Top-Line Results of the Phase 2/3 booster Trial for COVID-19 Recombinant-based Vaccine, S-268019

March 4, 2022

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Agenda

1. **Vaccine classification**
2. **Overview of S-268019**
3. **Clinical trials of S-268019**

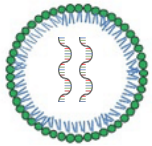
Top-line results of the Phase 2/3 booster trial for S-268019

- Subject background
- Immunogenicity
- Neutralizing antibody titer against omicron variant
- Safety
- Summary

1. Vaccine classification

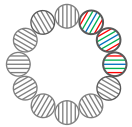
Types of Vaccine Antigen Production Technology

mRNA vaccine
(*COMIRNATY)
(*Spikevax)



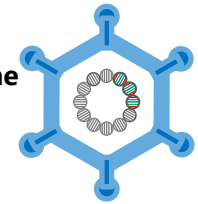
Stabilization by conversion from RNA to DNA

DNA vaccine
(AG0302-COVID19)



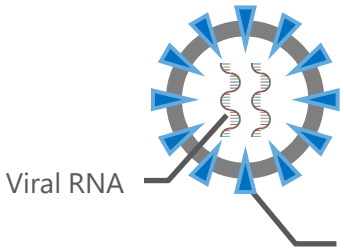
Protection of DNA by shells such as adenovirus

Virus vector vaccine
(*Vaxzevria)



New generation technology

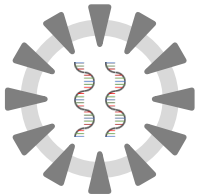
SARS-CoV-2 virus particle
(RNA virus)



Recombinant protein vaccine (S-268019)

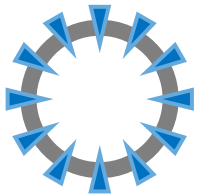
Inactivation of virus by heat/chemical treatment

Inactivated vaccine
(KD-414)



Empty virus particles without genome

****VLP vaccine**
(*COVIFENZ)



Traditional technology

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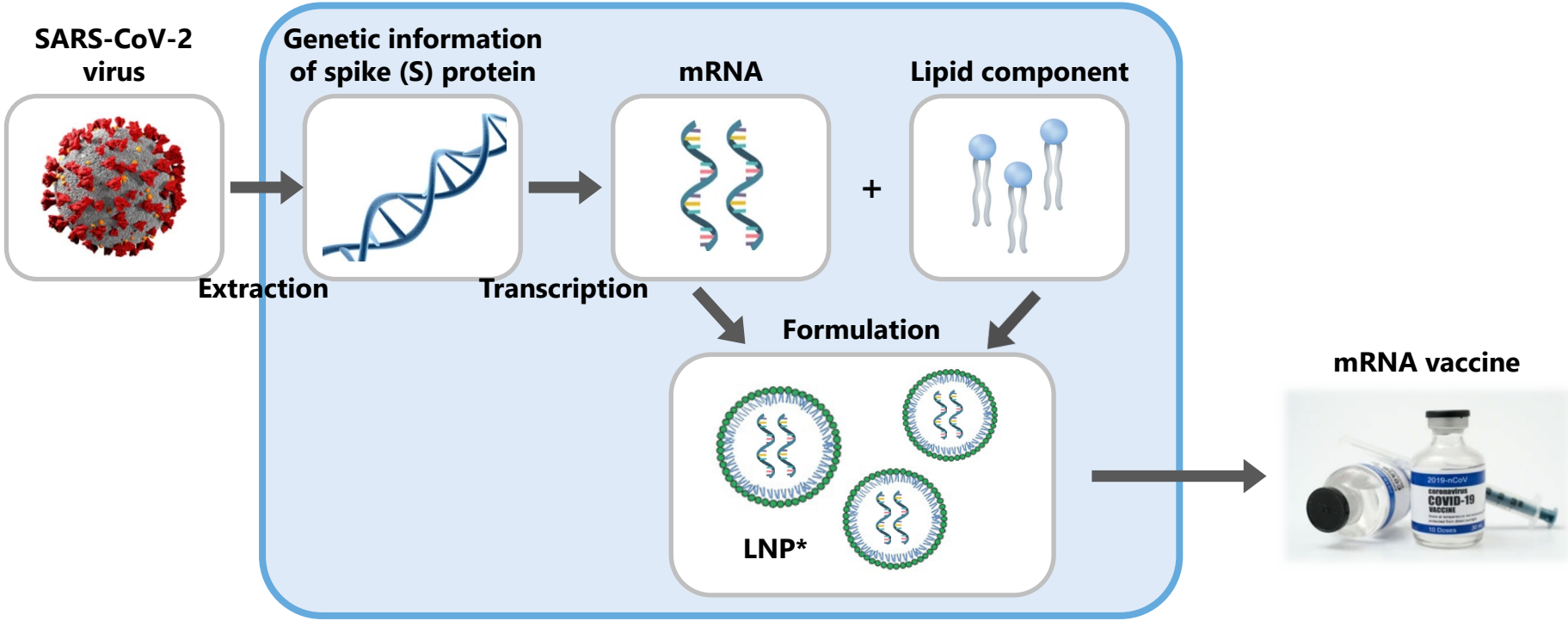
* COVID-19 vaccine currently in use ** virus-like particle

