Poster 549

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Ensitrelvir for the treatment of COVID-19 infection: evaluation of taste disorder and smell disorder in the Phase 3 part of the Phase 2/3 SCORPIO-SR randomized controlled trial

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Introduction

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- Ensitrelvir is a selective SARS-CoV-2 3CL protease inhibitor, which is active against different variants of SARS-CoV-2, including several omicron sublineages circulating globally.[1]
- Ensitrelvir 125 mg, once-daily, oral treatment for 5 days significantly shortened the time to resolution of five key COVID-19 symptoms vs placebo in the Phase 3 part of the SCORPIO-SR study.[2]
- In addition to respiratory symptoms of COVID-19, acute and long-term impairment in taste and smell are frequently reported.[3]

Objective

- To assess the effects of ensitrelvir treatment on taste and smell impairment in outpatients with COVID-19 in the Phase 3 part of the SCORPIO-SR Phase 2/3 trial[4]

Methods

Enrollment period: February 2022–July 2022

- Multicenter, randomized, double-blind, placebo-controlled study in Japan, South Korea, and Vietnam
- Treatment arms: ensitrelvir 125 mg oral (PO), once daily (QD) [375 mg loading dose on Day 1], 250 mg PO QD [750 mg loading dose on Day 1], and placebo PO QD for 5 days

Stratification:
Vaccination status
Time from onset to treatment
(<3 days, ≥3 days)

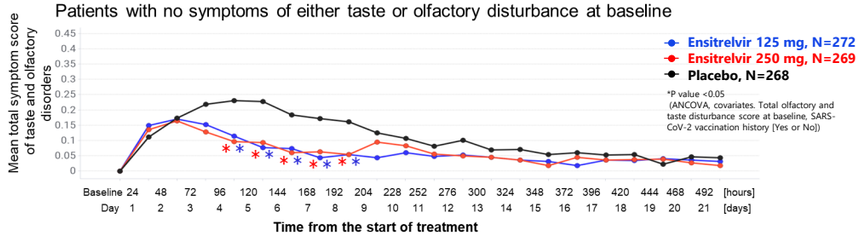
Symptoms assessment

Report of taste/smell symptoms: twice daily from Day 1 to Day 9, and once daily from Day 10 to Day 21
Symptom score: 0 – same as usual; 1 – moderate loss of taste/smell; 2 – complete loss of taste/smell

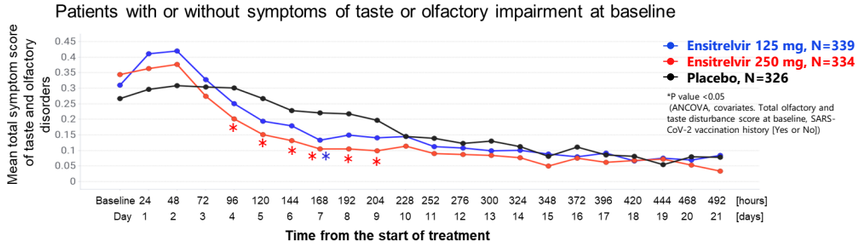
- **Inclusion criteria**: patients (aged 12–70 years) with mild/moderate symptoms within 5 days, regardless of vaccination status or risk factors for severe disease
- **Exclusion criteria**: patients requiring hospitalization, mechanical ventilation, or oxygen supplementation

Results

Total taste/smell symptom score* was significantly reduced with ensitrelvir 125 mg or 250 mg treatment vs placebo when initiated within 3 days

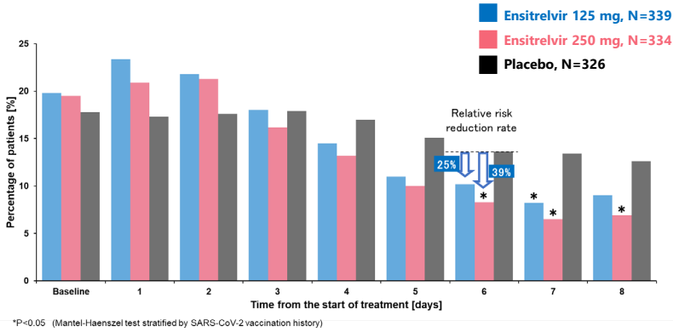


Total symptom score* was significantly reduced overall in patients treated with ensitrelvir 250 mg vs placebo by Day 4 and with ensitrelvir 125 mg by Day 7



***Total symptoms score: self-assessed by patients regarding taste disorder and smell disorder using a 3-point scale of 0 to 2.**

Ensitrelvir treatment initiated within 3 days reduced the risk of impairment in taste or smell



*P<0.05 (Mantel-Haenszel test stratified by SARS-CoV-2 vaccination history)

Conclusions

- **Early treatment with ensitrelvir 125 mg or 250 mg** in patients with COVID-19 resulted in a **rapid improvement in taste and smell symptoms** or prevention of their onset.
- The long-term effects of ensitrelvir treatment on loss of taste or smell and other "long COVID" symptoms are still under evaluation.

References

1. Kawashima S, et al. Ensitrelvir is effective against SARS-CoV-2 3CL protease mutants circulating globally. Biochem Biophys Res Commun. 2023;645:132–136.
2. Uehara T, et al. Ensitrelvir for mild-to-moderate COVID-19: Phase 3 part of Phase 2/3 study. Presented at CROI 2023; February 19–22, 2023; Seattle, WA, USA. Abstract 166. Oral presentation. https://www.croiconference.org/abstract/ensitrelvir-for-mild-to-moderate-covid-19-phase-3-part-of-phase-2-3-study/
3. Long B, et al. Clinical update on COVID-19 for the emergency clinician: presentation and evaluation. Am J Emerg Med. 2022;54:46–57.
4. ClinicalTrials.gov. NCT05305547. Accessed: August 14, 2023. https://www.clinicaltrials.gov/study/NCT05305547?term=NCT05305547&rank=1

Conflict of interest

These clinical trials were funded by Shionogi & Co., Ltd., Osaka, Japan. YT, TS, and TI are employees of Shionogi & Co. HY, NO, YD, MY, and HM are study medical experts, principal investigators, or coordinating investigators, and members of the Ensitrelvir Advisory Board.

Data previously presented in Japanese at the Japanese Association for Infectious Diseases conference 2023; April 28–30, 2023; Yokohama, Kanagawa, Japan. Abstract #O-004.