

# BofA Global Healthcare Conference 2021

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September 16, 2021

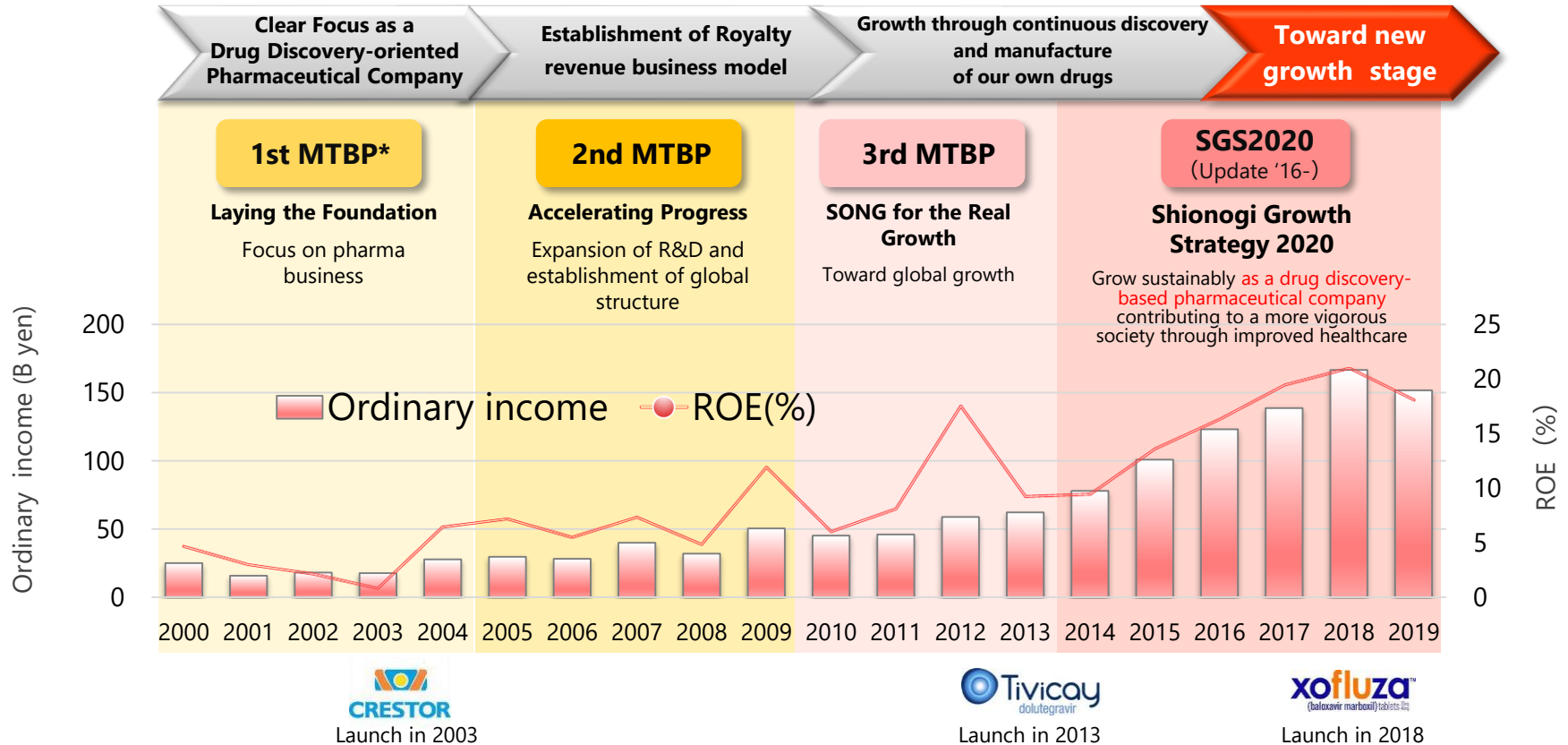


# Forward-Looking Statements



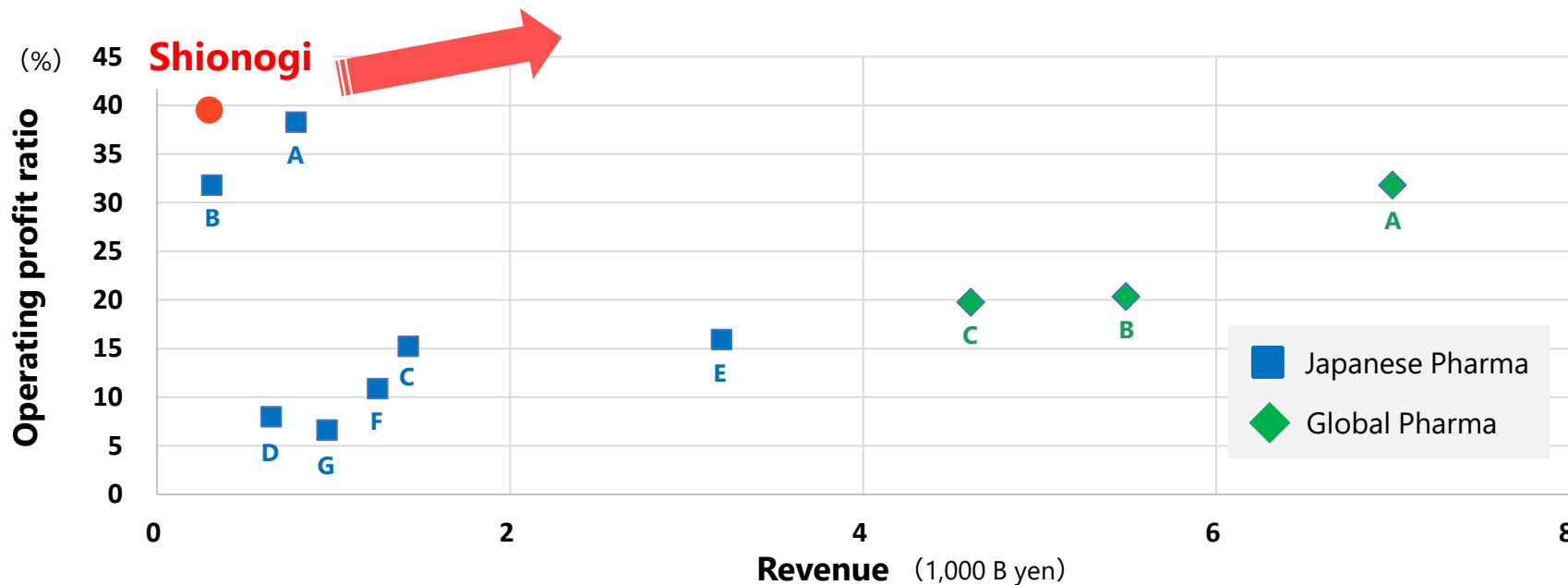
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# Shionogi's Growth History



# Shionogi With A Strong Presence

Comparison of operating profit ratio of major pharmaceutical companies\*



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

# Recent Achievements - Infectious Disease Area -

## HIV infection

**Tivicay**



**Cabenuva**



## Influenza

**Xofluza**



## Multidrug-resistant Gram-negative bacterial infection

**Fetroja/Fetcroja**



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



## Epidemic forecasting



## Prevention



## Diagnosis



## Treatment



## Exacerbation suppression



## Monitoring

## Acquisition of immunity

## Appropriate diagnosis

## Elimination /reduction of pathogens

## Control of host response

- Sewage epidemiology surveillance service for early detection of COVID-19 incursion and outbreak trends
- Development of a recombinant vaccine for COVID-19  
⇒ **S-268019 (p.7, 8)**
- Antibody/antigen-test kit, and Th2 chemokine TARC\*  
kit for assisting in predicting exacerbations  
• Development of new rapid diagnostic method
- Discovery and development of novel antiviral drug  
⇒ **S-217622 (p.9)**
- Licensing out asapirant, an exacerbation controlling candidate

