



BofA Global Healthcare Conference 2021

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September 16, 2021

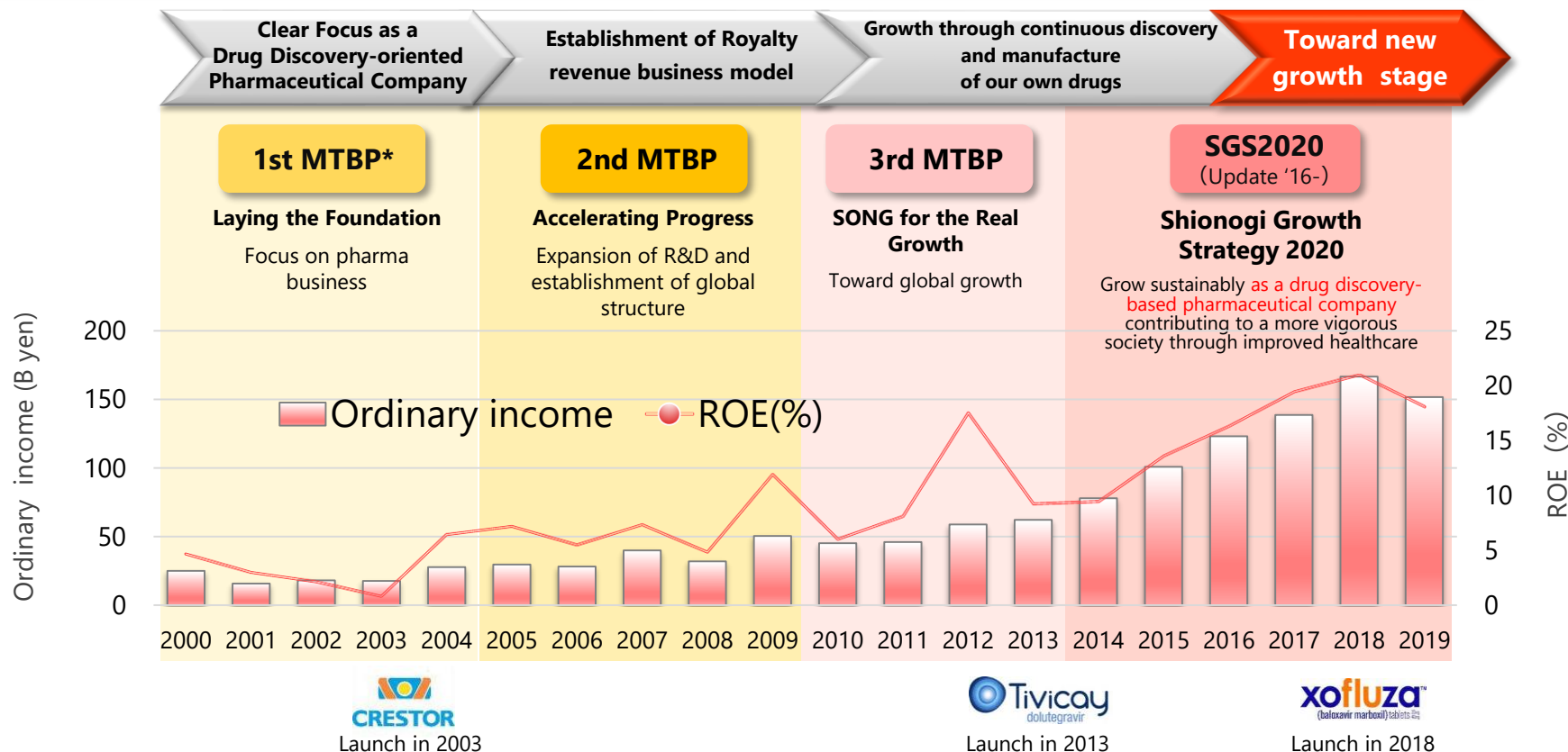


Forward-Looking Statements



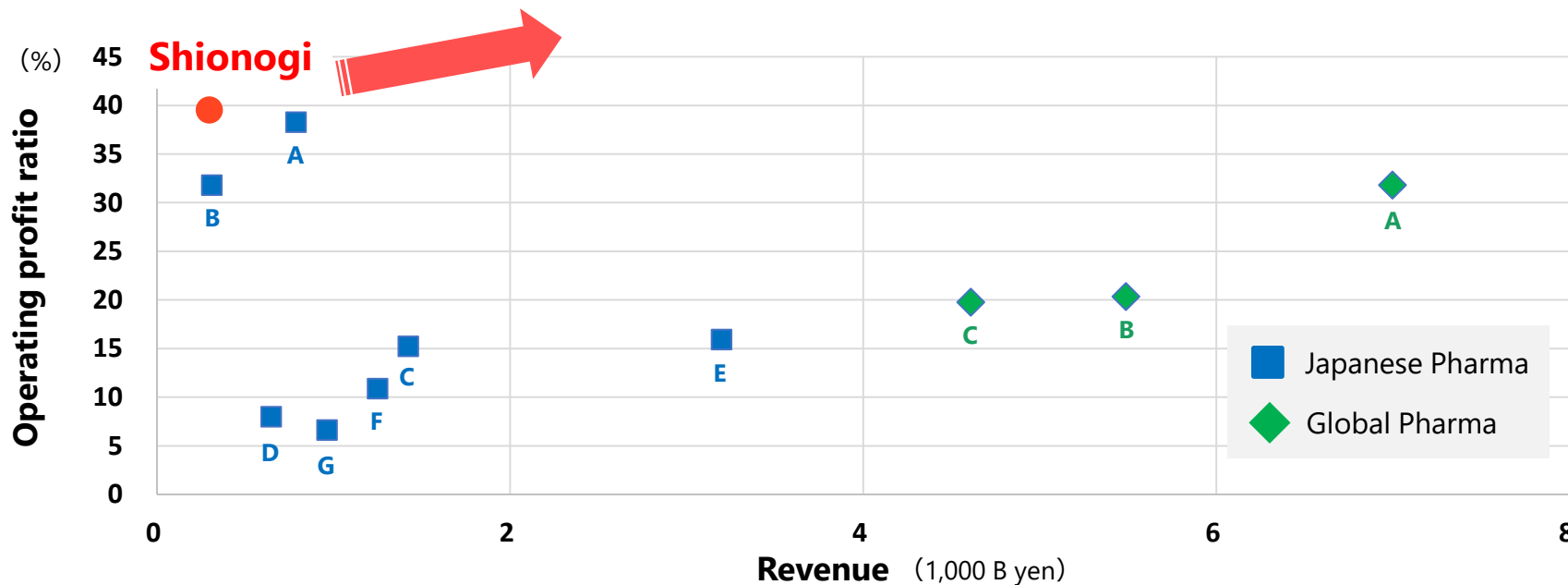