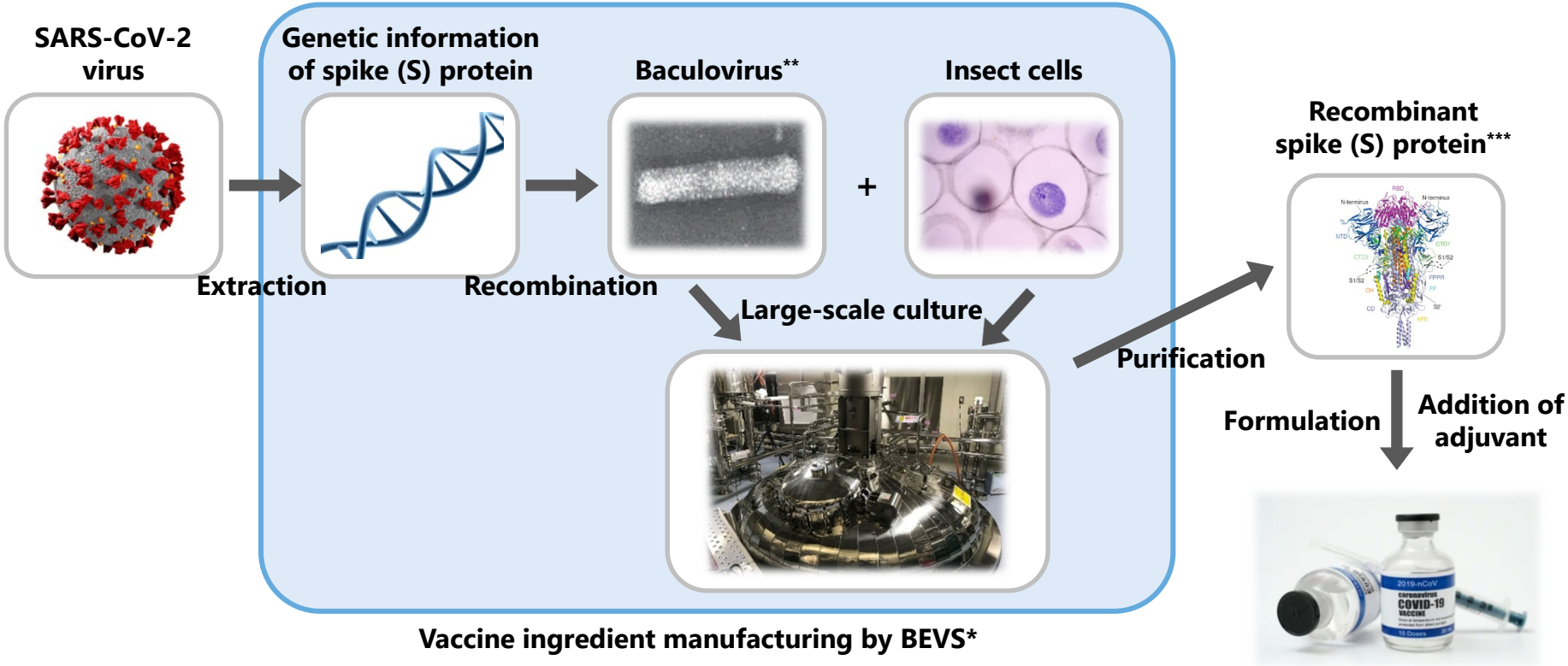
Manufacturing Process of mRNA Vaccine



mRNA is encapsulated in LNP so that it is not degraded in the body

* lipid nanoparticle

Manufacturing process of recombinant protein vaccine by BEVS*



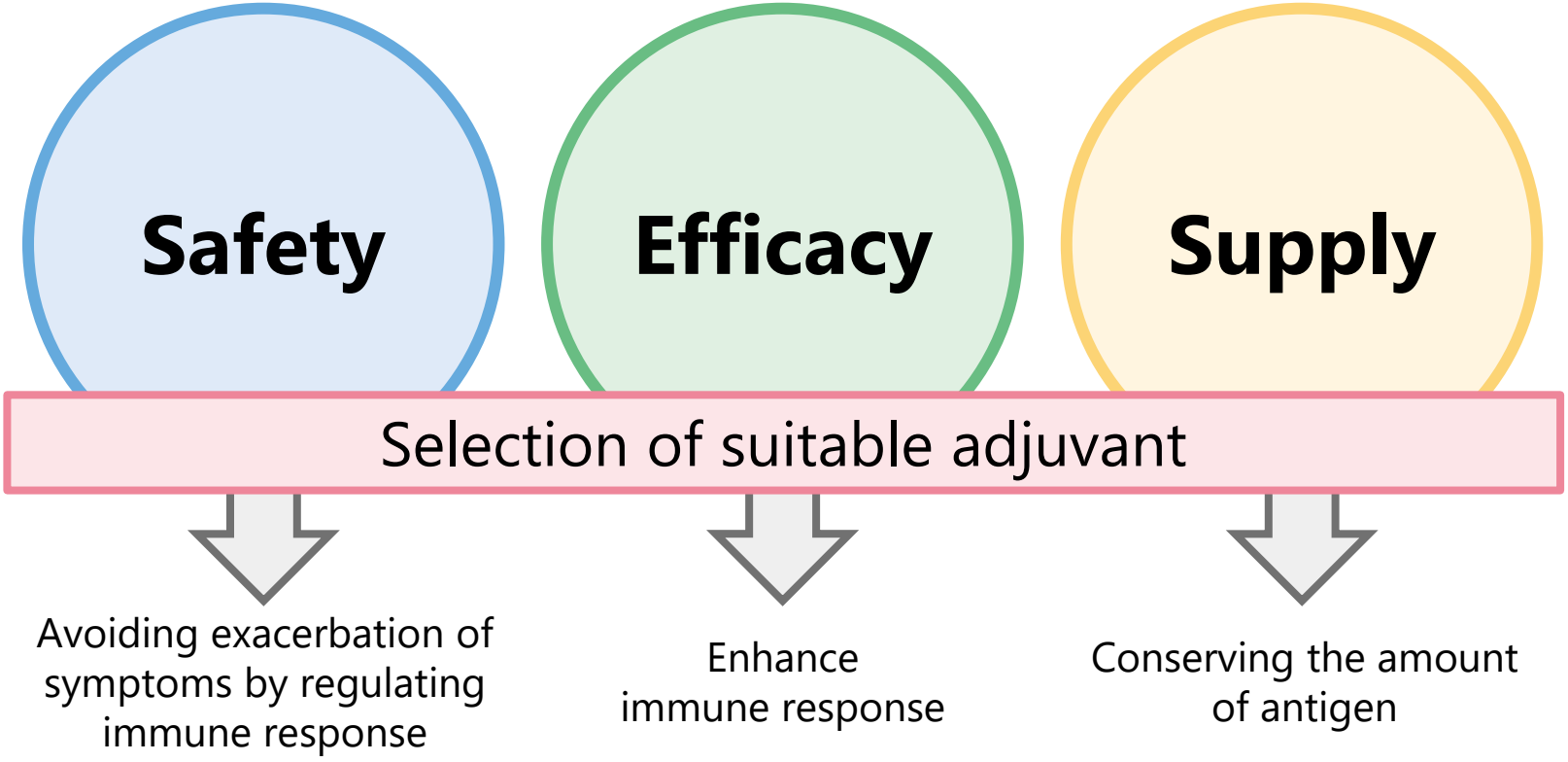
Vaccine ingredient manufacturing by BEVS*

* Baculovirus Expression Vector System

** YAKUKENSHA CO., Ltd.

*** Science, 2020, 369, 1586–1592, Cai et al.

Importance of Suitable Adjuvant Selection



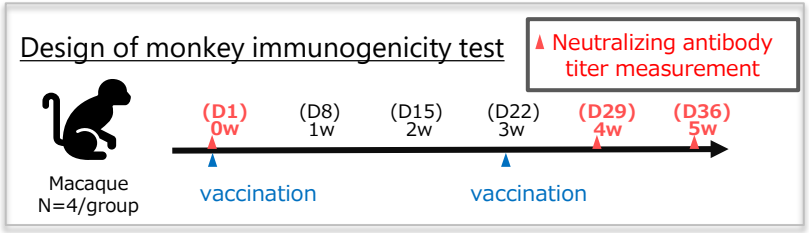
2. Overview of S-268019

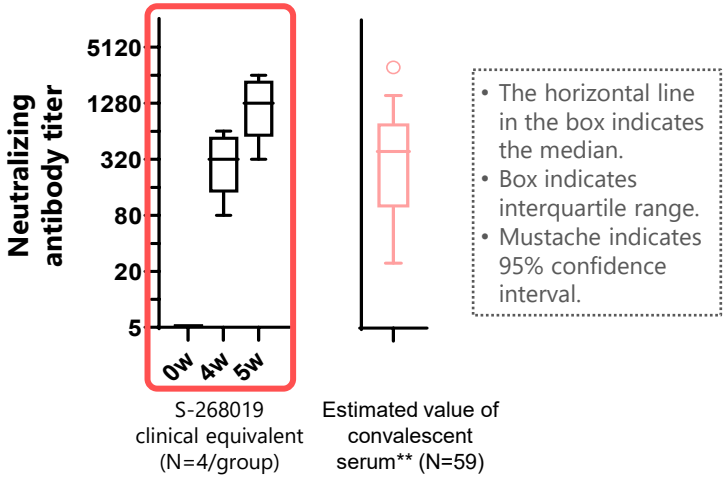
Overview of S-268019

Antigen manufacturing technology	BEVS*
Product characteristics	Full-length spike (S) protein + adjuvant
Adjuvant	A-910823
Expected dosage	• Priming vaccine; 0.5 mL twice, usually every 4 weeks, intramuscular injection • Booster vaccine; 0.5 mL once, intramuscular injection

Previous nonclinical results

- Monkey immunogenicity test
  - 2 vaccinations (3 weeks intervals)
  - Measure neutralizing antibody titers 29 and 36 days after vaccination





S-268019 showed neutralizing antibody titers similar to or exceeding recovered patient serum

* Baculovirus Expression Vector System
** Estimate from measurements in another test

Positioning of S-268019

Significance of domestic vaccine

- Domestic vaccines are extremely important from a national security perspective
  - Building a system that can rapidly provide vaccines at the required timing in Japan
  - Response to new variants that may occur originally in Japan