\* TARC (thymus and activation-regulated chemokine)

One of the chemokines driving migration of Th2 cells, a type of lymphocyte, to the site of inflammation

# Action for COVID-19

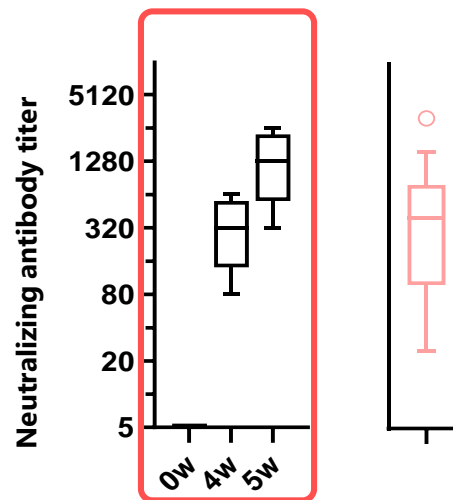
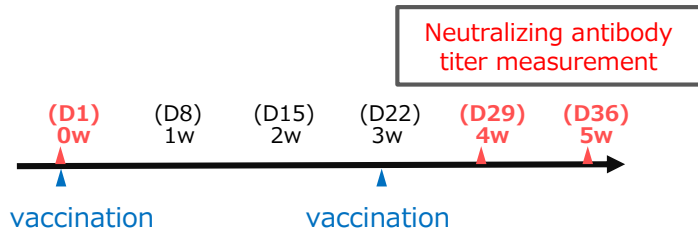


## Development of recombinant protein vaccine (S-268019)

### Tested with a combination of various adjuvants

- Monkey immunogenicity test
  - Very high correlation with clinical data accumulated so far

#### Design of monkey immunogenicity test



New formulation  
clinical equivalent  
(N=4/group)

Estimated value  
of convalescent  
serum\* (N=59)

**Confirmed similar neutralizing antibody titer compared to recovered patient serum**



## Development of recombinant protein vaccine (S-268019)

- **Our vaccine can be expected to induce higher neutralizing antibody titers in humans while avoiding VDE/ADE risk**
  - Good data confirmed in immunogenicity tests using monkey models well correlated with humans
    - › High neutralizing antibody titer (equal to or better than recovery patient serum)
    - › Expect to maintain a favorable Th1>Th2 type balance

### • Domestic clinical trial plan

- Phase 1/2 trial in progress
- Immediately progress to the next phase after the above trial
  - › Plan to evaluate safety and efficacy in around 3,000 cases

### • Aim to begin pivotal trials in 2021

- Preparing a comparative study with an approved vaccine
- In addition to the above, preparing a placebo controlled trial in Asia and Africa
- Continued discussions with regulators and ministries for domestic provision based on the earliest pivotal trial results
- Production capacity is in preparation



## Development of therapeutic drugs with superior efficacy and safety

- **Initiated phase 1 trial of COVID-19 therapeutic drug (S-217622) in Japan**
  - In-house small molecule oral antiviral drug, 3CL protease inhibitor
    - › **Efficacy: significant reduction in viral load**
    - › **Safety: no major concerns so far**
    - › Does not require PK booster\*
- Efforts for early provision
  - Plan to start large-scale clinical trials in Japan by the end of 2021
  - Preparing for global development
  - Preparing production capacity