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Shionogi's Growth History



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

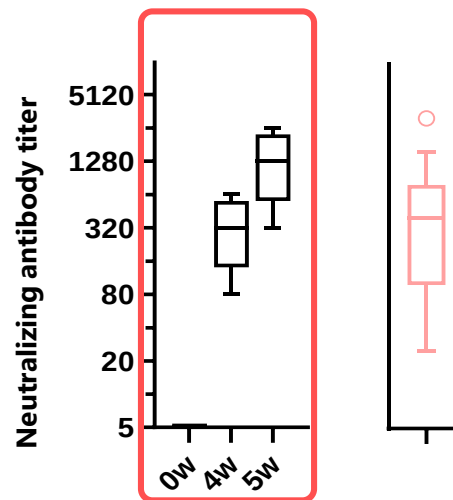
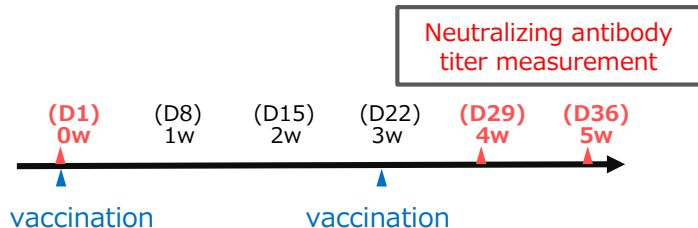


