Top-Line Results for S-033188 Phase III Study in Otherwise Healthy Influenza Patients

Conference Call

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S-033188：Profile

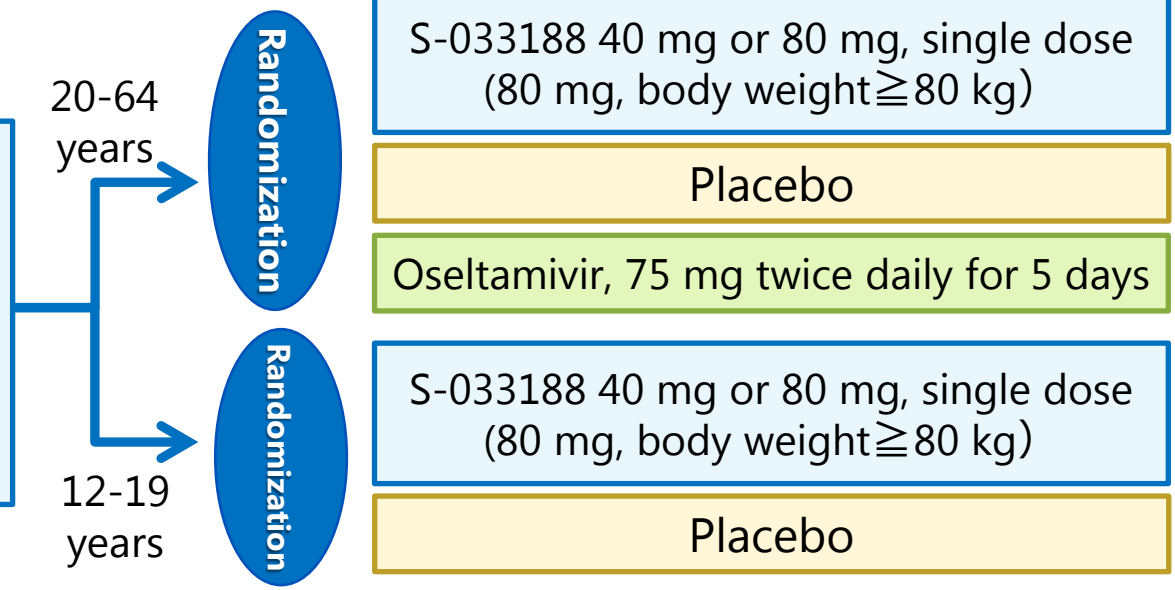
Indication	Influenza virus infection
Mechanism of action	Cap-dependent endonuclease inhibition (novel mechanism of action)
Special characteristics	Influenza type A/B viruses Highly pathogenic avian influenza viruses Single oral dose
Stage	Japan/Global: Phase III study
Future plan	Japan: NDA submission in FY2017
Note	Designated for “priority review system” by Ministry of Health, Labour and Welfare (MHLW)

Global Phase III Study Design (OwH* Study)

OwH* study

(CAPSTONE-1)

- Uncomplicated otherwise healthy patients aged 12-64 years
- 0-48 hours from onset
- Japan/North America /Asia
- **N=approximately 1,500**

