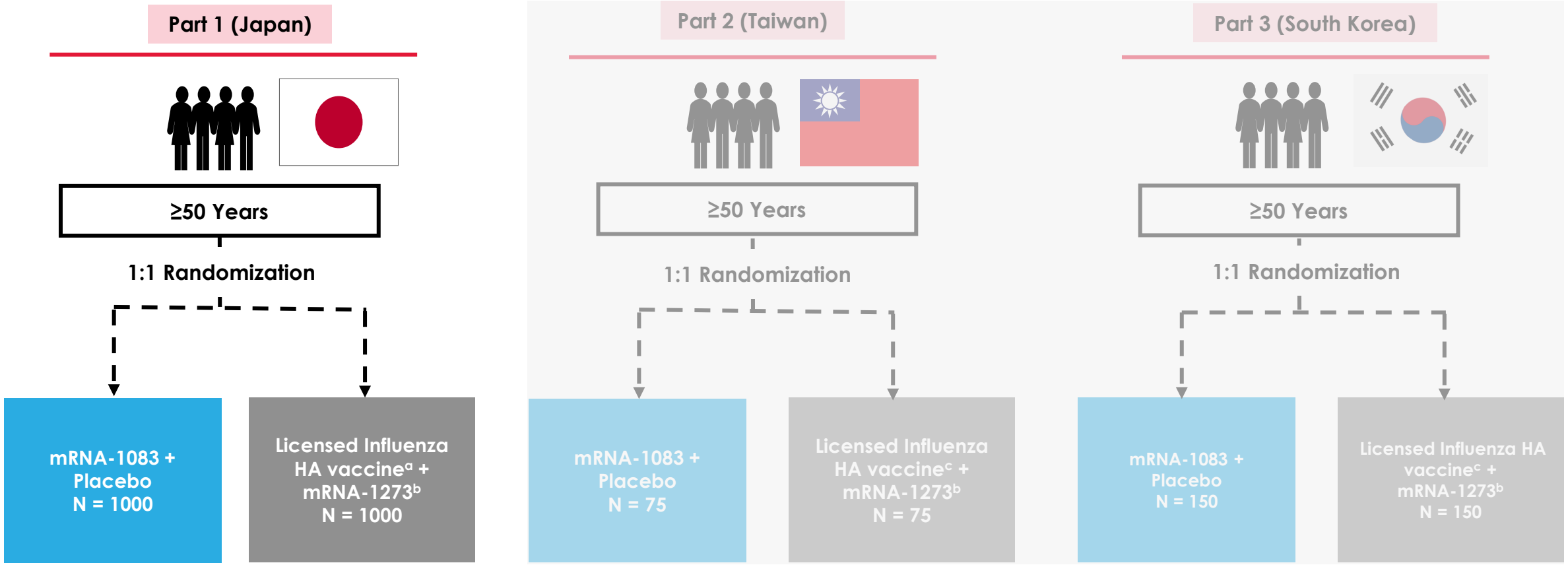
Study Design

Phase 3, Randomized, Observer-Blind, Active Controlled Study Evaluating Immunogenicity, Reactogenicity, and Safety of mRNA-1083 in Adults (NCT06694389)



HA, hemagglutinin.
Comparator vaccines: [a]Japan-licensed influenza HA vaccine; [b]SPIKEVAX®; [c]Fluarix Tetra.
Database Lock: August 11, 2025.

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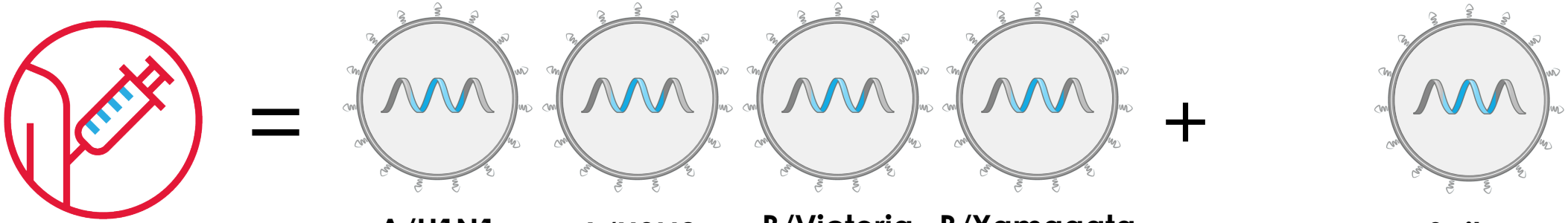
mRNA-1083: Investigational Multicomponent Vaccine against Seasonal Influenza and COVID-19

mRNA-1083

Influenza Components (mRNA-1010)