# Action for COVID-19



## Diagnostic markers that can predict exacerbation

- **HISCL® TARC reagent**

- Launched in June 2021 as an auxiliary for detection of COVID-19 aggravation



## Establishment of analysis system for SARS-CoV-2 in sewage

- **Sewage epidemiology surveillance service**

- Initiated the service for detecting SARS-CoV-2 in June 2021



## Rapid and highly sensitive antigen test

- **LumiraDx Ag Test and LumiraDx Instrument**

- Launched in May 2021



## Suppression of exacerbations in asymptomatic individuals and mild patients

- **Asapiprant (S-555739)**

- Phase 2 trials in US and South America are ongoing by BioAge



## Driving Growth of HIV Franchise with ViiV Healthcare

- **Focusing on four products/projects in the strategic collaboration with ViiV**
- In addition to the above activities, pursuing functional cure of HIV infection

### Products

**Dovato**

(dolutegravir/lamivudine)



**Cabenuva**

(cabotegravir/rilpivirine)



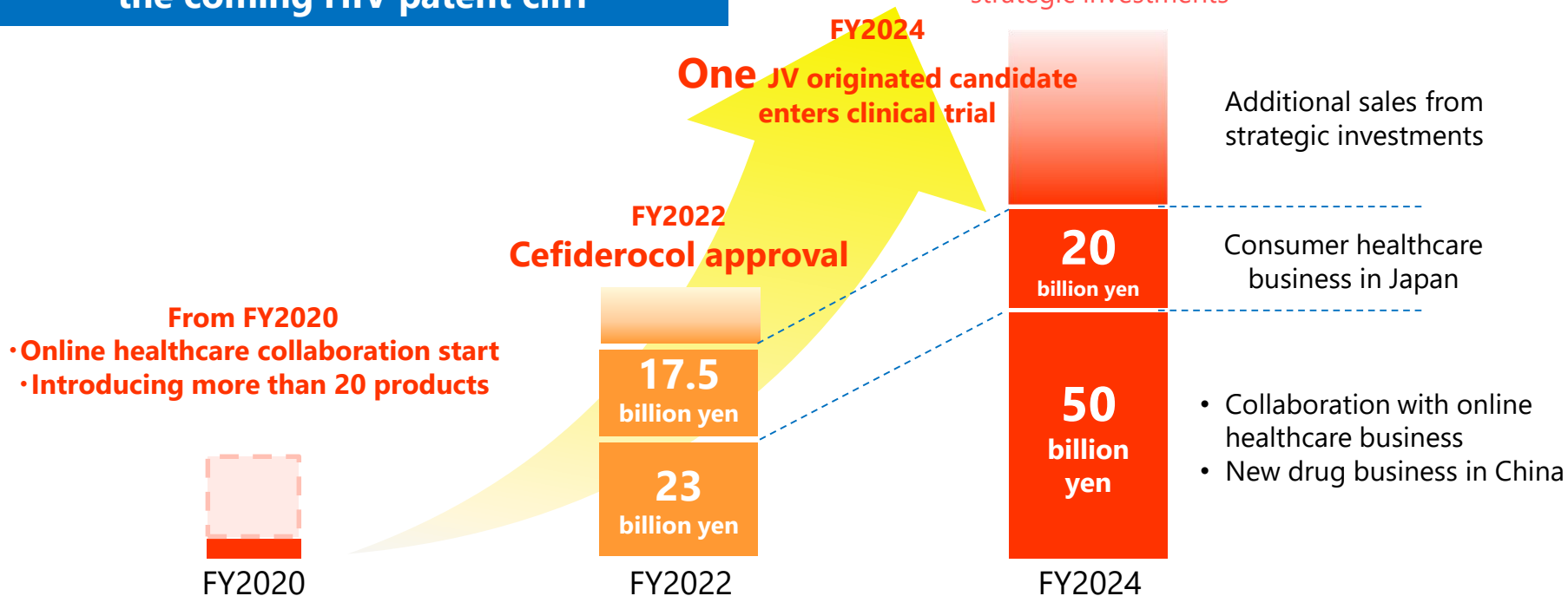
### Projects

**Cabotegravir  
PrEP**

(Pre-Exposure Prophylaxis)

**Ultra long-acting  
formulation**

Establish early profitability and stable earnings base to reduce the impact of the coming HIV patent cliff



The background of the slide is a close-up, slightly blurred image of a person's finger being scanned on a device. Overlaid on the finger and the background are various digital and medical-themed graphics. These include a heart icon inside a circular target, a cross icon inside a circular target, and several small, glowing blue and green dots scattered across the finger's surface. The overall color palette is light blue and white, giving it a high-tech, futuristic feel.