Environment surrounding booster vaccine

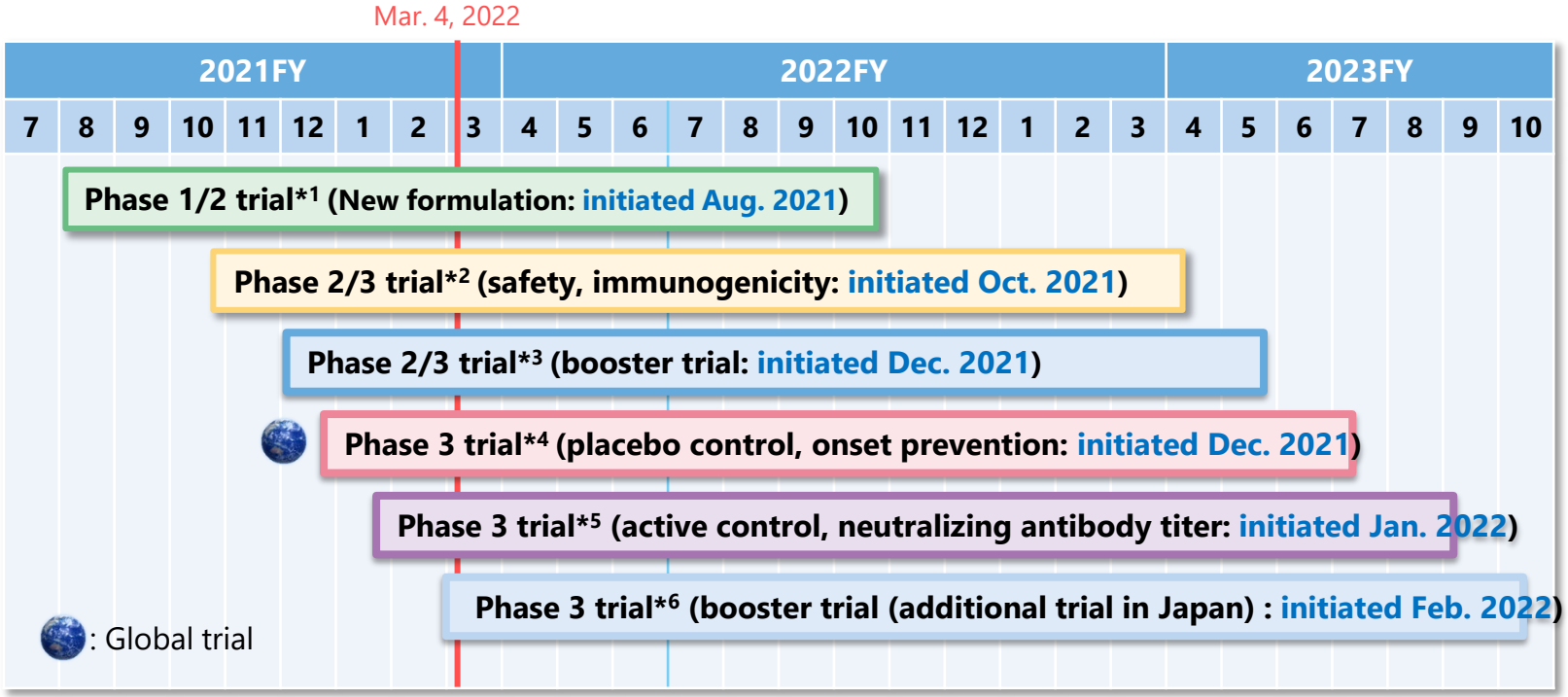
- Since the prevention of onset/the exacerbation prevention effect by the priming vaccination decreases with the passage of time, the third booster vaccination is urgent
- Many people have experienced side effects with the priming vaccination and the booster vaccination, and the 3rd vaccination has not progressed in Japan

Domestic vaccine that can be boosted with a good balance between efficacy and safety

The addition of new vaccine options will increase the rate of booster vaccinations, leading to prevention of the spread of infection and suppression of exacerbations

3. Clinical trials of S-268019

S-268019：List of Ongoing Clinical Trials



*1 jRCT2031210269, *2 jRCT2031210383, *3 jRCT2031210470, *4 NCT05212948, *5 jRCT2051210151, *6 jRCT2031210613

Phase 1/2 Clinical Trial was supported by Japan Agency for Medical Research and Development (AMED)

S-268019 : Overview of Ongoing Clinical Trials 1/2

	Phase 1/2 trial	Phase 2/3 trial	Active control, neutralizing antibody titer trial	Placebo control, onset prevention trial
Priming/Booster	Priming	Priming	Priming	Priming
Subjects	Healthy adults between the ages of 20 and 64	Adults over 20 years old, elderly over 65 years old (including subjects with COVID-19 history, vaccinated subjects)	Adults over 18 years old, elderly	Adults over 18 years old
Study design	Randomized, observer-blind	Multicenter, open-label	Multicenter, randomized, active control, parallel-group, observer-blind	Placebo-controlled cross-over
Primary endpoints	AEs, treatment-related AEs, SAEs, solicited AEs, vital signs, laboratory tests, ECG	Safety at the end of the evaluation period (at 28 days following the second vaccination)	SARS-CoV-2 neutralizing antibody titer at 28 days following the second vaccination	Number of participants with occurrence of SARS-CoV-2 RT-PCR-positive symptomatic COVID-19
Target sample size	60 subjects in 3 groups (S-268019: 24 subjects x 2 groups, placebo: 12 subjects)	3,100 subjects (naïve: over 2,000 subjects, subjects with COVID-19 history: over 30 subjects, vaccinated subjects: over 30 subjects, elderly: 100 subjects)	1,000 subjects (500 subjects: VAXZEVRIA intramuscular injection, 500 subjects: S-268019)	54,915 subjects (S-268019: 36,610, placebo: 18,305)
Dosing regimen	Intramuscular injection, two dose (Day1, Day22)	Intramuscular injection, two dose (Day1, Day29)	Intramuscular injection, two dose (Day1, Day29)	1st period Intramuscular injection, two dose (Day1, Day29) 2nd period Intramuscular injection, two dose (Day225, Day253)
Status	• Disclosed at the Japan Society for Vaccinology (December 4, 2021) • Follow-up evaluation for 1 year after inoculation of each index is ongoing • Additional vaccination for subjects in active drug group who wish to receive the third vaccination is ongoing	• Completed the 2nd inoculation of all subjects • Completed observation through Day 57 with no major safety concerns • Topline results including GMT of neutralizing antibody will be presented at Annual Meeting of Japanese Association for Infectious Diseases in April 2022	• Superiority trial to compare GMT of neutralizing antibody to a licensed vaccine (VAXZEVRIA intramuscular injection) • Completed the 1st inoculation of all subjects	• Initiated in Vietnam from December 2021 • Subject registration is progressing smoothly

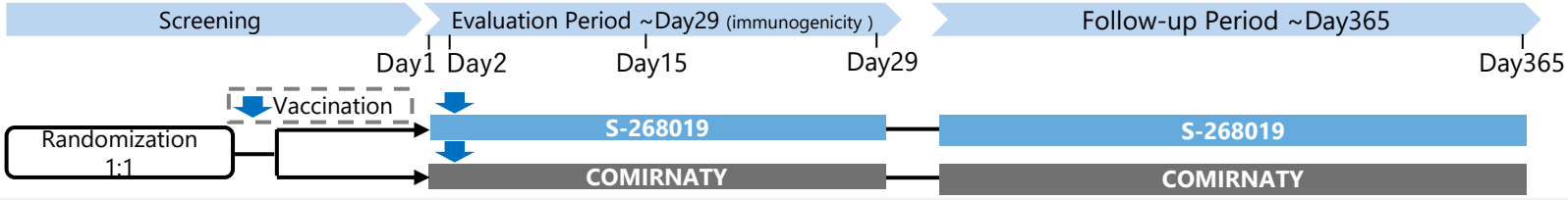
Phase 1/2 Clinical Trial was supported by Japan Agency for Medical Research and Development (AMED)

