The European Scientific Working Group on Influenza （ESWI）2023 Follow-up Meeting

September 19, 2023
Shionogi & Co., Ltd.

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Agenda

- **Ensitrelvir as a Treatment Option for Persistent SARS-CoV-2 Infection After Remdesivir in Hospitalized Patients With Comorbidities: A Single-Center Case Series From Japan**
  - **Dr. Masaya Yamato / M.D., Infectious Diseases Center director, Rinku General Medical Center Hospital**

- **Effect of Ensitrelvir on Long COVID in Patients with Mild-to-Moderate COVID-19: A Post-Hoc Analysis of the Phase 3 SCORPIO-SR Study**
  - **Takeki Uehara / D.V.M., Ph.D. / Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division, SHIONOGI&CO.,LTD.**

- **Q&A**

Ensitrelvir as a Treatment Option for Persistent SARS-CoV-2 Infection After Remdesivir in Hospitalized Patients With Comorbidities

Rinku General Medical Center

Department of General Internal Medicine and Infectious Diseases

Masaya Yamato

There are no companies with COI relationships that should be disclosed in connection with this announcement.

Background and Purpose

Ensitrelvir

- Ensitrelvir is an oral inhibitor of 3 CL protease of SARS-CoV-2 approved under the emergency regulatory approval system in Japan
  - Ensitrelvir has shown early alleviation of symptom and cessation of viral shedding in patients with mild-to-moderate COVID-19

Current status of ensitrelvir

There is insufficient evidence regarding the efficacy and safety of ensitrelvir in patients suffering from persistent COVID-19, those with comorbidities, and hospitalized patients.

Purpose of trial

To assess the clinical outcomes, including background and treatment outcomes, of hospitalized patients with risk factors for severe disease who were treated with ensitrelvir in Japan

(UMIN Clinical Trials identifier: UMIN000051300)

Trial Outline

- A retrospective chart review was conducted at Rinku General Medical Center (Osaka, Japan)
- All patients with COVID-19 who were hospitalized between November 2022 and April 2023, and were treated with ensitrelvir after ≥3-day remdesivir treatment were eligible for the analysis
  - ✓ Ensitrelvir was administered orally once daily (375 mg on Day 0, 125 mg on Days 1 to 4) according to the product label
  - ✓ Ensitrelvir was administered after at least 72 hours of onset
- Data on evaluation items were retrospectively captured until Day 13

Primary endpoint

- **Post-treatment virologic outcomes** ----------

Virus measurement methods, cutoff values, and viral clearance definitions

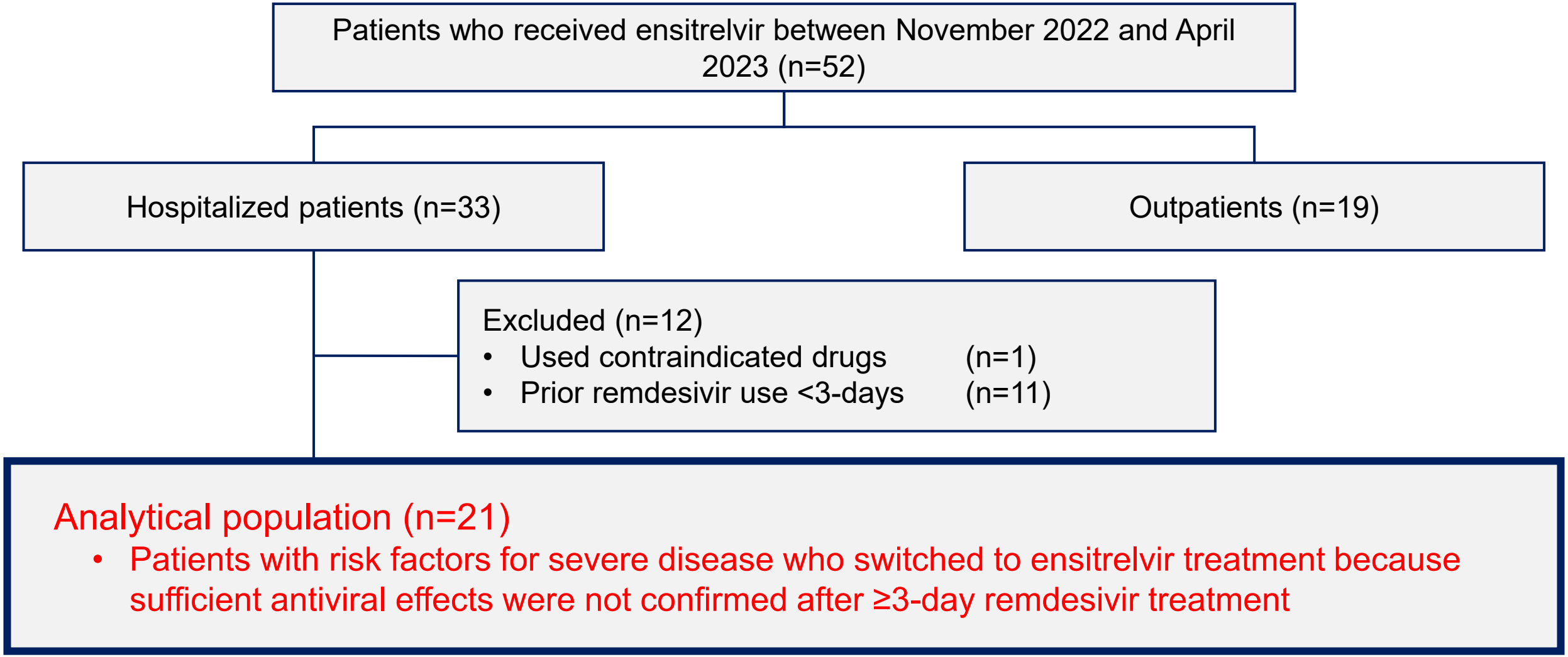
- ➢ Quantitative antigen levels in patients' nasal swabs were assessed using Lumipulse®
- ➢ The maximum and cutoff viral antigen levels were set at 5000 pg/mL and 1.34 pg/mL
- ➢ Viral clearance was defined as an antigen level of <89.73 pg/mL based on the published literature*

Other endpoints

- **Clinical outcomes**
  (e.g., improvement, admission to the intensive care unit [ICU], disease progression, and death)
- **Drug-related adverse events**

* Kase F, et al. *Igaku Kensa.* 2022;71(2):250–6 (article in Japanese)

Patient disposition



Patient demographics and clinical characteristics on Day 0

	Overall (n=21)	Mild (n=17)	Moderate I (n=2)	Moderate II (n=2)
Male sex, n (%)	10 (47.6)	6 (35.3)	2 (100.0)	2 (100.0)
Age (years), mean±SD	78.0±8.9	77.4±8.4	73.5±12.0	87.5±9.2
Prior treatment for SARS-CoV-2 infection, n (%)				
Remdesivir	20 (95.2)	16 (94.1)	2 (100.0)	2 (100.0)
Remdesivir + casirivimab/imdevimab	1 (4.8)	1 (5.9)	0 (0.0)	0 (0.0)
Duration of remdesivir treatment (days), mean±SD	6.6±3.9	6.5±4.2	7.5±3.5	6.0±2.8
No SARS-CoV-2 vaccination, n (%)	5 (23.8)	4 (23.5)	0 (0.0)	1 (50.0)
Concomitant use of systemic corticosteroids, n (%)	5 (23.8)	5 (29.4)	0 (0.0)	0 (0.0)
Comorbidity, n (%)				
Malignant tumors	7 (33.3)	6 (35.3)	0 (0.0)	1 (50.0)
Diabetes mellitus	6 (28.6)	2 (11.8)	2 (100.0)	2 (100.0)
Renal failure	4 (19.0)	3 (17.6)	0 (0.0)	1 (50.0)