## Building Innovation Platforms to Shape the Future of Healthcare

# Appendix

# R&D Progress: 8 Core Projects



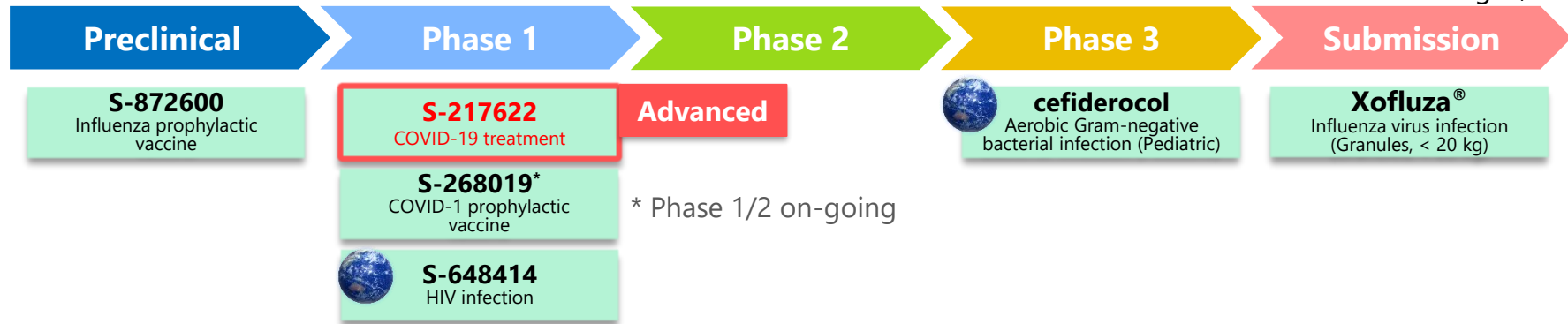
	Pipeline	Indication	Status
Infectious disease	<b>S-540956</b>	HIV infection, cancer	Preparing Phase 1 study
Psycho-neurological diseases	<b>S-600918</b> <b>[sivopixant]</b>	①Refractory chronic cough ②sleep apnea syndrome	①Phase 2b study in progress ②Phase 2a study in progress
	<b>S-637880</b>	Neuropathic low back pain	Phase 2a study in progress
	<b>S-812217</b> <b>[zuranolone]</b>	Depression	Phase 2b study in progress
	<b>BPN14770</b> <b>[zatolmilast]</b>	①Alzheimer's disease ②Fragile X Syndrome	①Phase 2 study in progress ②Preparing Phase 2b and Phase 3 study (US)
	<b>S-874713</b>	Psycho-neurological diseases	Preparing Phase 1 study
New growth areas	<b>S-531011</b>	Solid tumor	Preparing Phase 1b/2 study
	<b>S-005151</b> <b>[redasemtide]</b>	①Epidermolysis bullosa ②Acute stroke ③Osteoarthritis ④Chronic liver disease	①Preparing for application ②Phase 2 study in progress ③④Investigator initiated clinical trial (Phase 2 trial) in progress

**Steady progress of 8 core projects and COVID-19 project**  
**(Details to be reported at R&D day on Sep. 29, 2021)**

# Pipeline: Infectious Disease



as of Aug. 2, 2021



Stage change (Changes from May. 10, 2021)

S-217622 (COVID-19 Treatment): Phase 1 start (Japan)