SARS-CoV-2 Component (mRNA-1283)



In phase 3 trials, mRNA-1010 and mRNA-1283 demonstrated efficacy, and were well tolerated and immunogenic[1-3]

HA, hemagglutinin; NTD, N-terminal domain; RBD, receptor binding domain.

1. Soens M, et al. *Vaccine*. 2025; 50: 126847. 2. Malkin E et al. Presented at IDWeek 2025; October 20, 2025; Atlanta, Georgia, USA. 3. Chalkias, S et al. *Lancet Infect Dis.*2025; 25(11):1230-1242.
Fukase H, et al. Immunogenicity, reactogenicity, and safety of an mRNA-based seasonal influenza and SARS-CoV-2 multicomponent vaccine, mRNA-1083, in adults aged ≥50 years in Japan. Presented at: ESCMID 2026; April17-23, 2026; Munich, Germany.

Study Design: Part 1 (Japan)

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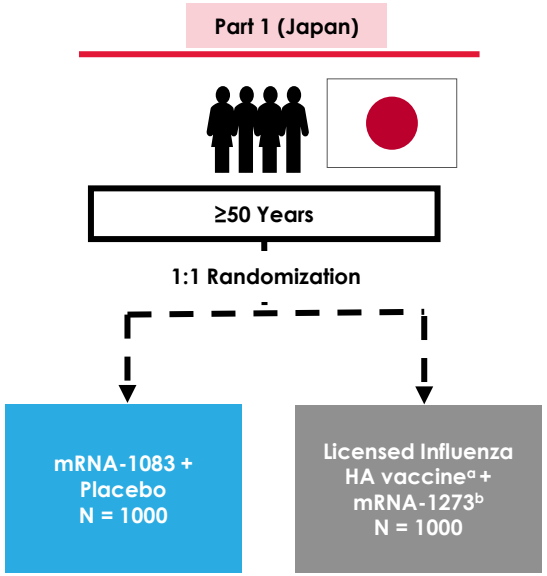

Assessments

Vaccination
- Participants received study injection on Day 1

Sample collection
- Blood samples were collected on Days 1 and 29
- Blood samples were collected from a subset of participants on Day 181

Safety Follow-up
- Solicited ARs through 7 days after study injection
- Unsolicited AEs through 28 days after study injection
- MAAEs, AESIs, AEs leading to discontinuation, and SAEs from Day 1 to the end of study (Day 181)

Duration
- Study Initiation: November 2024
- Study completion: June 2025

Study Objectives

Primary
- NI of mRNA-1083 versus active comparators against SARS-CoV-2 and influenza (strains in mRNA-1083) at Day 29
- NI of mRNA-1083 versus active comparator against influenza (strains in active comparator) at Day 29
- Reactogenicity and safety (through Day 181/end of study)

Key Secondary
- NI of mRNA-1083 versus active comparator against SARS-CoV-2 and influenza (strains in active comparator) at Day 29 in high-risk participants[c]
- Superiority of mRNA-1083 versus active comparators against SARS-CoV-2 and influenza (strains in the active comparator) at Day 29

AE, adverse event; AESI, AE of special interest; AR, adverse reaction; HA, hemagglutinin; MAAE, medically attended AE; NI, non-inferiority; SAE, serious AE.
Comparator vaccines: [a]Japan-licensed HA vaccine; [b]SPIKEVAX®; [c]aged ≥65 years or those aged 60–65 years with at least one comorbidity of interest.
Database Lock: August 11, 2025.