COVID-19 disease severity criteria (according to Japanese guideline)

Severity	SpO_2	Clinical condition
Mild	$SpO_2 \geq 96\%$	No respiratory symptoms or cough only (no dyspnea, no evidence of pneumonia)
Moderate I	$93\% < SpO_2 > 96\%$	Dyspnea, pneumonia
Moderate II	$SpO_2 \leq 93\%$	Requires oxygen
Severe		ICU admission or requires mechanical ventilator

Antiviral Effect of Ensitrelvir

Confirmed strong antiviral effect in patients with risk factors for severe disease

patients	Last remdesivir dose	Remdesivir treatment period (days)	Individual patient characteristics and viral antigen levels (pg/mL)														
				Ensitrelvir administration period													
			Day-2,-1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
1	Day 0	8	5000	5000		5000	5000	5000				1233	495		255	8.67	44.6
2	Day 0	4	5000	5000			87.07	25.39	8.5	6.81	7.94	94.59	0.14	2.29	0.05	1.73	0.57
3	Day -2	5	206	3430	235	10.35	1.06	0.95									
4	Day 0	10	5000	5000			538		84.4	7.89	43.06	3.56	2.08	0.01	0.06		
5	Day -1	5	5000	5000		571			21.75	18.67	9.43	2.81	0.06	4.79	0.01	0.1	
6	Day -1	5	255	5000			36.55		25.72	1.61	0.3	0.01					
7	Day -1	5	5000	5000		1394		39.12	43.49	46.3		28.65	0.83	0.89			
8	Day 0	4		5000		1676					27.73						
9	Day -1	8	5000	2729	3736	142		13.5	0.3								
10	Day 1	22	5000	5000		2588		4.77	1211		5000	5000	5000				
11	Day 0	8	5000	5000	5000		1087	4091			16.27	11.83	3.76	1.73	0.01		
12	Day -1	7	5000			1.04	0.11										
13	Day -1	6	5000	5000		53.22			2.1	0.62							
14	Day 0	5	4329	5000		5000			2468		5000		3637			114.93	12.95
15	Day 0	5	1728	2393		1354			2.51	1.61	1.05	2.59	1.03	0.01			
16	Day -6	5	5000		5000			7.42	8.09	1.97	4.39	0.71	2.78	0.67	1.72	0.08	0.24
17	Day 0	3	5000	5000			224		2.37	8.01	5.99	41.02		1.23	0.01		
18	Day -1	7	1305	5000			1021				19.95	1.89	0.57	0.24			
19	Day -1	6	5000			1767	275	246	148	111			3.44	6.81	1.92	1.15	0.56
20	Day -2	5	5000	5000		5000		1330									
21	Day -1	5	5000	5000		1292			63.29		9.86	11.31	1.56	0.01			

Red : Areas where virus clearance has not been achieved （> 89.73pg/ml）

: Period the patient has been in the hospital

: The day when viral clearance was achieved by the next day of ensitrevir treatment

Viral clearance was achieved in 66.7% (14/21 patients) of patients by the next day after ensitrelvir treatment

Outcomes

- **All patients who did not achieve viral clearance after remdesivir treatment for 3 to 22 days, Ensitrelvir efficacy was confirmed in all cases after 5 days of ensitrelvir treatment.**
  - ✓ **Viral clearance was achieved in 66.7% (14/21 patients) of patients by the next day after ensitrelvir treatment**
    - ➢ Viral clearance was ultimately achieved in all 21 patients (one patients received remdesivir treatment between Day 7 and Day 11)
  - ✓ **Achievement of clinical improvement in all patients and 20 patients were discharged** (by Day 77)
    - ➢ Patient17 died on day 59 due to an underlying comorbidity of ANCA-associated vasculitis
  - ✓ Five patients developed a transient increase of body temperature (≧37.5 degree Celsius) after completion of ensitrelvir treatment
  - ✓ Two patients experienced viral rebound* (viral antigen level ≥89.73 pg/mL) after viral clearance by Day 13
    - ➢ Neither of the two reported rebound of symptoms nor received additional antiviral

* Defined as antigen level exceeding 89.73 pg/ml again after viral clearance

anti-neutrophil cytoplasmic antibody: ANCA

Conclusion

- This trial was conducted in hospitalized patients who showed persistent SARS-CoV-2 infection after remdesivir and switched to ensitrelvir treatment
  - ✓ Hospitalized patients with comorbidities
- Ensitrelvir showed potent antiviral efficacy, and all patients improved clinically after ensitrelvir treatment.
- High efficacy confirmed for patients with risk factors for severe disease
  - ✓ No patients were admitted to the ICU due to severe disease through Day 28 period
  - ✓ Survival rate at day 28 is 100%
- Confirming the efficacy and safety of ensitrelvir even when treatment starts after 72 hours

These results indicate that ensitrelvir is a treatment option for patients with persistent SARS-CoV-2 infection and risk factors for severe disease

Effect of Ensitrelvir on Long COVID in Patients with Mild-to-Moderate COVID-19: A Post-Hoc Analysis of the Phase 3 SCORPIO-SR Study

Takeki Uehara / D.V.M., Ph.D. / Corporate Officer, Senior Vice President,
Drug Development and Regulatory Science Division, SHIONOGI&CO.,LTD.

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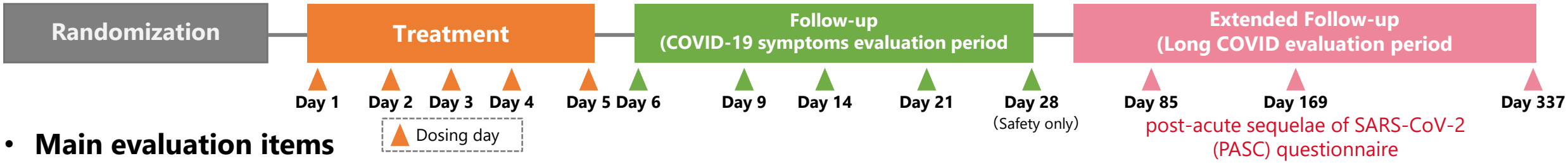
Phase 3 part of Phase 2/3 trial Outline

- **Trial purpose**
  - To evaluate the efficacy and safety of ensitrelvir once-daily, 5 days oral treatment in patients with mild/moderate SARS-CoV-2 infection, aged 12-69 years regardless of SARS-CoV-2 vaccination, and risk factors for severe disease
- **Trial design**
  - Multicenter, randomized, double-blinded, placebo-controlled study conducted in Japan, South Korea and Vietnam from February to November in 2022



