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Efforts to Develop COVID-19 Therapeutic Drugs/ Vaccines and Realize Total Care for Infectious Diseases

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SHIONOGI's Growth History



1st MTBP*
(FY2000 – FY2004)

Focus on pharma
business

2nd MTBP
(FY2005 – FY2009)

Expansion of R&D and
establishment of global
structure



"Crestor"
Launch in 2005



"Finibax"
Launch in 2005

3rd MTBP
(FY2010-FY2013)

Toward global
growth



"Tivicay"
Launch in 2014



"Xofluza"
Launch in 2018



"Fetroja"
Launch in 2019 (US)



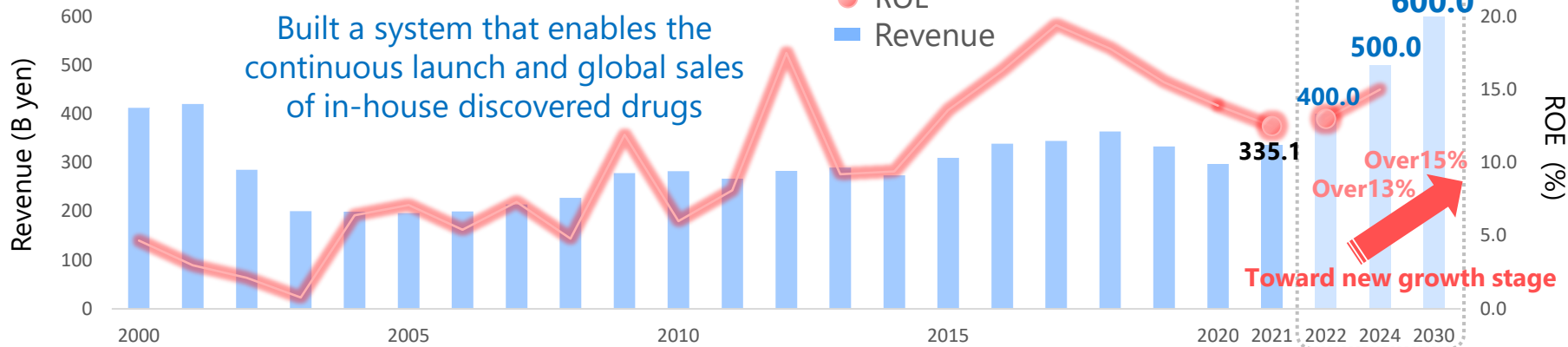
"CABENUVA"
Launch in 2021 (US)

SGS2020**
(FY2014 – FY2019)

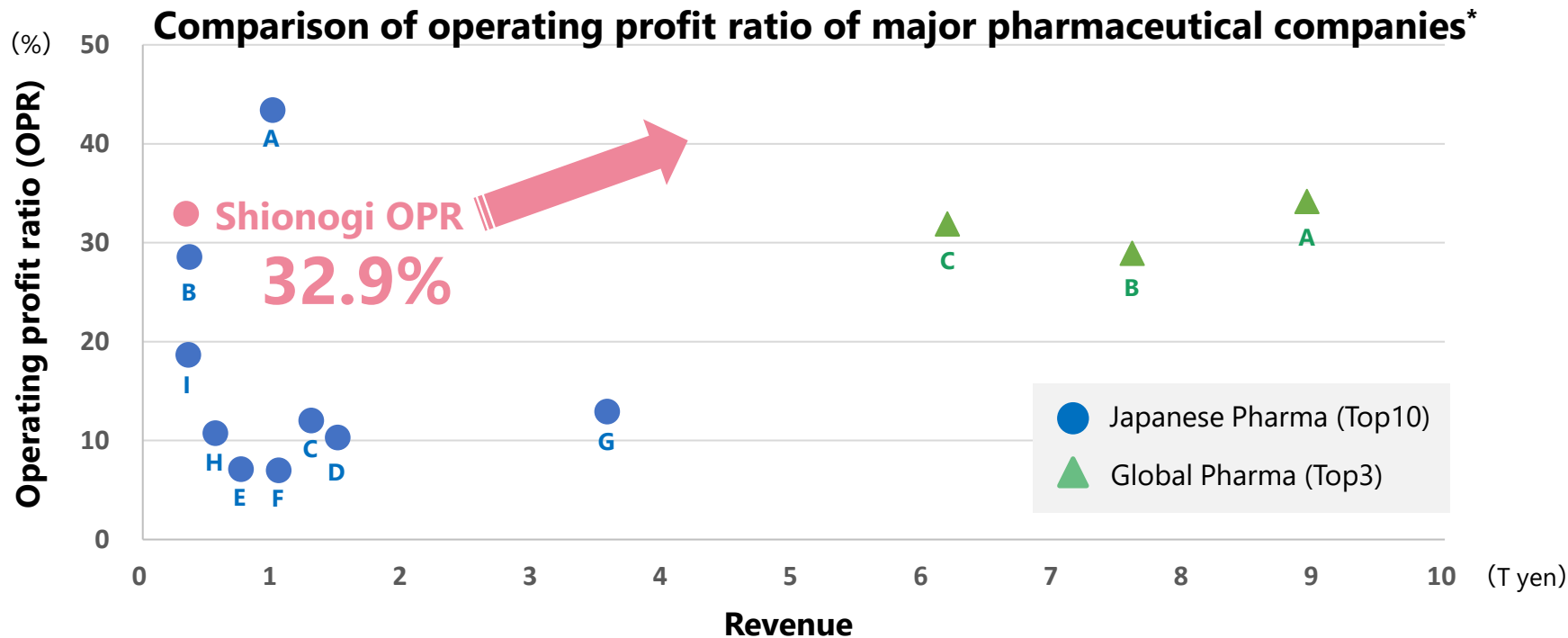
Grow sustainably as a drug
discovery-based pharmaceutical
company with society