: Global development



## Out license

**S-555739**

Treatment by suppressing aggravation of COVID-19

**cabotegravir LAP**

Prophylaxis of HIV infection

**Xofluza® (US)**

Influenza virus infection (Pediatric, over 1 year old)

**Xofluza®**

Influenza virus infection (Pediatric, < 1 year old)

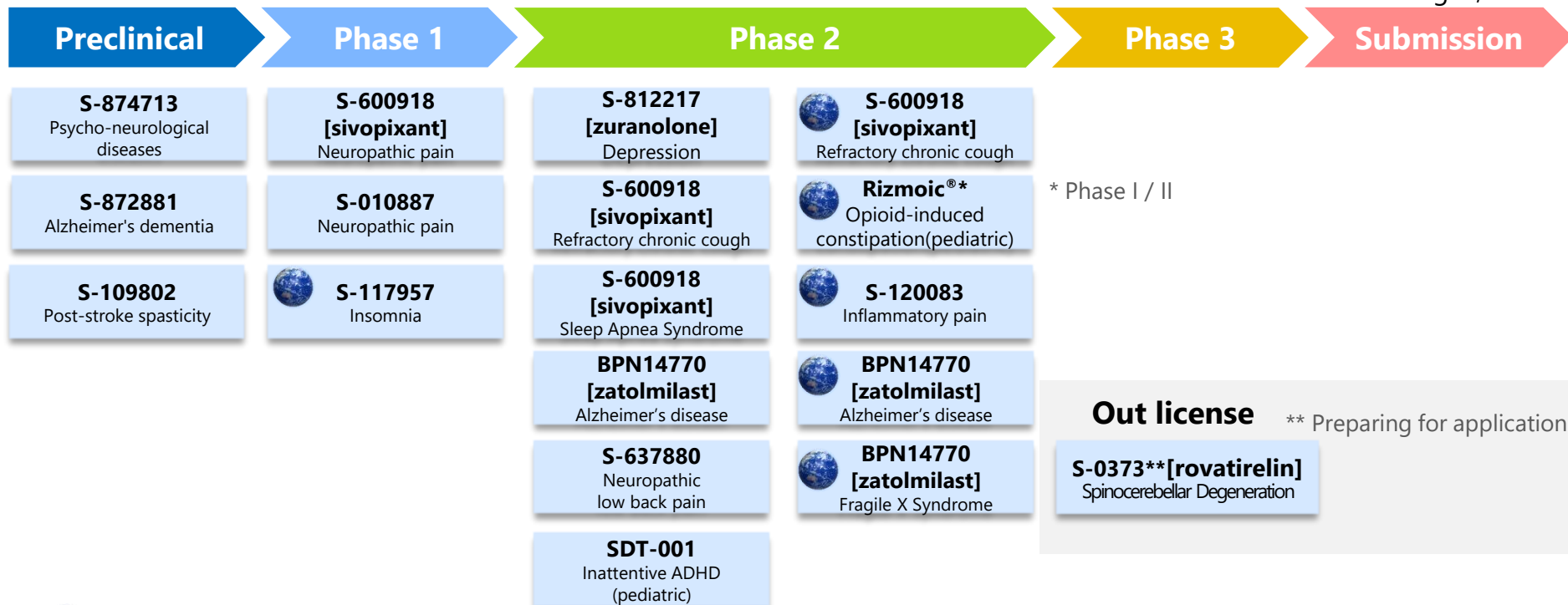
**Xofluza®**


Influenza virus infection (Transmission)