- **Main evaluation items**
  - Primary endpoint：Time to resolution[a] of five key Covid-19 symptoms
  - Key secondary endpoint：antiviral effect（viral RNA amount、virus titer)
  - Safety（Until the Day 28）
  - Exploratory endpoint: Presence of Long COVID symptoms evaluated by PASC questionnaire (27 symptoms)
    - Data up to Day 169 has already been reported at CROI 2023 in February 2023, and data up to Day 337 is the subject of this report

[a] Time to return to pre symptomatic state, defined as time to “recovery” in the trial protocol

Summary of Patient Background

※The trial results only include the domestically approved dose of 125 mg of ensitrelvir.
(See Appendix for results at 250 mg)

Background information on patients who completed the PASC questionnaire for at least one timepoint in the Intention-To-Treat (ITT*) population

	125 mg N = 341	**Placebo** N = 333
Male sex (%)	54.8%	58.3%
Age (years)	36.4	35.6
BMI (kg/m^2)	23.3	22.8
SARS-CoV-2 vaccination received	91.5%	92.8%
Total score of 14 symptoms[a] at baseline		
N	334	326
Median (range)	9.0 (1–30)	9.0 (2–28)

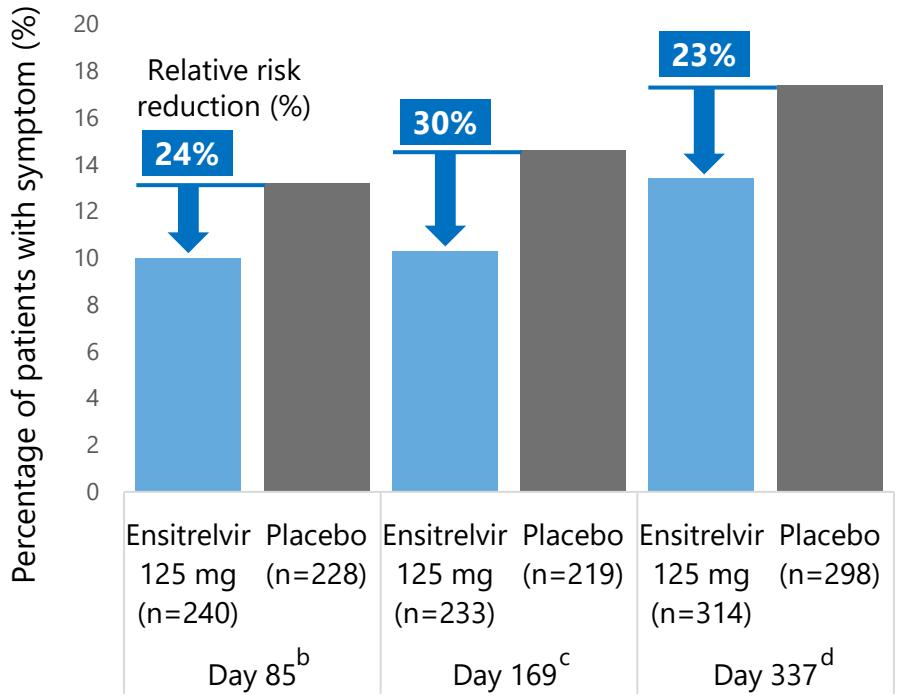
* Intention-to-treat (ITT)：All subjects who were randomly assigned to the trial intervention and had a SARS-Cov-2 infection based on RT-PCR. 1,798 subjects excluding 23 subjects that were PCR negative at baseline (from 1,821 subjects)

[a] Stuffy or runny nose, sore throat, shortness of breath, cough, low energy or tiredness, muscle or body aches, headache, chills or shivering, feeling hot or feverish, nausea, vomiting, diarrhea, loss of smell, and loss of taste. Each symptom was self-assessed using a 4-point scale of 0 to 3 (3-point scale of 0 to 2 for loss of smell and loss of taste).
BMI, body mass index; range, minimum-maximum

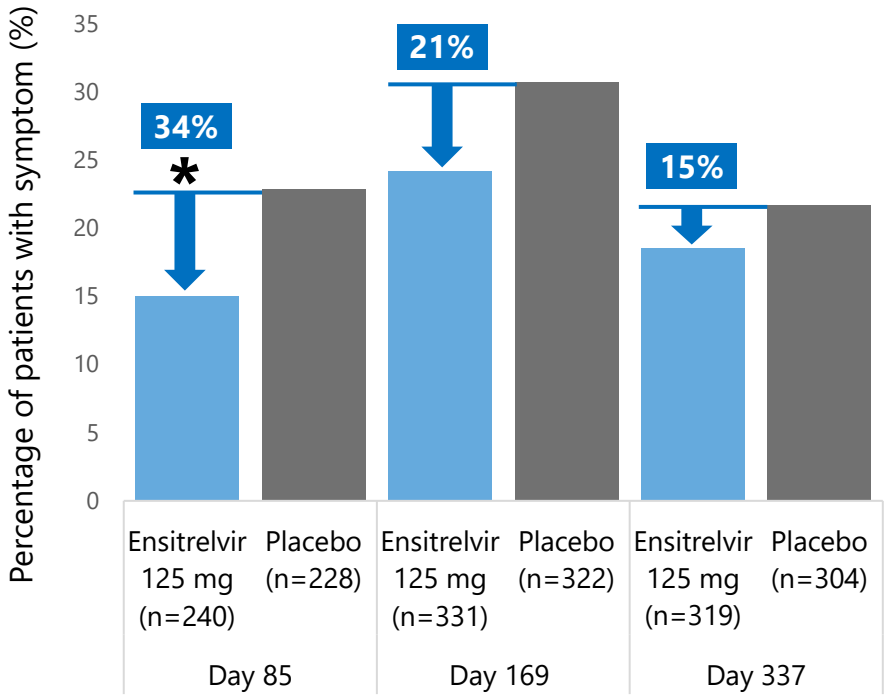
Proportion of Patients with Long COVID Symptoms and Effect on Long COVID Symptoms

Definition of Long COVID symptoms: At least one specified symptom self-judged as related to COVID-19

Percentage of patients with any of the 14 symptoms



Percentage of patients with any of the 4 neurological symptoms[a]



*P value of <0.05 using Fisher's exact test.

The proportion of patients with Long COVID symptoms in the ensitrelvir 125 mg was lower than that in the placebo group at all timepoints.

[a] Difficulty with concentration and thinking, difficulty reasoning and solving problems, memory loss, or insomnia.
[b] Patients who perceived any of the symptoms at both last observation in the follow-up period (e.g., Day 21) and Day 85.
[c] Patients who perceived any of the symptoms at both Day 85 and Day 169. [d] Patients who perceived any of the symptoms at both Day 169 and Day 337.

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Proportion of patients who did not return to usual (pre-COVID) health

Patients who answered "No" to the question "Have you returned to your usual (pre-COVID) health?".

	125 mg N = 379	**Placebo** N = 362
Day 85	7.5% (18/240)	11.8% (27/228)
Day 165	7.6% (25/331)	10.2% (33/322)
Day 337	6.0% (19/319)	8.2% (25/304)

The proportion of patients not having returned to usual health in the ensitrelvir treatment group was lower than that in placebo group at all the timepoints.