S-268019：Overview of Ongoing Clinical Trials 2/2

	Phase 2/3 booster trial	Phase 3 booster trial
Priming/Booster	Booster	Booster
Subjects	Adults over 20 years old who at least 6 months have passed after completion of the second vaccination with COMIRNATY	Participant who have received 2 doses of SARS-CoV-2 vaccine (Adults between the ages of 20 and 64: only SPIKEVAX, elderly over 65 years old: COMIRNATY or SPIKEVAX) and 6 months or more and 8 months or less after second dose
Study design	Randomized, observer-blind, active-controlled	Single center, open-label
Primary endpoints	Geometric mean titer (GMT) of SARS-CoV-2 neutralizing antibody on Day 29 Seroresponse rate of SARS-CoV-2 neutralizing antibody on Day 29	Safety
Target number of participants	204 participants (S-268019 group: 102 participants, COMIRNATY group: 102 participants)	150 participants (100 adults, 50 elderly)
Dosing regimen	Intramuscular injection, one dose	Intramuscular injection, one dose
Status	• Completed the 1st inoculation of all subjects • **Disclosed top-line results** (Mar. 4, 2022)	• Initiated subject registration (Feb. 28, 2022)

Overview of the Phase 2/3 Booster Trial

Objectives	To evaluate if the immunogenicity of S-268019 demonstrates noninferiority compared to COMIRNATY and safety as a booster dose after completion of vaccination with two doses of COMIRNATY
Subjects	Adults over 20 years old who at least 6 months have passed after completion of the second vaccination with COMIRNATY
Study design	Randomized, observer-blind, active-controlled
Endpoints	• Primary: GMT of SARS-CoV-2 neutralizing antibody titer and seroresponse rate on Day 29 • Secondary: immunogenicity other than the primary endpoint (GMT of neutralizing antibody titer and IgG antibody titer, GMFR, seroresponse rate), safety (AEs/treatment-related AEs/SAEs and others), clinical efficacy (number of SARS-CoV-2-positive participants) • Exploratory: Immunological indices (cellular immunity, Th1/Th2 balance, assessment of immunity after booster vaccination (analysis of functions and characteristics of antibody to SARS-CoV-2 and immune cells))
Target number of participants	204 participants
Dosing regimen	Intramuscular injection, one dose
Dose	S-268019 group: A solution in which 10 mg of antigen is dissolved in a 50% v/v oil in water emulsion containing an adjuvant COMIRNATY group: 0.3mL tozinameran (30μg, diluted with physiological saline)
Duration	Nov. 2021~Jan. 2023
Study site	Tokyo Shinagawa Hospital



Top-Line Results (Interim Report) of the Phase 2/3 booster Trial for COVID-19 Recombinant protein Vaccine, S-268019

Tokyo Shinagawa Hospital

Vice President and Director, Clinical trial Development & Research Center

Masaharu Shinkai, MD, PhD

COI Disclosure Information

- Tokyo Shinagawa Hospital is entrusted with this clinical trial by Shionogi.
- There are no financial relationships that should be disclosed as an individual regarding this announcement.

Overview of the Phase 2/3 Booster Trial

Objectives	To evaluate if the immunogenicity of S-268019 demonstrates noninferiority compared to COMIRNATY and safety as a booster dose after completion of vaccination with two doses of COMIRNATY
Subjects	Adults over 20 years old who at least 6 months have passed after completion of the second vaccination with COMIRNATY
Study design	Randomized, observer-blind, active-controlled
Endpoints	• Primary: SARS-CoV-2 neutralizing antibody titer on Day 29 • Secondary: immunogenicity other than the primary endpoint (GMT of neutralizing antibody titer and IgG antibody titer, GMFR, seroresponse rate), safety (AEs/treatment-related AEs/SAEs and others), clinical efficacy (number of SARS-CoV-2-positive participants) • Exploratory: Immunological indices (cellular immunity, Th1/Th2 balance, assessment of immunity after booster vaccination (analysis of functions and characteristics of antibody to SARS-CoV-2 and immune cells))
Target number of participants	204 participants
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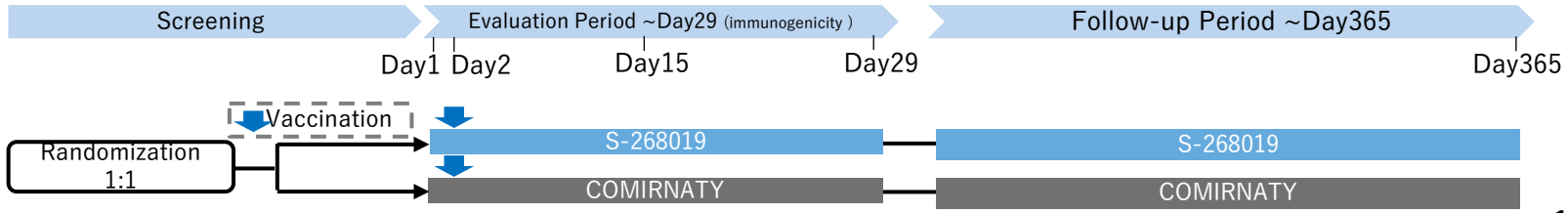
Study site	Tokyo Shinagawa Hospital



Key Demographics of Participants

Immunogenicity Subset

		S-268019 N=103	COMIRNATY N=102*
Sex	Male	72	73
	Female	31	29
Age (years)	Min	21	21
	Max	59	60
BMI	Min	16.1kg/m^2	16.4kg/m^2
	Max	54.4kg/m^2	41.8kg/m^2

- Randomized：206 (S-268019: 103, COMIRNATY: 103)
- Safety analysis population：206 (S-268019: 103, COMIRNATY: 103)
- Immunogenicity subset：205 Analyzed at Baseline (S-268019: 103, COMIRNATY: 102*)
  Analyzed at Day15、29 (S-268019: 103, COMIRNATY: 101*, **)

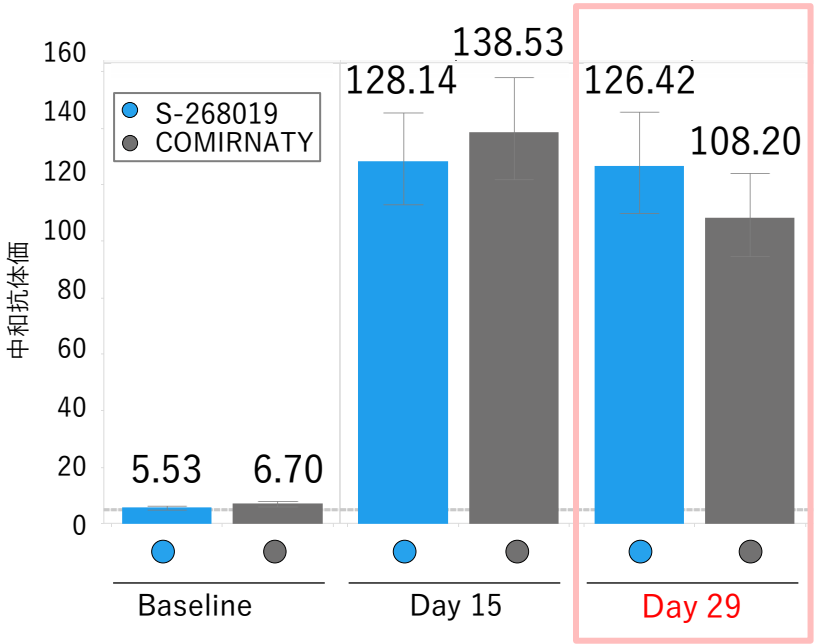
* at screening: Exclude from analysis (n=1); Confirmed positive anti-SARS-CoV-2 N-protein antibody test after the booster dose
** at Day15 and Day29: Exclude from analysis (n=1); Confirmed positive anti-SARS-CoV-2 N-protein antibody test at Day15

Immunogenicity

< Statistical Hypothesis Testing >

If both the lower limit of the 95% confidence interval (CI) for the GMTR (S-268019 to COMIRNATY) of SARS-CoV-2 neutralizing antibody is greater than 0.67 and the lower limit of the 95% CI for the difference in seroresponse rate (S-268019 minus COMIRNATY) of SARS-CoV-2 neutralizing antibody is greater than −10%, the noninferiority is confirmed.