STS2030***
FY2020~

Building Innovation Platforms
to Shape the Future of Healthcare



SHIONOGI with a Strong Presence



To be a company that consistently grows as it contributes to society

SHIONOGI's History in Infectious Disease (ID) Area



1878

Shiono Gisaburo Shoten founded as a drug wholesaler at the present site of the head office, Doshomachi, Osaka

1959

The sulfonamide drug "Sinomin®"

1982

The oxacephem antibiotic "Shiomin®"

1988

The oxacephem antibiotic "Flumarin®"

1997

The cephem antibiotic "Flomox®"

2005

The carbapenem antibiotic "Finibax®"

2014

The HIV treatment "Tivicay" ※Developed by ViiV

2018

The anti-influenza virus drug "Xofluza®"

2020

A siderophore cephalosporin antibiotic "Fetroja®" ※Not approved in Japan

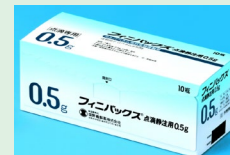
2021

The long-acting HIV treatment "Cabenuva" ※ Developed by ViiV

SHIONOGI has been engaged in research and development of ID drugs for about 60 years



"Sinomin"
Launch in 1959



"Finibax"
Launch in 2005



"Tivicay"
Launch in 2014



"Xofluza"
Launch in 2018

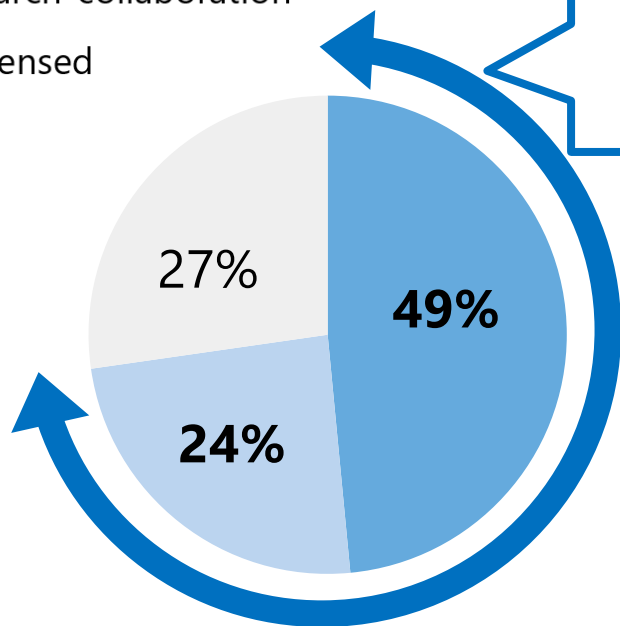


"Fetroja"
Launch in 2019 (US)