Revised definition of Long COVID

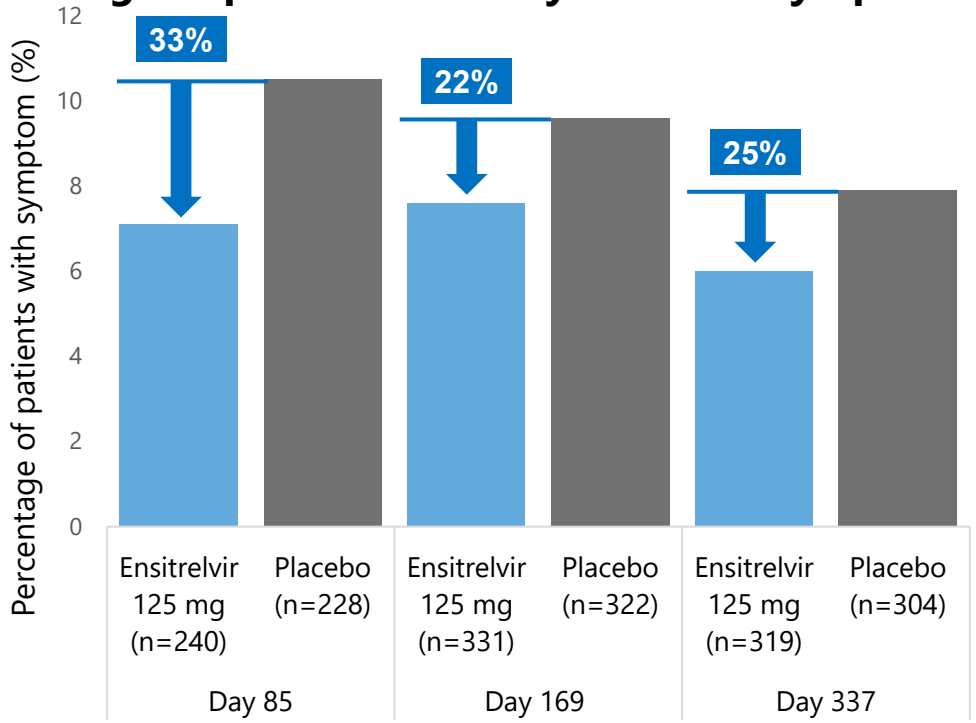
- Due to the following reasons, we have revised the definition to be more rigorous, considering that the previous definition may not be suitable for assessing long-term Long COVID over the period of a year.
  - Patients may not be able to accurately assess the relationship to COVID-19, especially at later time points (Day 337)
  - Some KOLs suggest that “patients who did not return to usual (pre-COVID) health” should be included in the definition

Before revision	After revision
Presence of at least one mild or more severe symptom, and has at least one symptom that self-judged as related to COVID-19	Presence of at least one mild or more severe symptom, not having returned to usual health

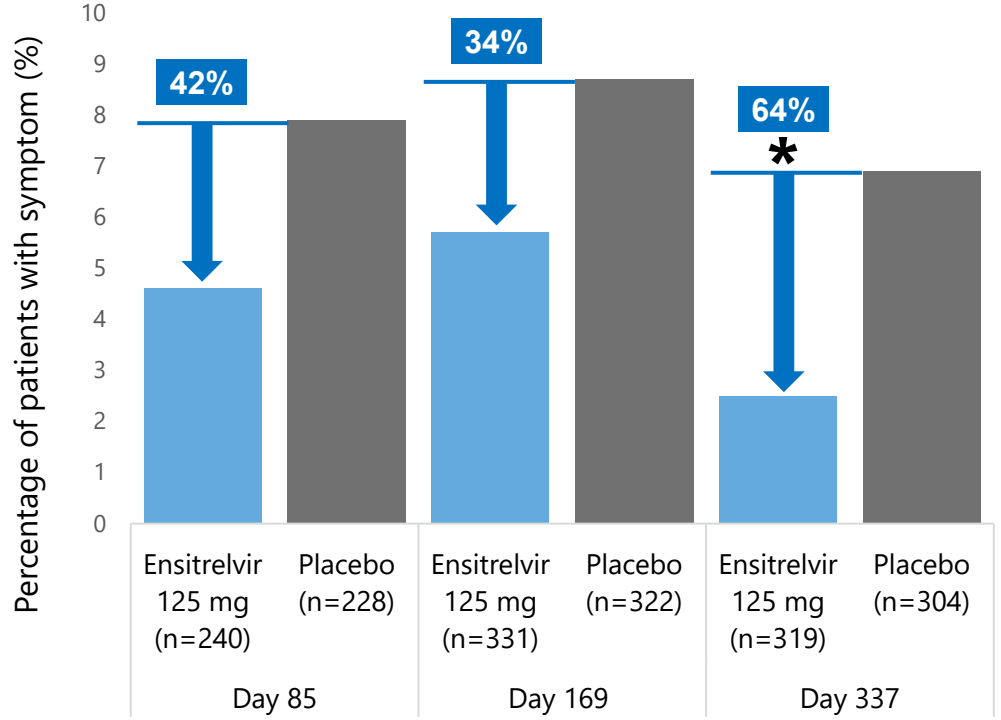
Proportion of Patients with Long COVID Symptoms and Effect on Long COVID Symptoms

Definition of Long COVID symptoms: Specified symptom in patients who answered "not returned to pre-COVID health"

Percentage of patients with any of the 14 symptoms



Percentage of patients with any of the 4 neurological symptoms



*P value of <0.05 using Fisher's exact test.

- **Even with the revised definition, the proportion of patients with Long COVID symptoms in the ensitrelvir 125 mg was lower than that in the placebo group at all timepoints.**
- **64% reduction in the proportion of patients presenting with the four most commonly reported post-acute neurological symptoms on Day 337**

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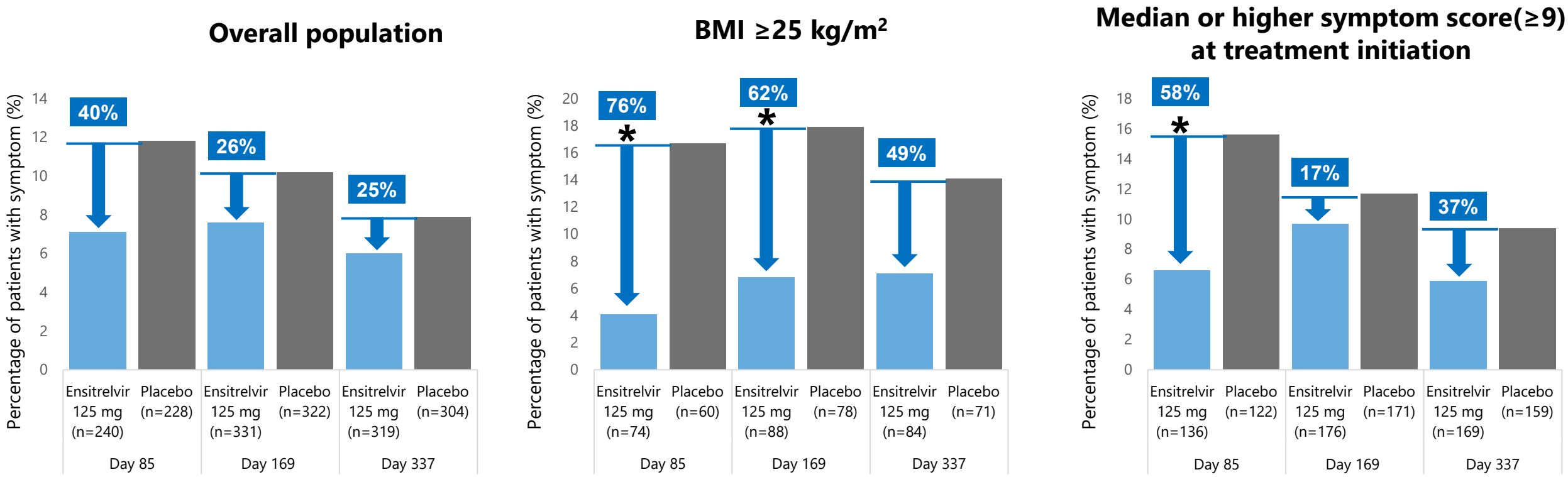
Proportion of Patients with Long COVID Symptoms and Effect on Long COVID Symptoms (Patients with any of the 27 symptoms of COVID-19)