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Demographics and Baseline Characteristics (Safety Set)

	mRNA-1083 + Placebo N=1013	Influenza HA + mRNA-1273 N=1000
Age, years		
Median (range)	67.0 (50, 88)	67.0 (50, 89)
Age group, n (%)		
50 to 65 years	303 (29.9)	298 (29.8)
≥65 years	710 (70.1)	702 (70.2)
Sex, n (%)		
Female	265 (26.2)	267 (26.7)
Race, n (%)		
Japanese	1009 (99.6)	999 (99.9)
Multiple	4 (0.4)	1 (0.1)
BMI group, n (%)		
<30 kg/m^2	954 (94.2)	952 (95.2)
Comorbidity of interest, n (%)[a]		
Yes	205 (20.2)	186 (18.6)
High-risk, n (%)[b]		
Yes	729 (72.0)	713 (71.3)
Influenza vaccine received in the past 12 mo., n (%)	74 (7.3)	63 (6.3)
COVID-19 vaccine received in the past 12 mo., n (%)	104 (10.3)	110 (11.0)

- **Demographics and baseline characteristics were balanced between groups**

BMI, body mass index; HA, hemagglutinin; mo, months.
Safety set consisted of all participants who were randomly assigned and received the study intervention. Participants were included in the study group corresponding to the intervention received.
[a]Comorbidities of interest: diabetes mellitus (type 1 or type 2); significant cardiac disease (eg, heart failure, coronary artery disease, congenital disease, cardiomyopathies, and pulmonary hypertension); chronic lung disease (eg, emphysema and chronic bronchitis), idiopathic pulmonary fibrosis, or moderate to severe asthma; renal disease (chronic kidney disease); autoimmune/immune-mediated disorders; blood disorders; nervous system disorders; hepatic disorders; mental impairment disorders; obesity, body mass index >30.
[b]Participants with high-risk conditions include those aged 65 years and older, as well as those aged 60-65 with at least one comorbidity of interest.
Database Lock: August 11, 2025.

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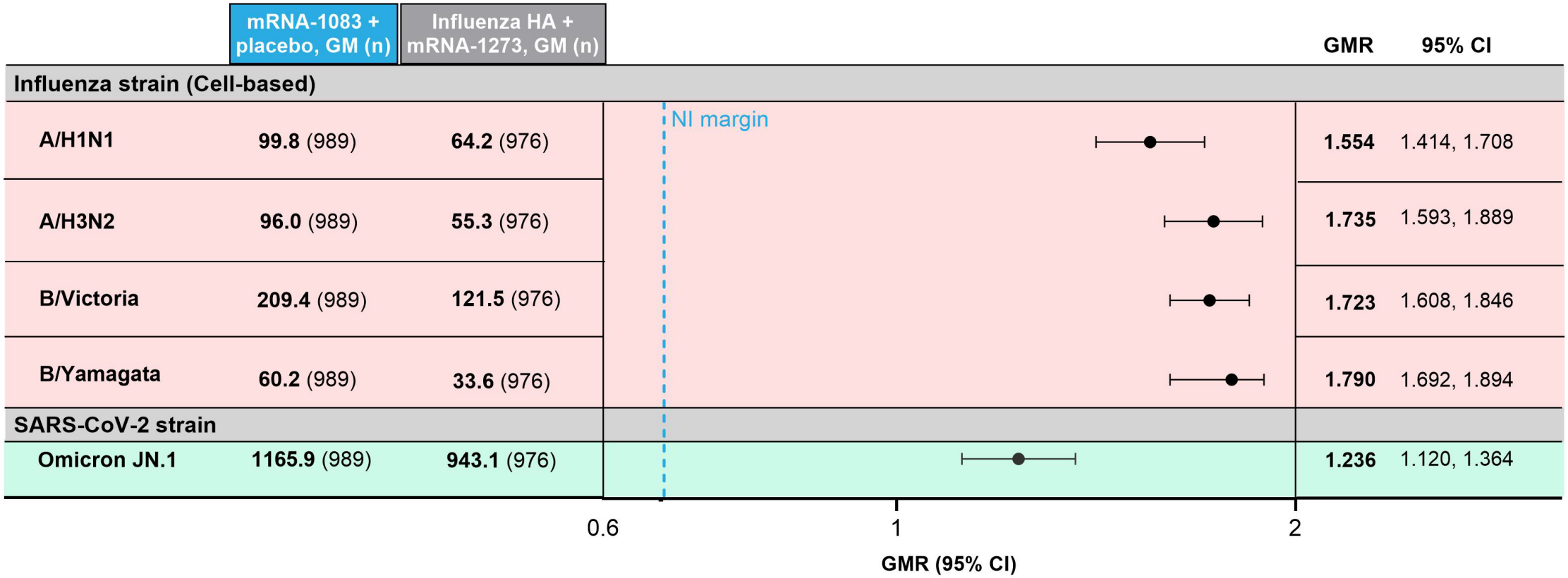
GMRs of Antibody Levels Against SARS-CoV-2 and Influenza (Strains in mRNA-1083) at Day 29 (PPIS)