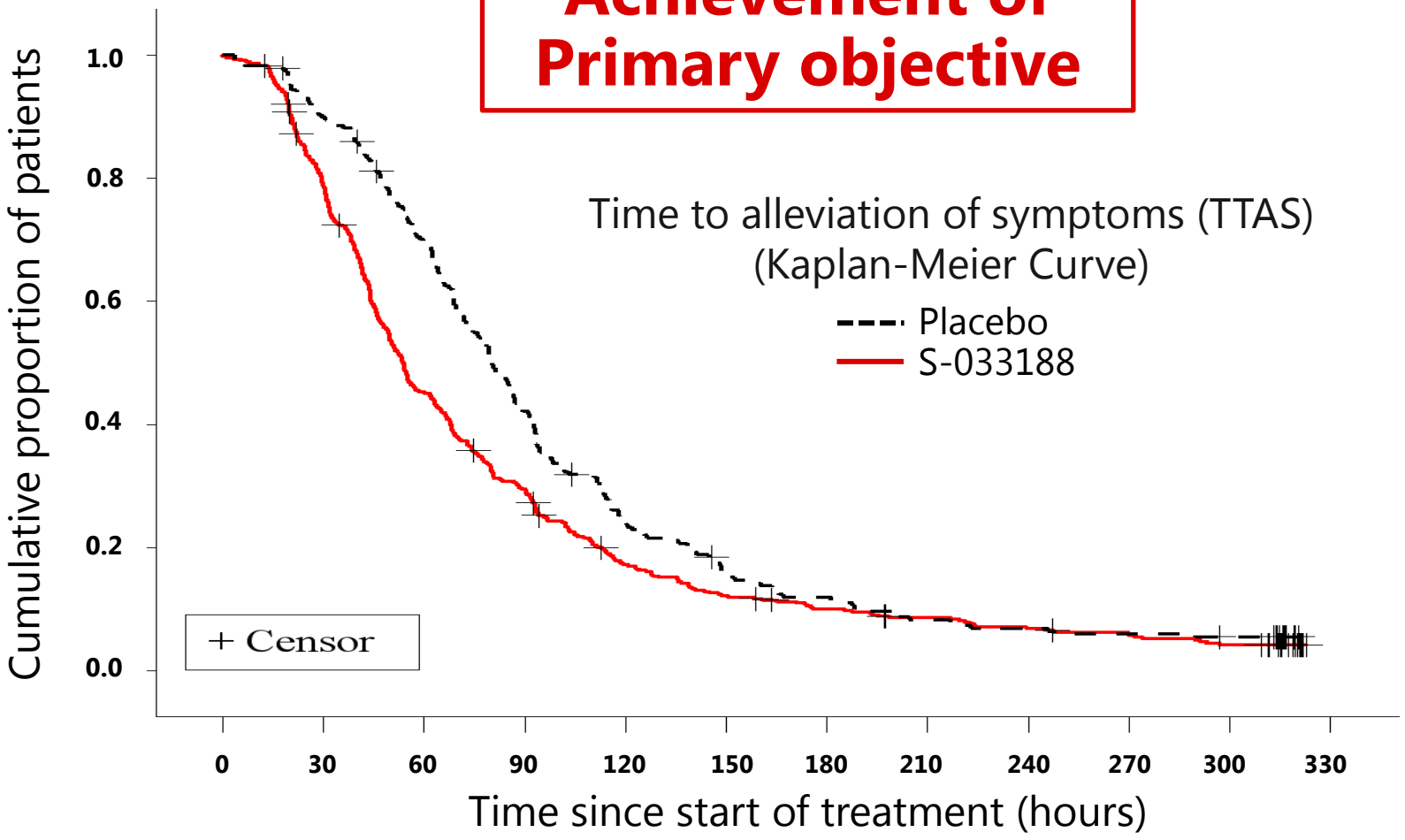


- Primary objective: Time to improvement of 7 major flu symptoms compared to placebo
- Major secondary objective: Time to improvement of 7 major flu symptoms compared to oseltamivir
  (Using stratified generalized Wilcoxon test)

* OwH: Otherwise healthy

Top-Line Results for OwH study - Primary objective -

Achievement of Primary objective



Top-Line Results for OwH study

- **Time to alleviation of symptoms (TTAS)**
  - S-033188 demonstrated a statistically significant reduction in TTAS compared to placebo and achieved the primary objective.
- **Viral titer**
  - S-033188 demonstrated statistically significant differences, in the early post-treatment period, both in the reduction of virus titer, and in the duration of viral shedding, compared to either placebo or oseltamivir.
- **Safety**
  - S-033188 was well tolerated. The incidence of treatment-related adverse events in the S-033188 treatment arm was comparable to that in the placebo arm.
  - The S-033188 treatment arm had statistically significantly fewer treatment-related adverse events compared to the oseltamivir arm.

S-033188：Future plan

Japan

- OwH study: Completed
- Preparing for NDA submission under the “priority review system” (SAKIGAKE designation) in Japan
  - The target premarket review period will be 6 months.

Submit NDA promptly

Global

- HR* Study: Ongoing
  - Patient enrollment rate is exceeding the original plan

Accelerate Global Phase III Studies

* HR: High risk

Appendix
- Global Phase III Study Design (HR* Study)-

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* HR: High risk

Global Phase III Study Design (HR* Study)

HR* study

(CAPSTONE-2)

- Uncomplicated high risk patients aged≧12 years
- 0-48 hours from onset
- Japan/US/Asia/ Southern Hemisphere
- **N=approximately 2,200**

→ Randomization

- S-033188 40 mg or 80 mg, single dose (80 mg, body weight≧80 kg)
- Placebo
- Oseltamivir 75 mg, twice daily for 5 days

- Primary objective: Time to improvement of 7 major flu symptoms compared to placebo
- Major secondary objective: Time to improvement of 7 major flu symptoms compared to oseltamivir
  (Using stratified generalized Wilcoxon test)

* HR: High risk

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