- On Day 337, 25% reduction in the proportion of patients with any of the 27 symptoms characteristic of COVID-19
- Greater risk reduction was observed in patients who with BMI ≥25 kg/m2 and patients with median or higher symptom score at the start of treatment
  - On Day 337, BMI ≥25 kg/m2; 49%, patients with median or higher symptom score at treatment initiation; 37%

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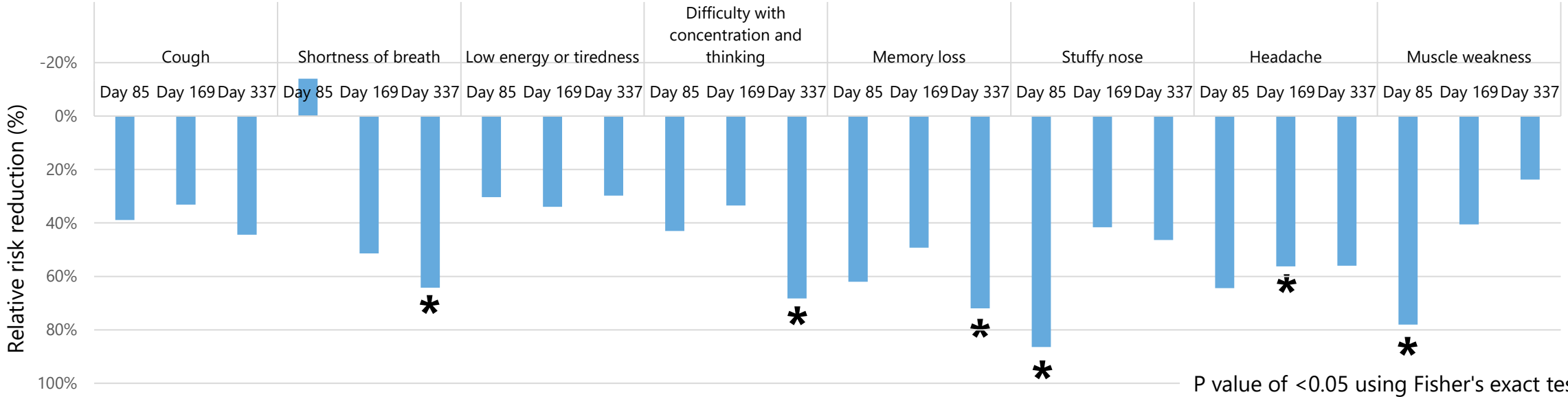
Effect on Long COVID Symptoms（overall population, individual symptom reported (≥5%)[a]）



P value of <0.05 using Fisher's exact test.

	Cough			Shortness of breath			Low energy or tiredness			Difficulty with concentration and thinking			Memory loss			Stuffy nose			Headache			Muscle weakness		
	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337
125mg	9/240	11/331	7/319	6/240	9/331	6/319	11/240	19/331	14/319	9/240	13/331	6/319	4/240	12/331	5/319	1/240	9/331	9/319	3/240	9/331	6/319	3/240	11/331	8/319
placebo	14/228	16/322	12/304	5/228	18/322	16/304	15/228	28/322	19/304	15/228	19/322	18/304	10/228	23/322	17/304	7/228	15/322	16/304	8/228	20/322	13/304	13/228	18/322	10/304

- **On Day 337, a statistically significant reduction in the risk of developing shortness of breath and cognitive symptoms (difficulty with concentration and thinking; memory loss) with ensitrelvir treatment was observed at some time points.**
- **On Day 337, reduction in shortness of breath: 64%, difficulty with concentration and thinking: 68%, memory loss: 72%**

[a] Long COVID symptoms seen in placebo group and at any time point with an incidence of ≥5% were shown

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Summary

- **Ensitrelvir treatment reduced the risk of developing Long COVID by 25% at follow-up one year after infection**
- **In particular, the risk was significantly reduced for symptoms such as shortness of breath (64%), decreased concentration and thinking (68%), and memory loss (72%)**
- **The Long COVID risk reduction by ensitrelvir was greater in patients with BMI ≥25 kg/m^2 or severe post-infection symptoms, with risk reductions of 49% and 37%, respectively**

- **The results indicate that early treatment of COVID-19 with ensitrelvir may reduce the risk of a number of symptoms associated with Long COVID over a long period of time (one year)**

- **Further research will be conducted in the Global Phase 3 Trial (SCORPIO-HR)**

Appendix

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Demographics and baseline clinical characteristics

Background information on the patients who completed the PASC questionnaire for at least one timepoint in the Intention-To-Treat (ITT*) population

	125 mg N = 341	250 mg N = 317	Placebo N = 333
Male sex (%)	54.8%	53.3%	58.3%
Age (years)	36.4	36.5	35.6
BMI (kg/m^2)	23.3	23.0	22.8
SARS-CoV-2 vaccination received	91.5%	92.1%	92.8%
Total score of 14 symptoms[a] at baseline			
N	334	309	326
Median (range)	9.0 (1–30)	8.0 (0-30)	9.0 (2–28)

* Intention-to-treat (ITT)：All subjects who were randomly assigned to the trial intervention and had a SARS-Cov-2 infection based on RT-PCR. 1,798 subjects excluding 23 subjects that were PCR negative at baseline (from 1,821 subjects)

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BMI, body mass index; range, minimum-maximum