- **mRNA-1083 met NI criterion relative to the active comparator for SARS-CoV-2 and all influenza strains included in mRNA-1083**

ANCOVA, analysis of covariance; GM, geometric mean; GMR, geometric mean ratio; HA, hemagglutinin; HAI, haemagglutination inhibition; NI, noninferiority; PPIS, per-protocol immunogenicity set; PsVNA, pseudovirus neutralization assay; RT-PCR, reverse transcription polymerase chain reaction.
PPIS included all participants in the full analysis set who complied with the injection schedule, the timings of the immunogenicity blood sampling to have Day 1 and post injection assessment at Day 29, had a negative RT-PCR test results for influenza and SARS-CoV-2 at Day 1, and had no major protocol deviations or conditions/medications that affected the immune response. Measured by HAI assay for influenza and PsVNA for SARS-CoV-2 on Day 29. Cell-based refers to influenza strains represented in mRNA-1083.
GM and GMR were estimated from an ANCOVA model including the vaccination group as a fixed effect, adjusting for randomization stratification factor(s) and log-transformed baseline antibody levels.
The vertical dotted line represents the noninferiority margin of 0.667.

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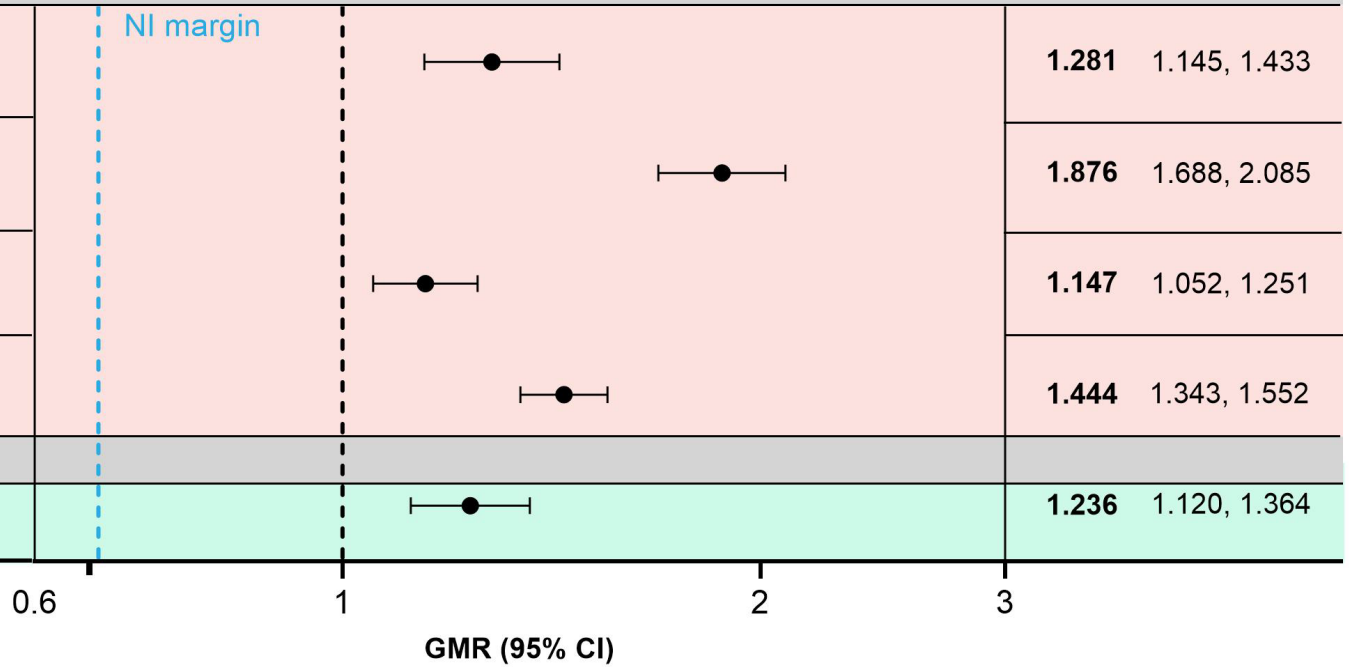
GMRs of Antibody Levels Against SARS-CoV-2 and Influenza (Strains in Active Comparator) in the Overall Population at Day 29 (PPIS)