Features of SHIONOGI's R&D pipeline



- Shionogi-originated
- Research-collaboration
- In-licensed

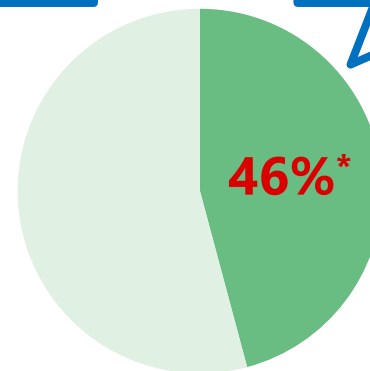


Percentage of pipeline products discovered through SHIONOGI research/research collaboration

73%*

Ratio of ID-related pipeline in SHIONOGI research/research collaboration compounds

46%*



SHIONOGI continues to invest in ID-related R&D

Actions for the Early Termination of COVID-19



Epidemic forecasting



Launch of sewage epidemiology surveillance survey service



Established AdvanSentinel
Early detection of BA.2

Prevention



Development of **S-268019**



Verification of non-inferiority to COMIRNATY intramuscular injection (Pfizer) in additional immunological tests

Diagnosis



Th2 chemokine TARC*
kit, antigen-test kit



Joint sale of antigen-test kit using saliva specimens

Treatment



Development of **S-217622**



Completion of domestic approval application based on the result of Phase 2a/2b

Exacerbation suppression



Development of Asapirant



Ph2 trial started

* TARC (thymus and activation-regulated chemokine): One of the chemokines driving migration of Th2 cells, a type of lymphocyte, to the site of inflammation

** SARS-CoV-2 antigen test kit that be able to use saliva as an adaptive specimen jointly sold with TAUNS



S-217622 (therapeutic drug)

Development status

- **Domestic manufacturing and marketing approval application based on the results and analysis from the Phase 2b part (February 25, 2022)**
- **Good efficacy and safety results from the Phase 2a/2b part announced at 32nd ECCMID* (April 23, 2022)**
- Continuation of Phase 2/3 trial
 - Phase 3 part (mild/moderate) and Phase 2b/3 part (asymptomatic/mild symptoms) are underway

Future plan

- Global Phase 3 trial started in collaboration with ACTG**
- Since April 2022, **production is expanding to supply more than 10 million people annually**



S-268019 (prevention vaccine)

Development status

- 6 Pivotal clinical trials in progress
 - Phase 2/3 trial active control, neutralizing antibody titer trial
 - Placebo control, onset prevention trial
 - Phase 2/3 booster trial
 - Phase 3 booster trial (additional trial in Japan)
 - Phase 2/3 trial in Japanese adolescents

Future plan

- Prior evaluation consultation based on the results of ongoing clinical trials
- Consulting with the regulatory authorities for domestic application
- Scheduled to establish a supply system of **more than 60 million shots annually**

What is SHIONOGI after FY2022



FY2021

Lessons from the special situation of the COVID-19 pandemic

- Progress R&D and production at an unprecedented speed by drastically shifting resources and changing processes
- Recommendations for policy changes through pharmaceutical industry organizations



From FY2022

Build a sustainable ID business model

- World-class drug discovery capability with speed, advanced decision-making, and effective resource allocation honed during the COVID-19 situation
- Further development of vaccine business

Promote pandemic experience-based ID business transformation without changing focus

Three Axes that Build a Sustainable ID Business

Chronic infection

(HIV, Malaria, TB/NTM, etc.)



**Possible to form a healthy pipeline
based on stable profits**

Vaccine

(Flu, COVID-19, etc.)



Acute infection

(Flu, COVID-19, RSV, etc.)



**The most important issue
is the management of
acute infections**

Current Status of Chronic ID & Vaccine Pipelines



Chronic infection

	Target	Non-clinical	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	Launched	Description
Dolutegravir	HIV								Tivicay, Juluca, Dovato
Cabotegravir	HIV								Cabenuva, Apretude (PrEP)
S-365598	HIV								License out to ViiV Healthcare
S-544110	TB/NTM*								Collaboration with HSIRI Therapeutics
—	Malaria								Collaboration with Nagasaki Univ.