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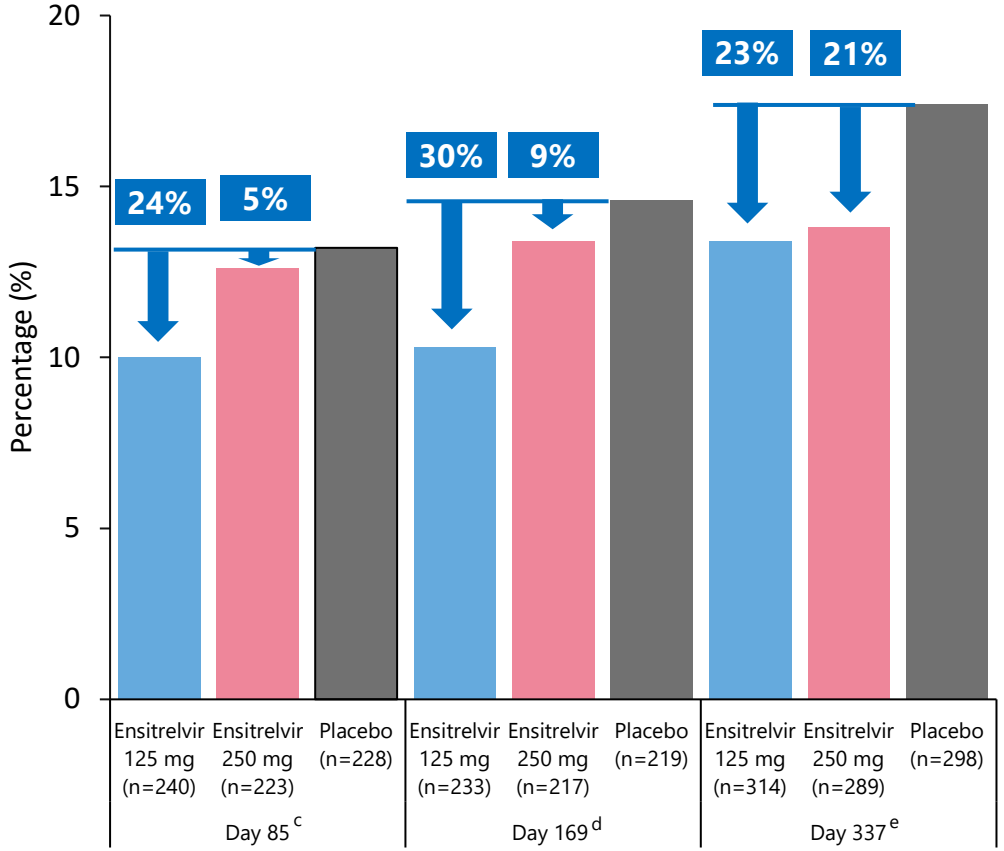
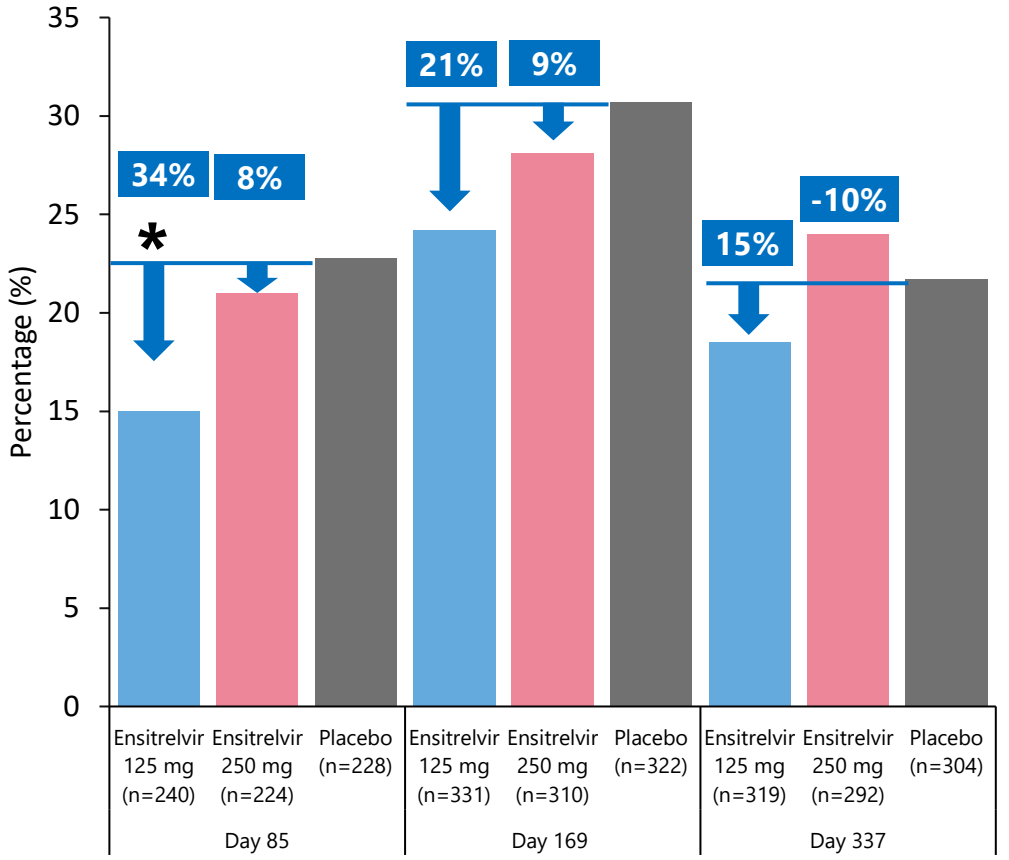
Proportion of patients with Long COVID and risk reduction versus placebo [presence of at least one symptom, with a self-judgment of its relationship to COVID-19]

Patients with any of the 14 COVID-19 symptoms[a]



Patients with any of the 4 neurological symptoms[b]



Data are summarized for patients who completed the PASC questionnaire for at least one timepoint in the ITT population.
[a] Stuffy or runny nose, sore throat, shortness of breath, cough, low energy or tiredness, muscle or body aches, headache, chills or shivering, feeling hot or feverish, nausea, vomiting, diarrhea, loss of smell, or loss of taste. [b] Difficulty with concentration and thinking, difficulty reasoning and solving problems, memory loss, or insomnia.
[c] Patients who perceived any of the symptoms at both last observation in the follow-up period (e.g., Day 21) and Day 85. [d] Patients who perceived any of the symptoms at both Day 85 and Day 169.
[e] Patients who perceived any of the symptoms at both Day 169 and Day 337. * P value of <0.05 using Fisher's exact test.

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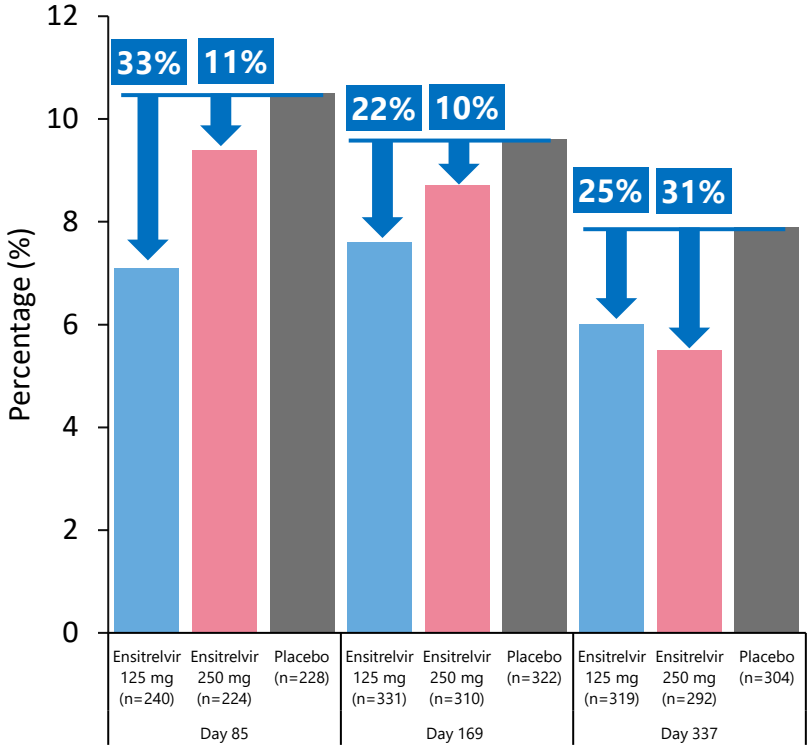
Proportion of patients who answered not returned to usual (pre COVID) health