	mRNA-1083 + placebo, GM (n)	Influenza HA + mRNA-1273, GM (n)	GMR	95% CI
Influenza strain (Egg-based)				
A/H1N1	**172.7** (989)	**134.8** (976)	**1.281**	1.145, 1.433
A/H3N2	**207.1** (989)	**110.4** (976)	**1.876**	1.688, 2.085
B/Victoria	**85.0** (989)	**74.1** (976)	**1.147**	1.052, 1.251
B/Yamagata	**34.6** (989)	**24.0** (976)	**1.444**	1.343, 1.552
SARS-CoV-2 strain				
Omicron JN.1	**1165.9** (989)	**943.1** (976)	**1.236**	1.120, 1.364



- **mRNA-1083 met NI and superiority criteria relative to active comparator for all influenza strains included in the comparator influenza HA vaccine, and SARS-CoV-2, in the overall population at Day 29**

ANCOVA, analysis of covariance; GM, geometric mean; GMR, geometric mean ratio; HAI, haemagglutination inhibition; NI, noninferiority; PPIS, per-protocol immunogenicity set; PsVNA, pseudovirus neutralization assay. RT-PCR, reverse transcription polymerase chain reaction.

Per-protocol immunogenicity set included all participants in the full analysis set who complied with the injection schedule, the timings of the immunogenicity blood sampling to have Day 1 and post injection assessment at Day 29, had a negative RT-PCR test results for influenza and SARS-CoV-2 at Day 1, and had no major protocol deviations or conditions/medications that affected the immune response. Measured by HAI assay for influenza and PsVNA for SARS-CoV-2 on Day 29. Egg-based refers to influenza strains represented in the comparator influenza HA vaccine.

GM and GMR were estimated from an ANCOVA model including the vaccination group as a fixed effect, adjusting for randomization stratification factor(s) and log-transformed baseline antibody levels.

The vertical dotted blue line represents the noninferiority margin of 0.667. The vertical dashed black line represents the superiority criterion (lower bound of the 95% CI for GMR>1).

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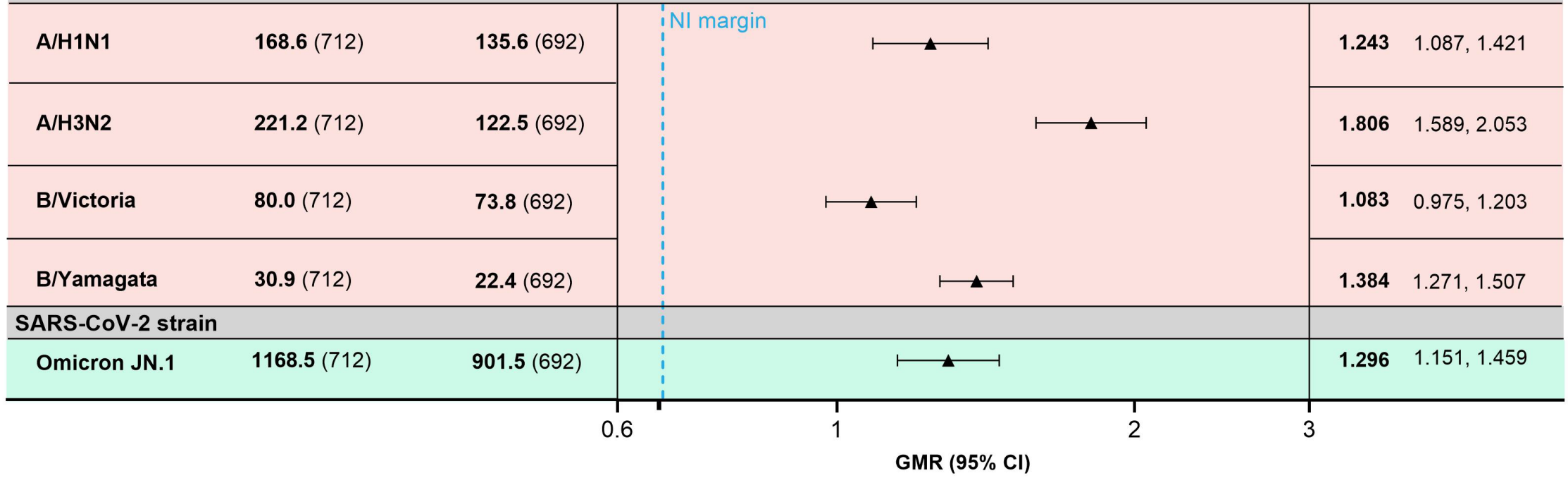
GMRs of Antibody Levels Against SARS-CoV-2 and Influenza (Strains in Active Comparator) in the High-Risk Population at Day 29 (PPIS)