Build a stable business like the HIV franchise

Vaccine

	Target	Non-clinical	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	Launched	Description
S-268019	COVID-19								6 Pivotal clinical trials in progress
S-875670	COVID-19								Nasal vaccine
S-872600	Flu								Nasal vaccine
S-540956	—								Nucleic acid adjuvant
—	HBV								Collaboration with NEC

Vaccine exclusivity is not patent-dependent and can be a source of stable profits from regular vaccinations

Dysfunctional Acute ID Market

- Social needs
- Huge R&D expenses
- Maintenance cost of production equipment

Investment



- Difficult epidemic prediction
- Antibiotic stewardship
- Promotion of switching to generics

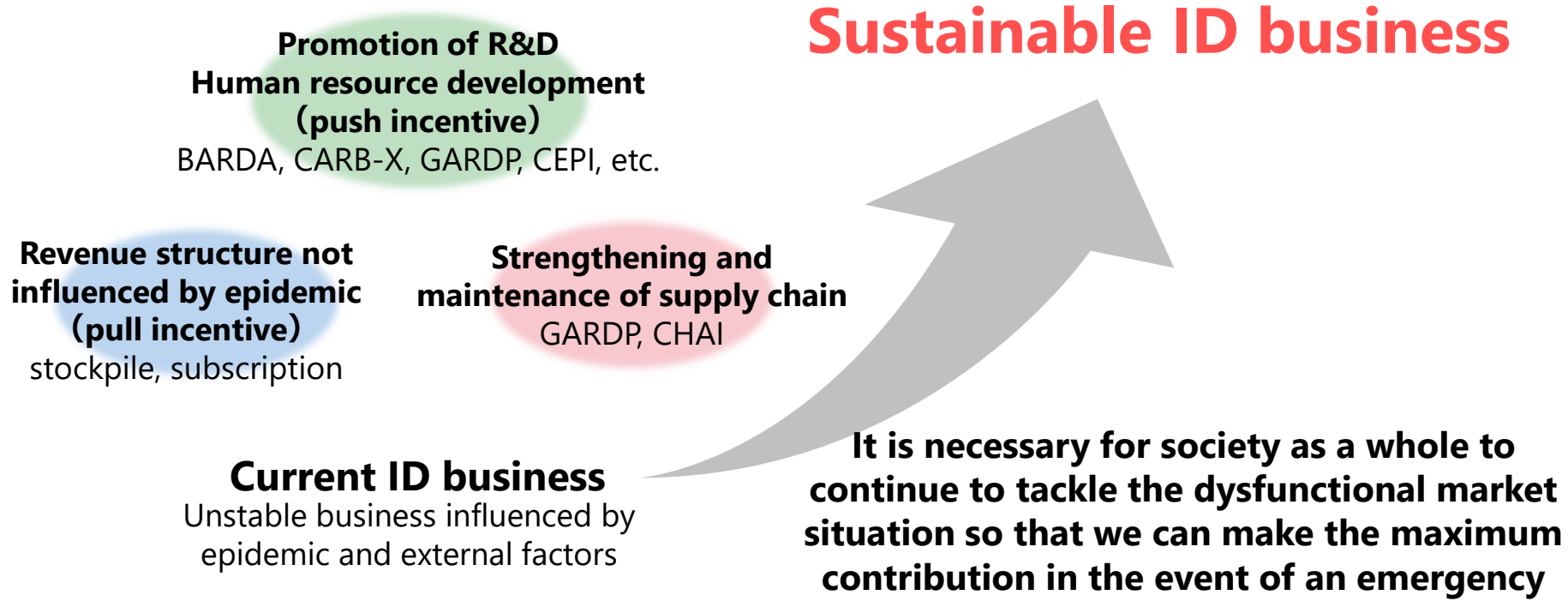
Unable to form a healthy pipeline because the investment cannot be recovered

Big Pharma withdraws from antimicrobial market

- **AstraZeneca** sold small molecule antimicrobial business to Pfizer (2016)
- **Sanofi** transferred ID department and 100 employees to Evotec (2018)
- **Novartis** withdraws from antimicrobial research (2018)

Bankruptcy or acquisition of biotech players

- **Achaogen** filed for bankruptcy (April 2019)
 - Within 1 year from plazomicin approval in July 2018
- **Melinta Therapeutics** filed for bankruptcy (December 2019)
- Acquisition of **Tetraphase Pharmaceuticals** (July 2020)
 - Elavacycline approved in August 2018



The background of the slide is a close-up of a human finger being scanned. Overlaid on the finger and the background are various digital and medical motifs. There are faint, glowing blue lines and dots, suggesting a digital interface or data flow. In the upper right, there are faint, semi-transparent icons: a heart with a pulse line, a person silhouette, and a medical cross. The overall color palette is light blue and white, with the red text providing a strong contrast.

Building Innovation Platforms to Shape the Future of Healthcare