	Endpoint	125 mg N = 379	250 mg N = 345	Placebo N = 362
Day 85	Not returned to usual health[a]	7.5% (18/240)	9.8% (22/224)	11.8% (27/228)
Day 169	Not returned to usual health[a]	7.6% (25/331)	8.7% (27/310)	10.2% (33/322)
Day 337	Not returned to usual health[a]	6.0% (19/319)	6.5% (19/292)	8.2% (25/304)

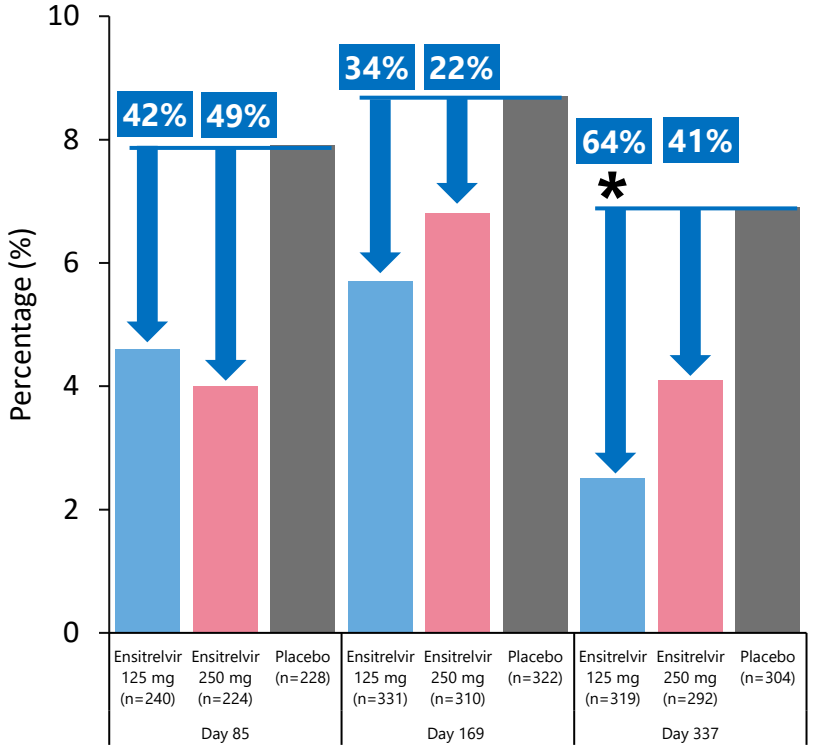
Data are summarized for patients who accepted to participate in the exploratory period in the ITT population and are presented as percentage (proportion).
[a] Patients who answered "No" to the question "Have you returned to your usual (pre-COVID) health?".

Proportion of patients with Long COVID (any of the 14 COVID 19 and 4 neurological symptoms) and risk reduction versus placebo of having at least one symptom and not returned to usual (pre COVID) health

Patients with any of the 14 COVID-19 symptoms



Patients with any of the 4 neurological symptoms



Data are summarized for patients who completed the PASC questionnaire for at least one timepoint in the Intention-To-Treat (ITT) population.
*P value of <0.05 using Fisher's exact test.

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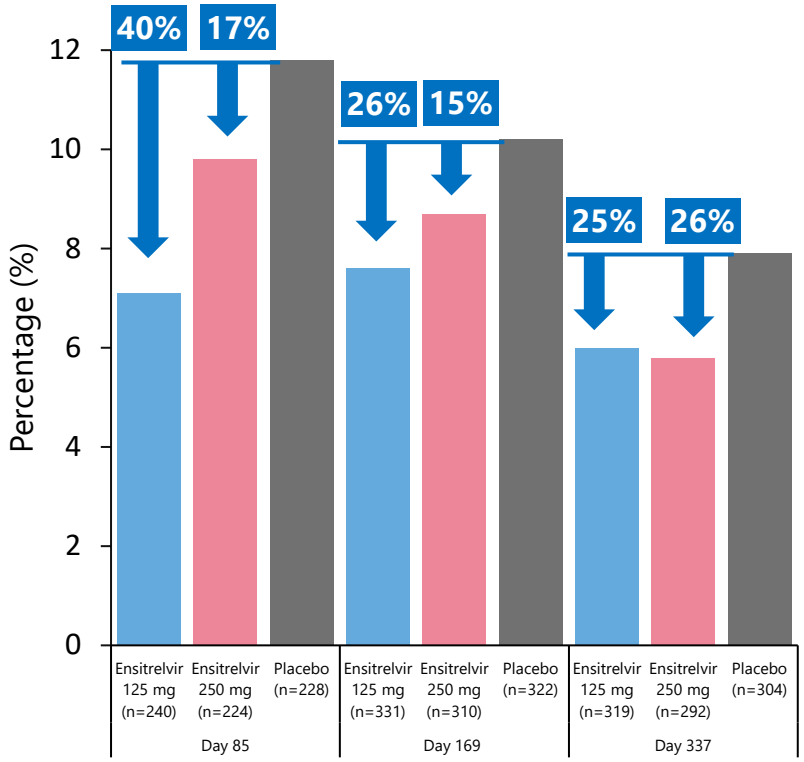
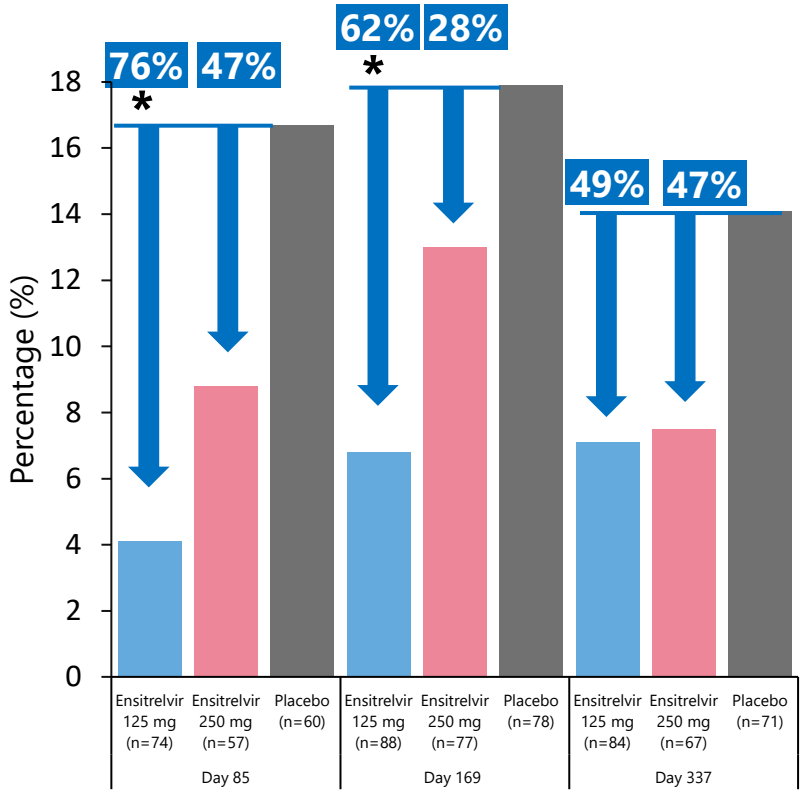
Proportion of patients with Long COVID and risk reduction versus placebo [presence of at least one symptom (among all 27 symptoms[a]), not having returned to usual health]