GMT of SARS-CoV-2 neutralizing antibody titer



GMT of SARS-CoV-2 neutralizing antibody on Day 29 (primary endpoints)

	S-268019 N=103	COMIRNATY N=101
GMT	126.42	108.20
95% confidence interval	109.76, 145.62	94.57, 123.80
GMT ratio*1	1.17	---
95% confidence interval *1	0.96, 1.42 0.67＜0.96	---
One-sided P-value for non-inferiority *2	<.0001	---

Titer values reported as below the LLOQ are replaced by 0.5 x LLOQ., LLOQ (5.0)
*1 The GMT, GMT ratio with corresponding 95% CI are estimated by back transformation of the adjusted mean, the intervention difference and its 95% CI which are obtained using analysis of covariance (ANCOVA) model fitted on the log-transformed titers. The model includes intervention group as fixed effect as well as age (continuous) and sex as covariates.
*2 The non-inferiority margin is 0.67.

Seroresponse Rate of SARS-CoV-2 neutralizing antibody titer on Day 29

Seroresponse Rate on Day 29*1 (primary endpoints)

*1 Seroresponse rate is defined as the proportion of participants with a ≥4-fold increase in post-vaccination antibody titer from baseline.

	S-268019 N=103	COMIRNATY N=101
Number of Seroresponse	103例	101例
Seroresponse Rate	100.0%	100.0%
Difference in proportion of seroresponse	0.0%	---
95% confidence interval	-5.8, 5.8 -10<-5.8	---
One-sided P-value for non-inferiority*2	0.0004	---

*2 The non-inferiority margin is -10%.

Interim results showed noninferiority of S-268019 to COMIRNATY in co-primary endpoints: GMT and seroresponse rate for neutralizing antibodies on day 29

Result of Primary Endpoints

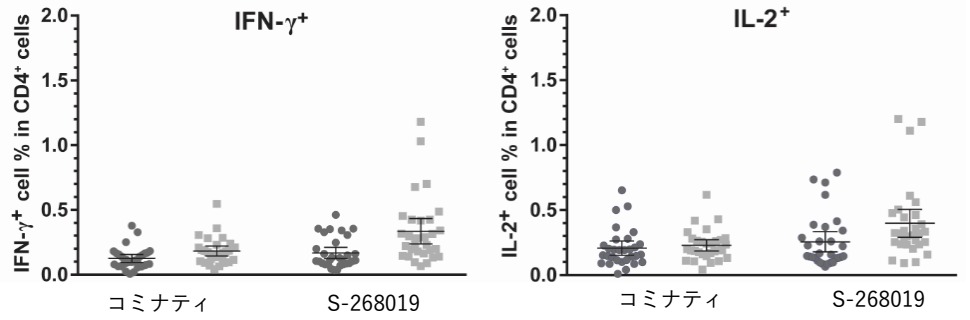
Interim results showed noninferiority of S-268019 to COMIRNATY in co-primary endpoints: GMT and seroresponse rate for neutralizing antibodies on day 29

In the interim report, this trial met its primary endpoint.

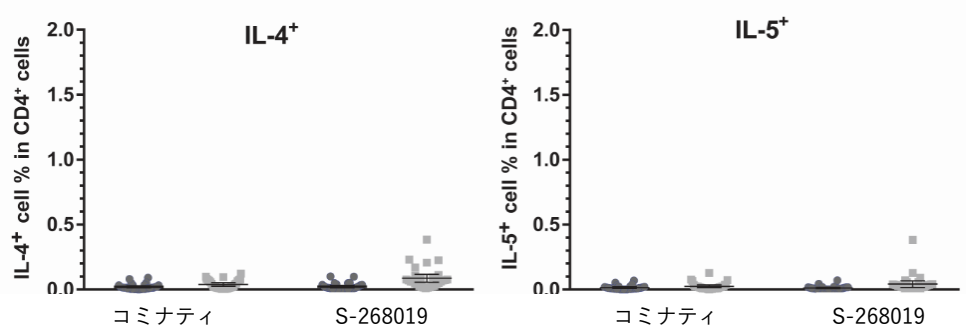
Immunologic Assays by Flow Cytometry (ICS-FCM)*

CD4+T Cell

T-helper type 1



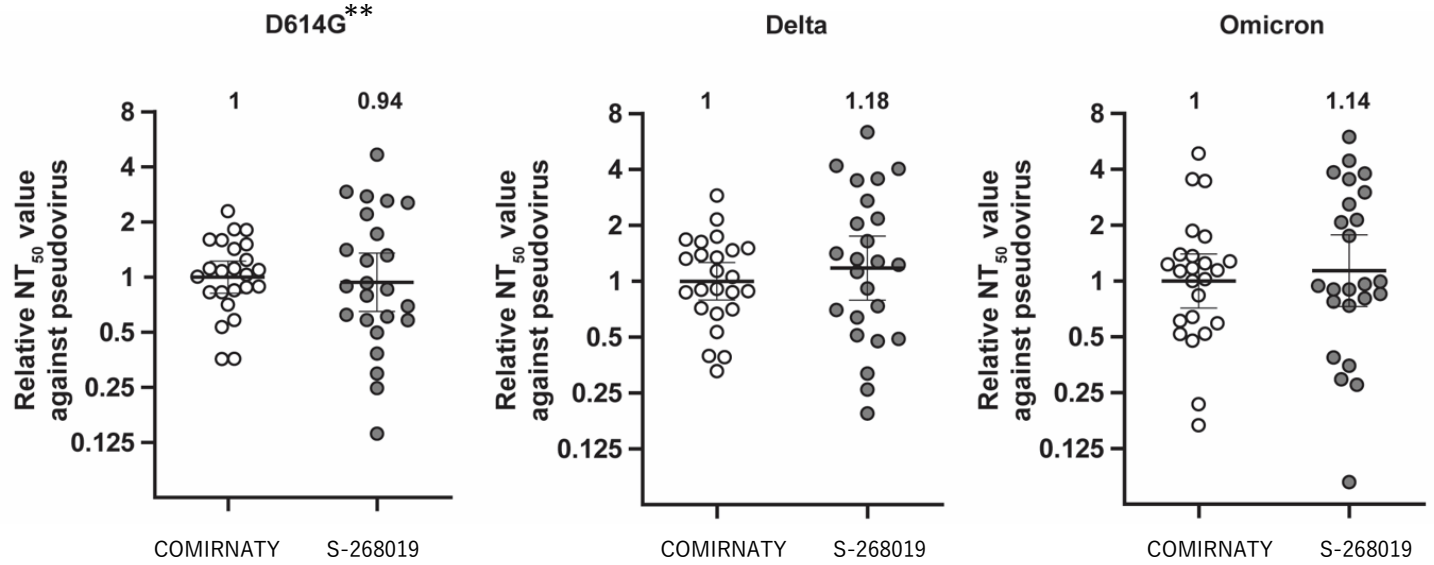
T-helper type 2



A strong bias toward the T-helper type 1 phenotype was noted

* T-cell responses were assessed for a subgroup (n=30/group) sampled from participants who gave consent to assess cellular immunity.