# Pipeline: Psychological and Neurological Disease



as of Aug. 2, 2021

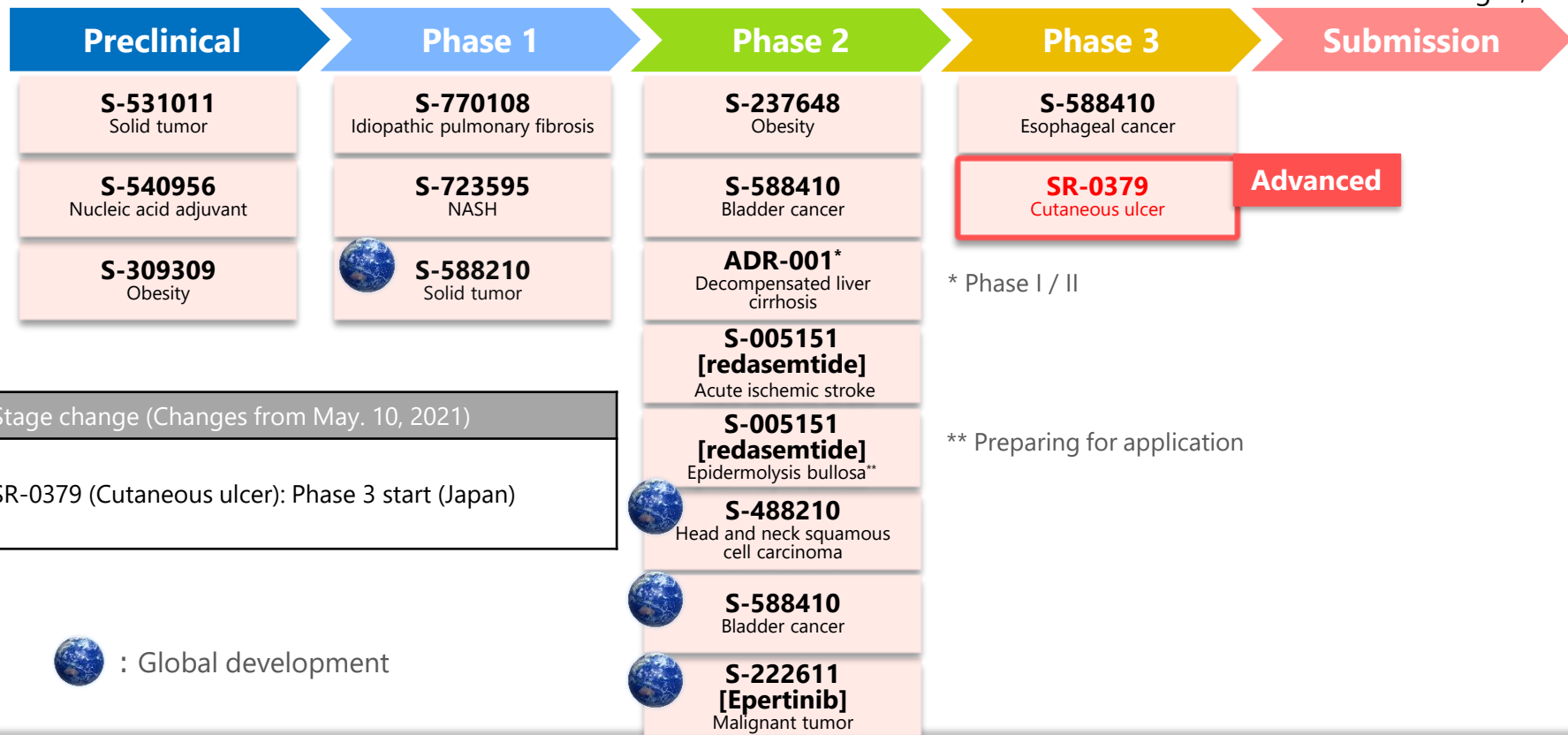


 : Global development

# Pipeline: New Growth Area



as of Aug. 2, 2021



## Three strategies for STS Phase1

New value creation

i. R&D strategy



Development of innovative pipeline

ii. Top-Line Strategy



Business growth through creation of diverse businesses

iii. Management Foundation Strategy



Building framework for new value creation

Infrastructure building