	mRNA-1083 + placebo, GM (n)	Influenza HA + mRNA-1273, GM (n)	GMR	95% CI
Influenza strain (Egg-based)				
A/H1N1	**168.6** (712)	**135.6** (692)	**1.243**	1.087, 1.421
A/H3N2	**221.2** (712)	**122.5** (692)	**1.806**	1.589, 2.053
B/Victoria	**80.0** (712)	**73.8** (692)	**1.083**	0.975, 1.203
B/Yamagata	**30.9** (712)	**22.4** (692)	**1.384**	1.271, 1.507
SARS-CoV-2 strain				
Omicron JN.1	**1168.5** (712)	**901.5** (692)	**1.296**	1.151, 1.459



- **mRNA-1083 met NI criterion relative to active comparator for all influenza strains included in the comparator influenza HA vaccine, and SARS-CoV-2, in the high-risk population at Day 29**

ANCOVA, analysis of covariance; GM, geometric mean; GMR, geometric mean ratio; HAI, haemagglutination inhibition; NI, noninferiority; PPIS, per-protocol immunogenicity set; PsVNA, pseudovirus neutralization assay. RT-PCR, reverse transcription polymerase chain reaction.

Per-protocol immunogenicity set included all participants in the full analysis set who complied with the injection schedule, the timings of the immunogenicity blood sampling to have Day 1 and post injection assessment at Day 29, had a negative RT-PCR test results for influenza and SARS-CoV-2 at Day 1, and had no major protocol deviations or conditions/medications that affected the immune response. Measured by HAI assay for influenza and PsVNA for SARS-CoV-2 on Day 29. Egg-based refers to influenza strains represented in the comparator influenza HA vaccine.

GM and GMR were estimated from an ANCOVA model including the vaccination group as a fixed effect, adjusting for randomization stratification factor(s) and log-transformed baseline antibody levels.

The vertical dotted line represents the noninferiority margin of 0.667.

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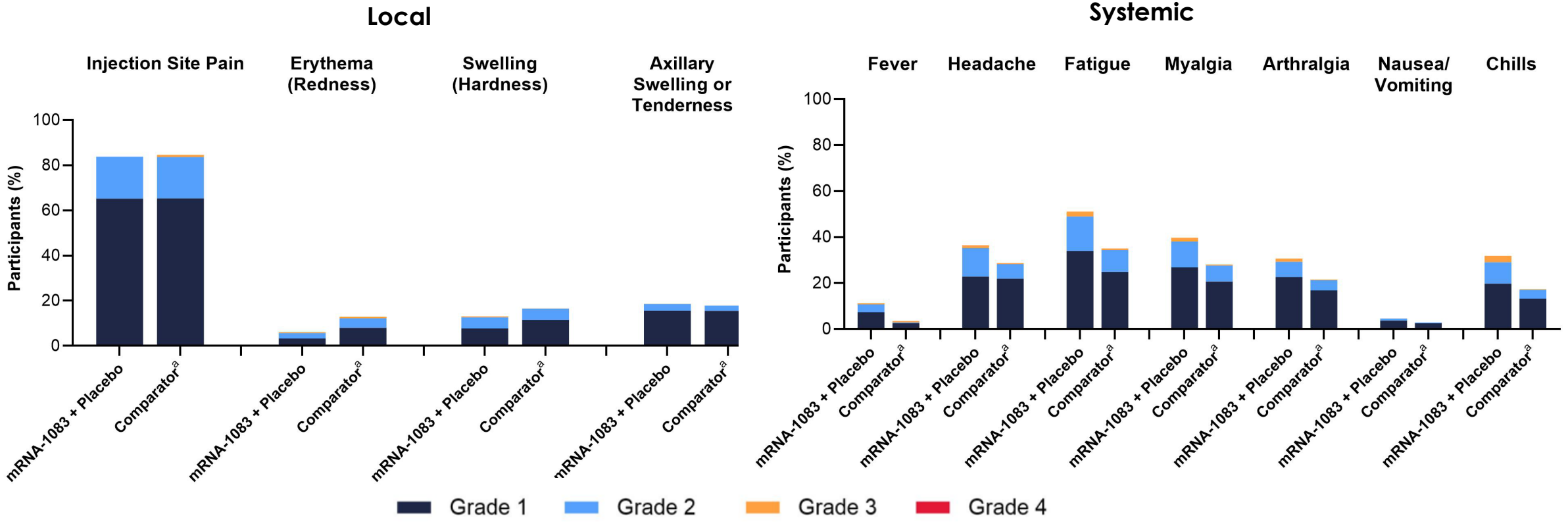
Solicited Local and Systemic Adverse Reactions through 7 Days After Injection (Solicited Safety Set)