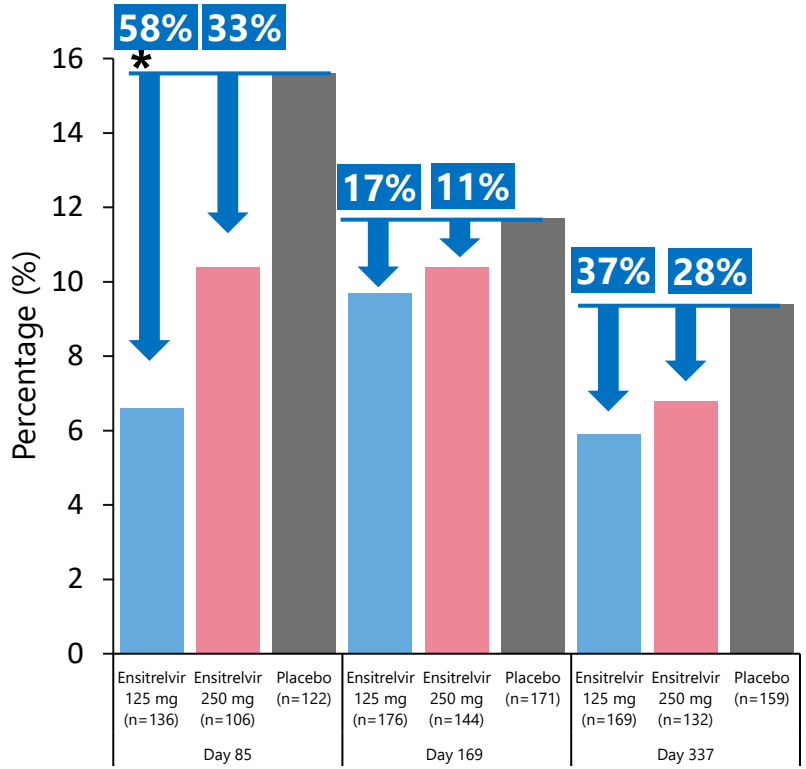
Overall population



Patients with BMI ≥25 kg/m²



Patients with median or higher symptom scores at treatment initiation[b]



Data are summarized for patients who completed the PASC questionnaire for at least one timepoint in the Intention-To-Treat (ITT) population. * P value of <0.05 using Fisher's exact test.

[a] Cough, Shortness of breath or difficulty breathing, Feeling feverish, Chills, Fatigue (low energy), Body pain or muscle pain or aches, Diarrhea , Nausea, Vomiting, Headache, Sore throat, Nasal obstruction or congestion (stuffy nose), Nasal discharge (runny nose), Muscle weakness, Insomnia, Hair loss, Smell disorder, Palpitations or fast heart beat, Joint pain, Decreased appetite, Taste disorder, Dizziness/balance issues, Chest pain, Skin rash, Difficulty with concentration and thinking, Difficulty reasoning and solving problems, Memory loss (short or long term)

[b] The total score of 14 symptoms at baseline of ≥ 9. BMI, body mass index

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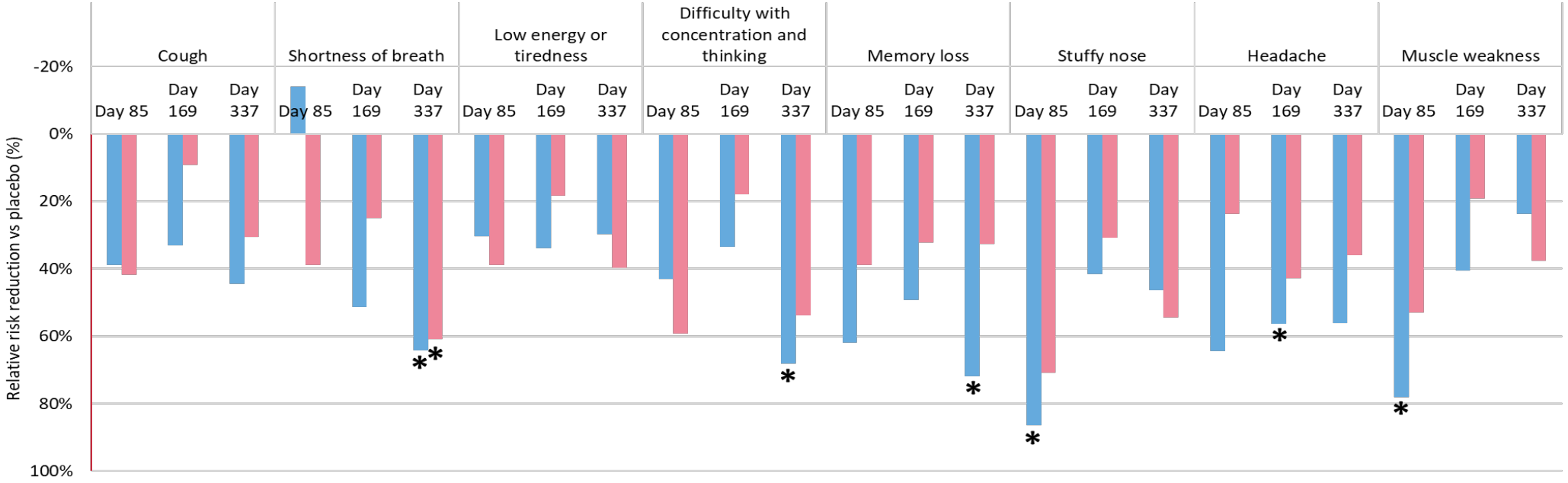
Relative risk reduction of individual Long COVID symptoms in the overall population [a breakdown of each key individual symptom reported (≥5%)[a] as not having returned to usual health]



	Cough			Shortness of breath			Low energy or tiredness			Difficulty with concentration and thinking			Memory loss			Stuffy nose			Headache			Muscle weakness		
	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337	Day 85	Day 169	Day 337
Ensitrelvir 125mg	9/240	11/331	7/319	6/240	9/331	6/319	11/240	19/331	14/319	9/240	13/331	6/319	4/240	12/331	5/319	1/240	9/331	9/319	3/240	9/331	6/319	3/240	11/331	8/319
Ensitrelvir 250mg	8/224	14/310	8/292	3/224	13/310	6/292	9/224	22/310	11/292	6/224	15/310	8/292	6/224	15/310	11/292	2/224	10/310	7/292	6/224	11/310	8/292	6/224	14/310	6/292
Placebo	14/228	16/322	12/304	5/228	18/322	16/304	15/228	28/322	19/304	15/228	19/322	18/304	10/228	23/322	17/304	7/228	15/322	16/304	8/228	20/322	13/304	13/228	18/322	10/304

Data are summarized for patients who completed the PASC questionnaire for at least one timepoint in the Intention-To-Treat (ITT) population.

[a] Long COVID symptoms seen in at least one time point with an incidence of ≥ 5% in placebo group were shown.

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