

## Challenging Journey for COVID-19 COVID-19への挑戦



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2019-現在 :	塩野義製薬会社 医薬開発本部長
2015-2018	同 信頼性保証本部長
2008-2014	同 医薬会開発本部 薬事部長
2006-2007	同 業務部部長
1986	塩野義製薬入社
2000-2008	日本製薬工業協会医薬品評価委員会臨床評価部会副部会長 ICHエキスパートメンバー (E5,E9,E11)
2016-現在	日本薬剤師会製薬部会幹事

Dr. Toshinobu Iwasaki is now serving as the global head of development in Shionogi. He has been taking a lead of many development programs in infection, CNS and respiratory diseases. Before the current position, he was in charge of quality assurance and regulatory affairs. Based on his broader experiences, he is intentionally contributing to development for both vaccine and drug of SARS-COV2. He was member of ICH ( International Conference for Harmonization) on drug development on behalf of Japanese Pharmaceutical Manufacturing Association.

弊社塩野義製薬は過去60年にわたり感染症に注力した創薬志向の製薬企業であり、過去、当領域において多くの医薬品を開発上市し、公衆衛生に寄与している。中国においてSARS-COV2が観察されたとの報告を受け、コロナパンデミックに取り組むことを社として決定した。この決定以降、下水モニタリングによるコロナ発生状況の観測、診断薬、予防ワクチンや治療薬の開発を進めている。この中で特に我々が優先としているのが、ワクチンと治療薬の開発である。ワクチンについては期待する中和活性と安全性が確認された後、複数の検証試験を国内および海外で実施中である。治療薬については、抗ウイルス効果と臨床効果から有効性を評価する目的のPh2/3試験を国内で実施中である。将来、ヘルスサイエンスに資するイノベーションの加速策や産官学の協業の在り方について製薬企業の立場から私見を述べたい。

Shionogi has conducted research and development in infectious diseases for over 60 years, bringing huge number of products for this disease area to global public health. We decided to commit to overcome Corona pandemic just after SARS-CoV-2 was observed in China. We are working towards total care through sewage epidemiology monitoring, diagnosis, prevention and treatment.

Our top priority is to distribute novel products combatting against SARS-CoV-2 to the world.

We, Shionogi, has been developing two compounds; vaccine and treatment drug.

Regarding a preventive vaccine, the four final stage clinical trials in Japan and global are now on-going after obtaining the promising result from Ph1/2 to evaluate neutralizing antibody titer and safety.

Stage of our treatment drug is Ph2/3 in Japan to evaluate virus titer reduction and improvement of clinical symptom as well as safety.

I would like to introduce the update of these developments and propose to encourage the innovation for health science and collaboration with academia, government and industry from the point of view of pharmaceutical company.

  
**Challenging Journey for COVID-19**  
**Toshinobu Iwasaki, Ph.D.**  
 Senior Executive Officer, SVP  
 Drug Development and Regulatory Science Division


Abstract

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**Shionogi's Actions for Total Care of COVID-19**

**Epidemic forecasting**

- Sewage epidemiology surveillance service for early detection of COVID-19 incursion and outbreak trends
- Conclude contracts with multiple local governments and expand services
- Under Discussion on business alliance with SHIMADZU that leverages the strengths of both parties

**Prevention**

- Development of a recombinant vaccine for COVID-19 (**S-268019**)
- Initiated Phase 2/3 trial (Oct. 20)
- Global Phase 3 trial planned
- Planning booster test (Japan and Global)

**Diagnosis**

- Differential diagnosis: Antigen-test kit
- Severely prediction: T2 chemoluminescent SATC™ kit for assisting in predicting exacerbations
- Shionogi discontinues efforts to commercialize by SATC™ method
- Under Discussion on business alliance with SHIMADZU that leverages the strengths of both parties
- Shionogi continues to hold licenses for the SATC™ method

**Treatment**

- Discovery and development of novel antiviral drug (**S-217622**)
- Phase 2/3 trial in progress
- Initiated discussions with FDA and EMA to conduct Global Phase 3 trial
- Discovery of developmental candidate peptide

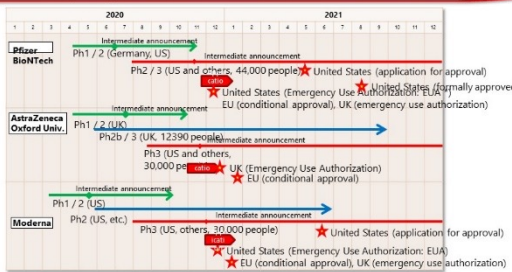
**Exacerbation suppression**

- Licensing out asapirant, an exacerbation controlling candidate
- Global phase 2 trial in progress

**Providing solutions for overwhelmed medical systems**

SHIONOGI \*SATC™: Signal Amplification by Ternary Initiation Complexes 2

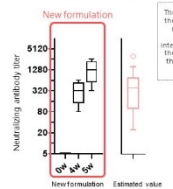
**Warp Speed of advanced vaccines**



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**S-268019: Change to New Adjuvant**

Monkey immunogenicity test: Neutralizing antibody titer Day29 / 36



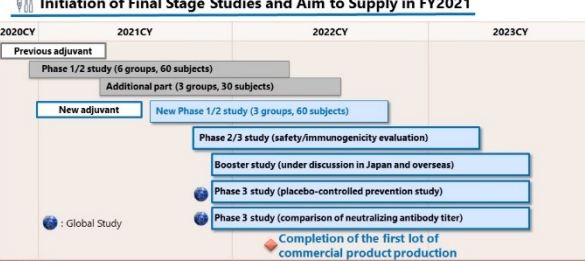
	S-268019 Sug (N=24)	S-268019 10µg群 (N=24)	Placebo (N=12)	Convalescent Serum (N=59)
Day 36	37.75	46.21	<5	28.45
Day 50	21.81	28.28	<5	

GMT in Ph1/2

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**S-268019 : Development Schedule**

Initiation of Final Stage Studies and Aim to Supply in FY2021



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**S-217622: Clinical development schedule**



- Domestic clinical trial and commercial drug supply plans**
  - Will submit data on symptom improvement / symptom occurrence reduction and antiviral effect in mild and asymptomatic patients from Phase 2/3
  - Preparation of domestic submission by the end of 2021

We intend to provide oral therapeutic agents that can be easily taken by large numbers of patients with limited treatment options

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**What should we learn from this disaster?**

**Strengthen preparations for a new pandemic**

- Accurate epidemic prediction of infectious diseases is difficult (COVID-19, influenza, etc.)
- While the expansion of COVID-19 has definitely improved public awareness of infectious diseases, the establishment of a crisis management system for new infectious disease epidemics is still inadequate.

**Infectious disease control is an important issue related to national security**

- Industry-government-academia collaboration can contribute to emergencies by strengthening preparations from normal times
- Need a framework to prepare for emergencies against infectious diseases
  - Incentives to enable continuous research and development and stable production and supply
  - Building a clinical trial system that can respond quickly to emergencies
  - Development of laws and alternative evaluation indexes

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