Neutralizing Antibody Titer against Pseudotyped Virus with SARS-CoV-2 Mutation Spike Protein*



Day29

Serum samples from both vaccine groups neutralized pseudovirus variants including Omicron variants with similar potency as indicated by NT50 values relative to COMIRNATY

* Before reassessment, a subgroup (n=24/group) sampled from participants were extracted from groups with the same distribution of neutralizing antibody titers and ages, and the neutralizing antibody titers were assessed using Pseudotyped virus.
** European strain with D614G mutation introduced into spikes of WK-521 strain

Safety

Treatment-related AEs (Treatment-related AEs will be defined as AEs considered to be “related” to the study intervention)

＜* Any systemic solicited TRAEs＞

- The following AEs were collected as solicited systemic AEs within 7 days after study intervention (Day1 to Day8)
  - Fever, Nausea/vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills

＜** Any local solicited TRAEs＞

- The following AEs were collected as solicited local AEs within 7 days after study intervention (Day1 to Day8)
  - Pain ,Erythema/redness ,Induration ,Swelling

		S-268019 N=103	COMIRTY N=103
Treatment-related AEs (TRAEs)	Participants	99	101
	(%) of participants	96.1%	98.1%
Any systemic solicited TRAEs*	Participants	72	81
	(%) of participants	69.9%	78.6%
Any local solicited TRAEs**	Participants	70	75
	(%) of participants	68.0%	72.8%

Treatment-related AEs (TRAEs) (Incidents, 5% or more)

		S-268019 N=103	COMIRNATY N=103
participants ((%) of participants)	**Participants with any Treatment-related AEs**	**99 (96.1%)**	**101 (98.1%)**
	Headache	26 (25.2%)	43 (41.7%)
	Diarrhea	4 (3.9%)	6 (5.8%)
	Myalgia	42 (40.8%)	49 (47.6%)
	Arthralgia	8 (7.8%)	11 (10.7%)
	Vaccination site pain	69 (67.0%)	75 (72.8%)
	Fatigue	45 (43.7%)	55 (53.4%)
	Pyrexia	40 (38.8%)	61 (59.2%)
	Vaccination site erythema	6 (5.8%)	9 (8.7%)
	Chills	4 (3.9%)	7 (6.8%)
	Neutrophil percentage increased	78 (75.7%)	81 (78.6%)
	C-reactive protein increased	34 (33.0%)	46 (44.7%)
	White blood cell count increased	9 (8.7%)	11 (10.7%)

Solicited Systemic AEs and Solicited Local TRAEs (Incidents)

			S-268019 N=103	COMIRNATY N=103
Any systemic solicited TRAEs	participants ((%) of participants)	Participants with any systemic solicited TRAEs	72 (69.9%)	81 (78.6%)
		Fever	40 (38.8%)	61 (59.2%)
		Nausea/Vomiting	5 (4.9%)	5 (4.9%)
		Diarrhea	4 (3.9%)	6 (5.8%)
		Headache	26 (25.2%)	43 (41.7%)
		Fatigue	45 (43.7%)	55 (53.4%)
		Myalgia	42 (40.8%)	49 (47.6%)
		Arthralgia	8 (7.8%)	12 (11.7%)
		Chills	4 (3.9%)	7 (6.8%)
Any local solicited TRAEs	participants ((%) of participants)	Participants with any local solicited TRAEs	70 (68.0%)	75 (72.8%)
		Pain	68 (66.0%)	75 (72.8%)
		Erythema/Redness	7 (6.8%)	9 (8.7%)
		Induration	0 (0.0%)	0 (0.0%)
		Swelling	1 (1.0%)	1 (1.0%)

Solicited Systemic AEs and Solicited Local TRAEs (Severity)

- Grade 5：Death related to AE.
- Grade 4：Life-threatening consequences; urgent intervention indicated.
- Grade 3：Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting selfcare ADL.Grade 2：Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.
- Grade 1：Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

A semicolon (;) indicates “or” within the description of grade.

				S-268019 N=103	COMIRNATY N=103
Any systemic solicited TRAEs	participants ((%) of participants)	Severity	**Total**	**72 (69.9%)**	**81 (78.6%)**
			Grade 5	0 (0.0%)	0 (0.0%)
			Grade 4	0 (0.0%)	0 (0.0%)
			Grade 3	1 (1.0%)	4 (3.9%)
			Grade 2	15 (14.6%)	31 (30.1%)
			Grade 1	56 (54.4%)	46 (44.7%)
Any local solicited TRAEs	participants ((%) of participants)	Severity	**Total**	**70 (68.0%)**	**75 (72.8%)**
			Grade 5	0 (0.0%)	0 (0.0%)
			Grade 4	0 (0.0%)	0 (0.0%)
			Grade 3	0 (0.0%)	0 (0.0%)
			Grade 2	2 (1.9%)	5 (4.9%)
			Grade 1	68 (66.0%)	70 (68.0%)

Solicited Systemic AEs and Solicited Local TRAEs (Timing of Onset)

				S-268019 N=103	COMIRNATY N=103
Any systemic solicited TRAEs	participants ((%) of participants)	Timing of Onset (Day)	1	36 (35.0%)	44 (42.7%)
			2	50 (48.5%)	61 (59.2%)
			3	2 (1.9%)	2 (1.9%)
			4	0 (0.0%)	0 (0.0%)
			5	0 (0.0%)	0 (0.0%)
			6	0 (0.0%)	2 (1.9%)
			>=7	0 (0.0%)	0 (0.0%)
Any local solicited TRAEs	participants ((%) of participants)	Timing of Onset (Day)	1	37 (35.9%)	43 (41.7%)
			2	35 (34.0%)	36 (35.0%)
			3	0 (0.0%)	1 (1.0%)
			>=4	0 (0.0%)	0 (0.0%)

Solicited Systemic AEs and Solicited Local TRAEs (Incidents, Severity) 1/3

			S-268019 N=103	COMIRNATY N=103
Fever participants ((%) of participants)	Severity	Total	40 (38.8%)	61 (59.2%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	1 (1.0%)	2 (1.9%)
		Grade 2	2 (1.9%)	7 (6.8%)
		Grade 1	37 (35.9%)	52 (50.5%)
Nausea/ Vomiting participants ((%) of participants)	Severity	Total	5 (4.9%)	5 (4.9%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	1 (1.0%)	0 (0.0%)
		Grade 1	4 (3.9%)	5 (4.9%)

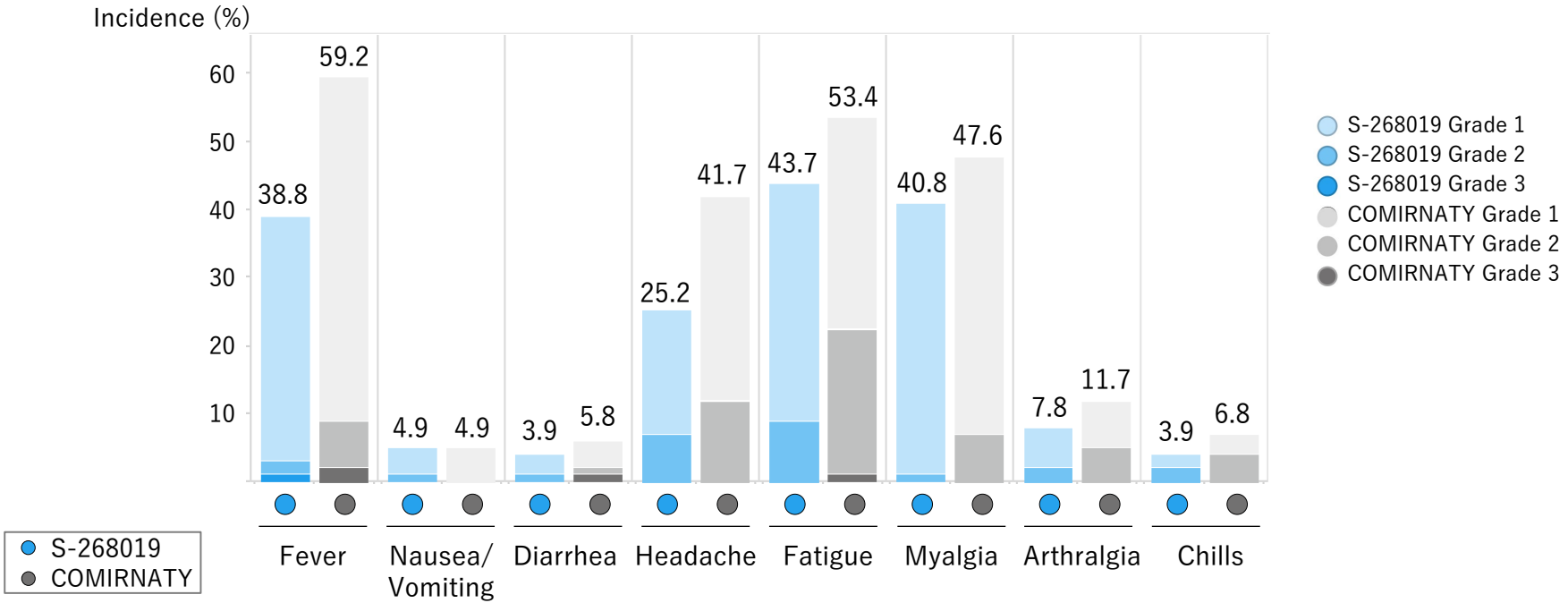
			S-268019 N=103	COMIRNATY N=103
Diarrhea participants ((%) of participants)	Severity	合計	4 (3.9%)	6 (5.8%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	1 (1.0%)
		Grade 2	1 (1.0%)	1 (1.0%)
		Grade 1	3 (2.9%)	4 (3.9%)
Headache participants ((%) of participants)	Severity	合計	26 (25.2%)	43 (41.7%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	7 (6.8%)	12 (11.7%)
		Grade 1	19 (18.4%)	31 (30.1%)