- mRNA-1083 was generally well-tolerated, with most solicited ARs reported as grade 1-2 in severity and of short duration; no ARs led to study discontinuation
- Most common solicited ARs were injection site pain, fatigue, myalgia and headache
  - The frequency of grade 3 local ARs was similar across both vaccine groups
  - Grade 3 solicited systemic ARs were reported more frequently in the mRNA-1083 + Placebo group than the Comparator group

AR, adverse reaction; HA, hemagglutinin.
Solicited Safety Set included all participants in the safety set who contributed any solicited AR data. Participants were included in the study group corresponding to the study intervention received.
[a]Influenza HA + mRNA-1273.

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Unsolicited AEs Up to End of Study (Day 181; Safety Set)

	mRNA-1083 + Placebo N=1013	Influenza HA + mRNA-1273 N=1000
Regardless of relationship to study vaccine, n (%)		
Any AE	158 (15.6)	160 (16.0)
Severe	7 (0.7)	10 (1.0)
Serious	10 (1.0)	18 (1.8)
Fatal[a]	1 (<0.1)	0
Medically attended	119 (11.7)	123 (12.3)
Leading to study discontinuation	0	1 (0.1)
AESI[a]	1 (<0.1)	4 (0.4)
Related to study vaccine, n (%)		
Any AE	0	6 (0.6)
Severe	0	0
Serious	0	0
Fatal	0	0
Medically attended	0	1 (0.1)
Leading to study discontinuation	0	0
AESI	0	0

- **Through Day 181/end of study, the frequency of unsolicited AEs were similar between vaccine groups**
- **No safety concerns were identified**
- **No cases of myocarditis/pericarditis were reported**

AE, adverse event; AESI, adverse event of special interest; AR, adverse reaction; SAE, serious adverse event.
Any solicited local or systemic adverse reactions that meet the definition of an SAE are considered as related SAEs. Severe AEs include both unsolicited severe AEs and grade ≥3 solicited ARs that meet SAE criteria. Safety set consisted of all participants who were randomly assigned and received the study intervention. Participants were included in the study group corresponding to the intervention received. Numbers are based on actual vaccination group and percentages are based on the number of participants in the safety set. Participants who received at least 1 dose of mRNA-1083 were assigned to the mRNA-1083 group, regardless of any other vaccines received.
[a]One fatal event and 1 AESI of cerebral infarction were reported in the mRNA-1083 group and were assessed as not related to study intervention by the investigator.

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Conclusions

- A single dose of mRNA-1083 elicited noninferior and superior immune responses against seasonal influenza and SARS-CoV-2 compared with licensed comparator vaccines in adults aged ≥50 years in Japan
  - Immune responses against seasonal influenza and SARS-CoV-2 among high-risk individuals were consistent with those observed in the overall population
- mRNA-1083 was generally well-tolerated, with an acceptable safety profile; no safety concerns were identified
- Safety and reactogenicity profiles of mRNA-1083 were consistent with those observed in the global mRNA-1083 phase 3 study

These findings support the potential of mRNA-1083 as a multicomponent vaccine to protect against two major respiratory pathogens in this population

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Thank you

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