Solicited Systemic AEs and Solicited Local TRAEs (Incidents, Severity) 2/3

			S-268019 N=103	COMIRNATY N=103
Fatigue participants ((%) of participants)	Severity	Total	45 (43.7%)	55 (53.4%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	1 (1.0%)
		Grade 2	9 (8.7%)	22 (21.4%)
		Grade 1	36 (35.0%)	32 (31.1%)
Myalgia participants ((%) of participants)	Severity	Total	42 (40.8%)	49 (47.6%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	1 (1.0%)	7 (6.8%)
		Grade 1	41 (39.8%)	42 (40.8%)

			S-268019 N=103	COMIRNATY N=103
Arthralgia participants ((%) of participants)	Severity	Total	8 (7.8%)	12 (11.7%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	2 (1.9%)	5 (4.9%)
		Grade 1	6 (5.8%)	7 (6.8%)
Chills participants ((%) of participants)	Severity	Total	4 (3.9%)	7 (6.8%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	2 (1.9%)	4 (3.9%)
		Grade 1	2 (1.9%)	3 (2.9%)

Solicited Systemic AEs and Solicited Local TRAEs (Incidents, Severity) 3/3

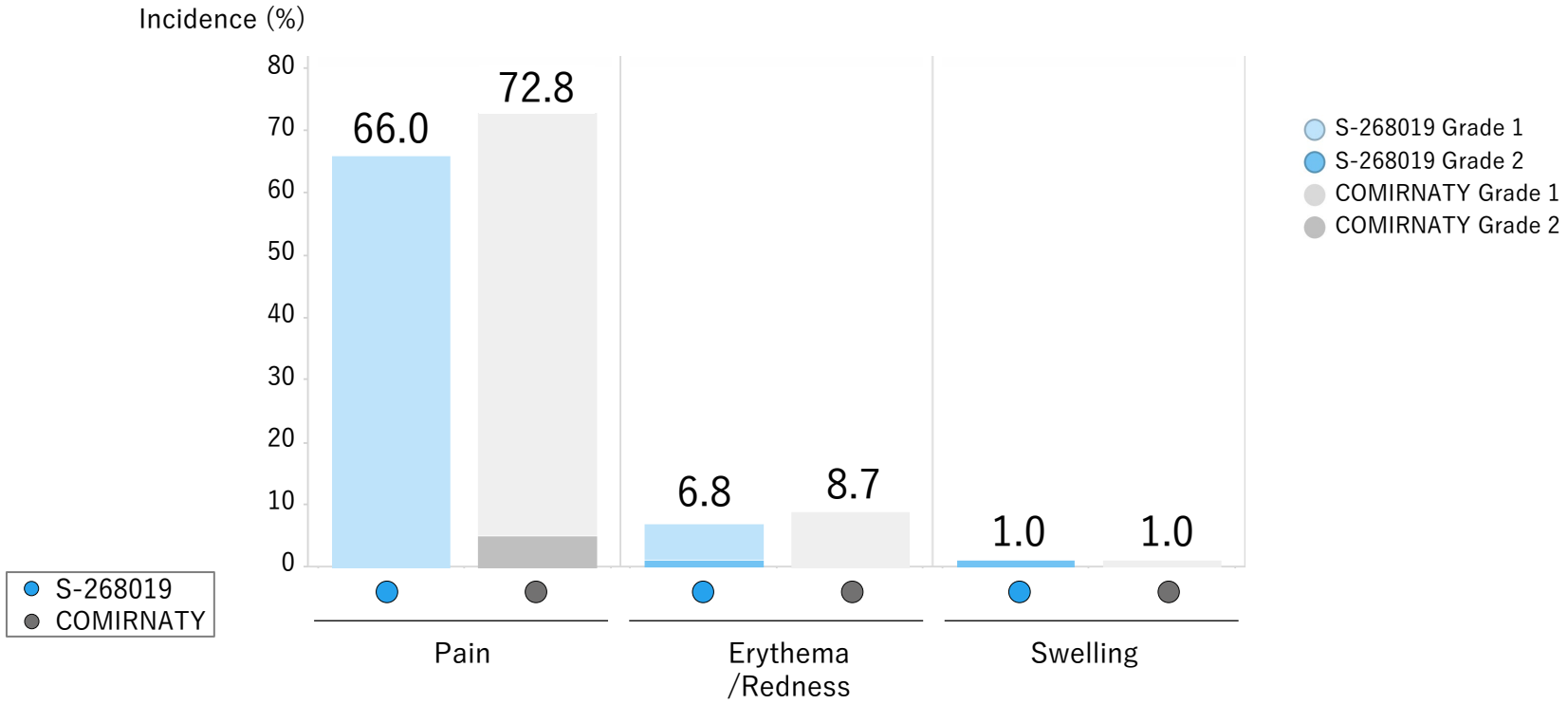


Solicited Local TRAEs (Incidents, Severity) 1/2

			S-268019 N=103	COMIRNATY N=103
Pain participants ((%) of participants)	Severity	Total	68 (66.0%)	75 (72.8%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	0 (0.0%)	5 (4.9%)
		Grade 1	68 (66.0%)	70 (68.0%)
Erythema /Redness participants ((%) of participants)	Severity	Total	7 (6.8%)	9 (8.7%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	1 (1.0%)	0 (0.0%)
		Grade 1	6 (5.8%)	9 (8.7%)

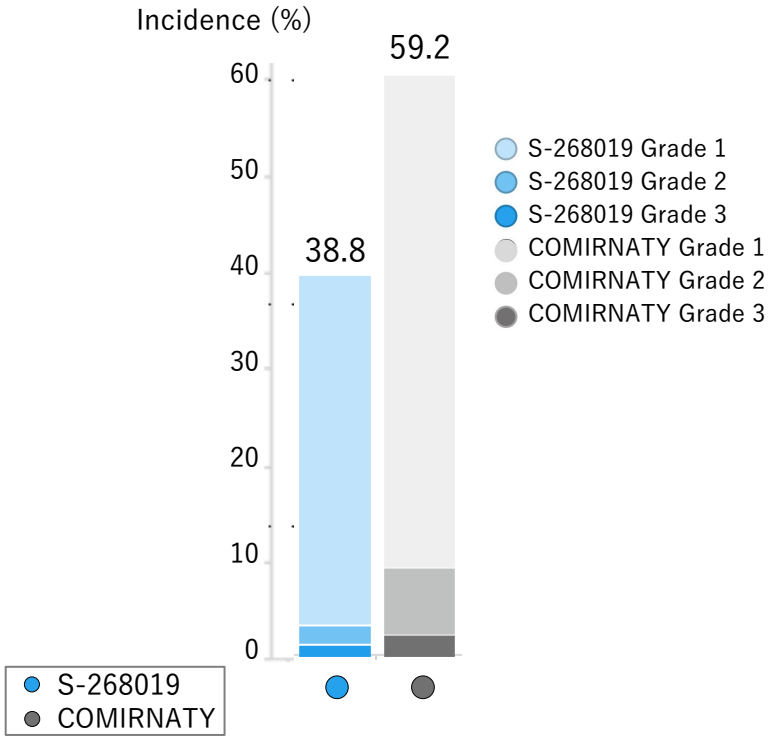
			S-268019 N=103	COMIRNATY N=103
Induration participants ((%) of participants)	Severity	Total	0 (0.0%)	0 (0.0%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	0 (0.0%)	0 (0.0%)
		Grade 1	0 (0.0%)	0 (0.0%)
Swelling participants ((%) of participants)	Severity	Total	1 (1.0%)	1 (1.0%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	0 (0.0%)
		Grade 2	1 (1.0%)	0 (0.0%)
		Grade 1	0 (0.0%)	1 (1.0%)

Solicited Local TRAEs (Incidents, Severity) 2/2



Solicited Systemic AEs ：Fever ((%) of participants, Severity, Timing of Onset)

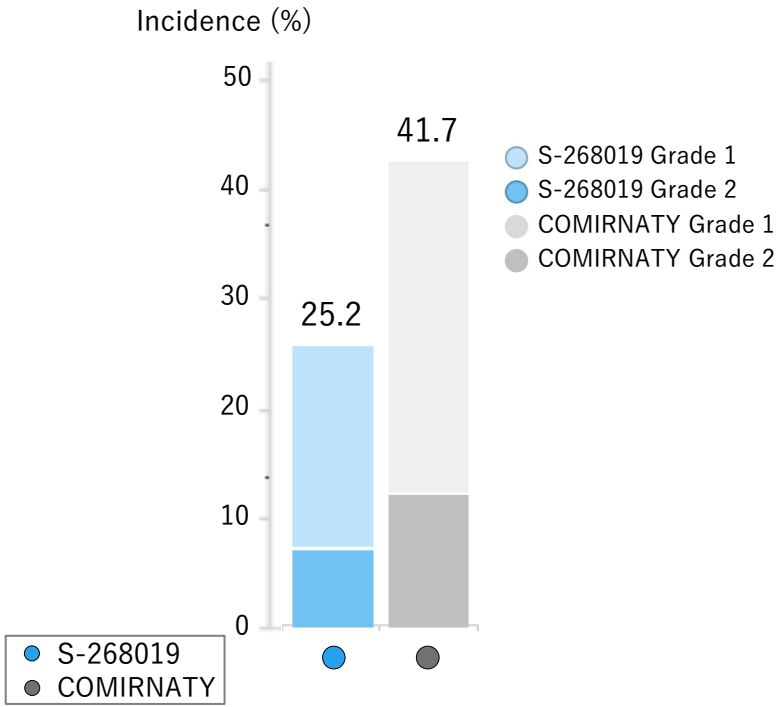
(%) of participants, Severity



			S-268019 N=103	COMIRNATY N=103
Fever participants ((%) of participants)	Severity	Total	40 (38.8%)	61 (59.2%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	1 (1.0%)	2 (1.9%)
		Grade 2	2 (1.9%)	7 (6.8%)
		Grade 1	37 (35.9%)	52 (50.5%)
	Timing of Onset	1	9 (8.7%)	19 (18.4%)
		2	30 (29.1%)	42 (40.8%)
		3	1 (1.0%)	0 (0.0%)
		>=4	0 (0.0%)	0 (0.0%)

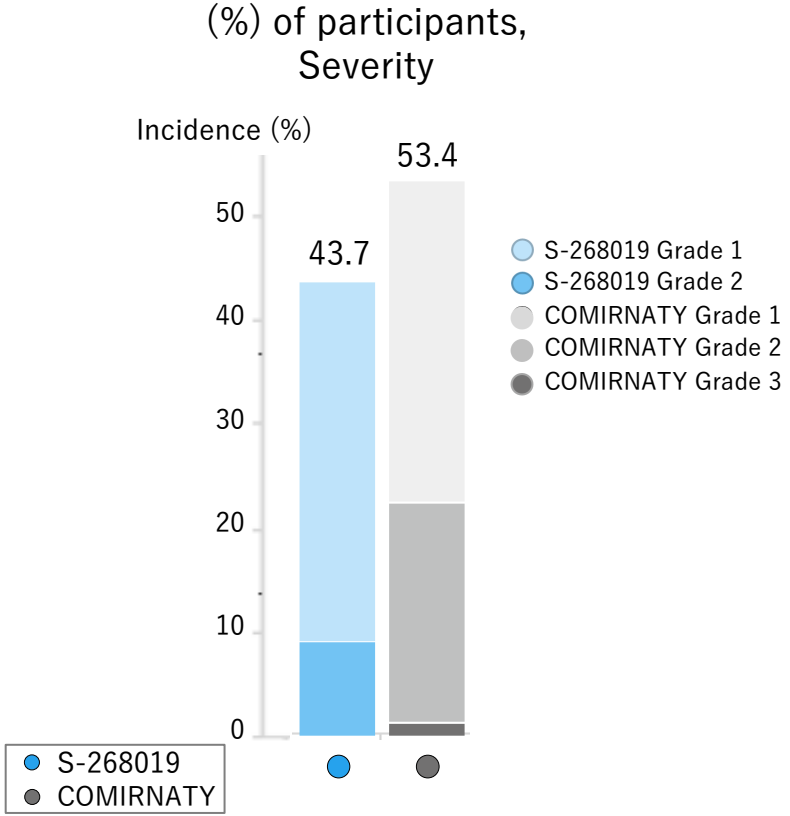
Solicited Systemic AEs ：Headache ((%) of participants, Severity, Timing of Onset)

(%) of participants, Severity



			S-268019 N=103	COMIRNATY N=103
Headache participants ((%) of participants	Severity	Total	26例 (25.2%)	43例 (41.7%)
		Grade 5	0例 (0.0%)	0例 (0.0%)
		Grade 4	0例 (0.0%)	0例 (0.0%)
		Grade 3	0例 (0.0%)	0例 (0.0%)
		Grade 2	7例 (6.8%)	12例 (11.7%)
		Grade 1	19例 (18.4%)	31例 (30.1%)
	Timing of Onset	1	5例 (4.9%)	16例 (15.5%)
		2	20例 (19.4%)	25例 (24.3%)
		3	1例 (1.0%)	1例 (1.0%)
		4	0例 (0.0%)	0例 (0.0%)
		5	0例 (0.0%)	0例 (0.0%)
		6	0例 (0.0%)	1例 (1.0%)
		>=7	0例 (0.0%)	0例 (0.0%)

Solicited Systemic AEs ：Fatigue ((%) of participants, Severity, Timing of Onset)



			S-268019 N=103	COMIRNATY N=103
Fatigue participants ((%) of participants	Severity	Total	45 (43.7%)	55 (53.4%)
		Grade 5	0 (0.0%)	0 (0.0%)
		Grade 4	0 (0.0%)	0 (0.0%)
		Grade 3	0 (0.0%)	1 (1.0%)
		Grade 2	9 (8.7%)	22 (21.4%)
		Grade 1	36 (35.0%)	32 (31.1%)
	Timing of Onset	1	24 (23.3%)	16 (15.5%)
		2	21 (20.4%)	39 (37.9%)
		>=3	0 (0.0%)	0 (0.0%)

Summary

- Immunogenicity
  - In the interim report, this trial met its primary endpoint.
    - > The results showed the noninferiority of S-268019 to COMIRNATY.

- Safety
  - There were no treatment-related serious AEs, deaths, grade 4-5 solicited TRAEs, or AEs of special interest in both group.
  - The most frequently reported TRAEs were fever, headache, fatigue, myalgia and injection site pain.
  - Most of the solicited TRAEs were grade 1-2 and one participant in the S-268019 group and four participants in the COMIRNATY group experienced grade 3 solicited TRAEs.
  - Compared with COMIRNATY, S-268019 led to a lower incidence of solicited TRAEs.

End of slides