Development of recombinant protein vaccine (S-268019)

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)



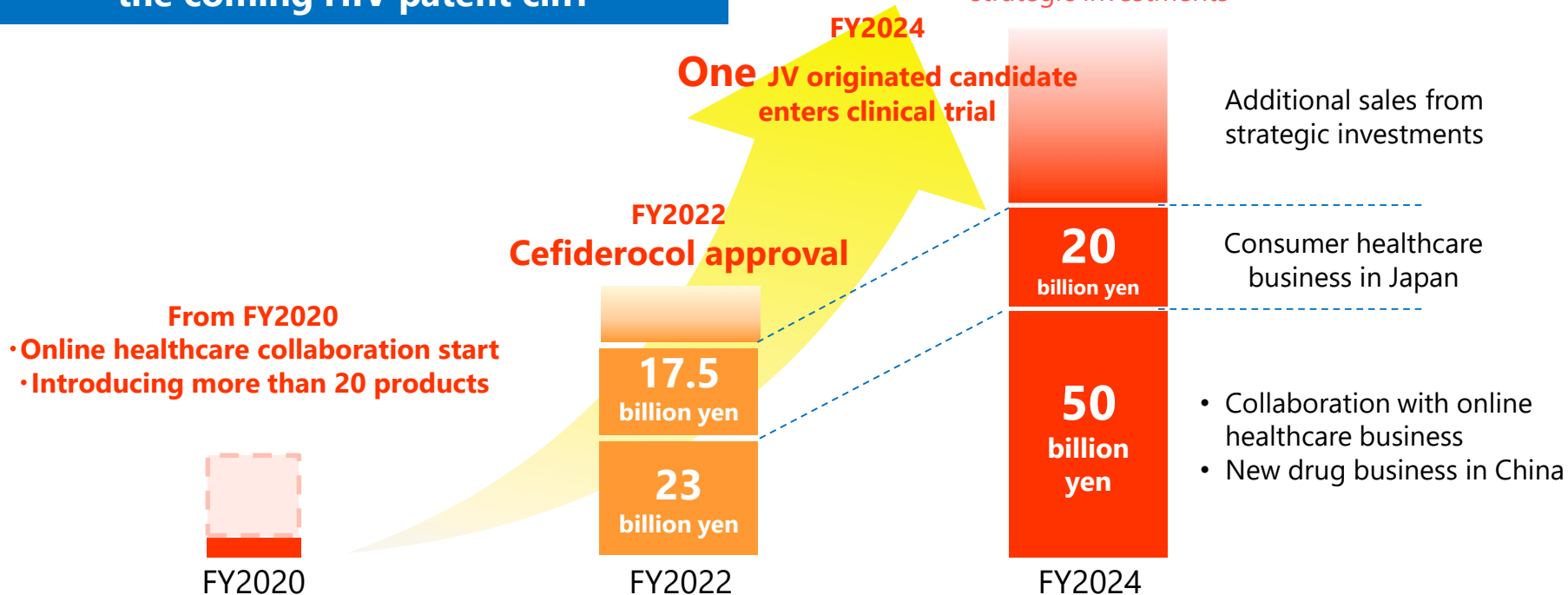
Projects

**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 this image are several semi-transparent, futuristic medical and technological icons. These include a heart with a pulse line, a brain, a DNA double helix, and various geometric shapes like hexagons and circles, some containing smaller icons like a cross or a person. The overall color palette is light blue and white, giving it a high-tech, clean feel.

Building Innovation Platforms to Shape the Future of Healthcare

Appendix

R&D Progress: 8 Core Projects



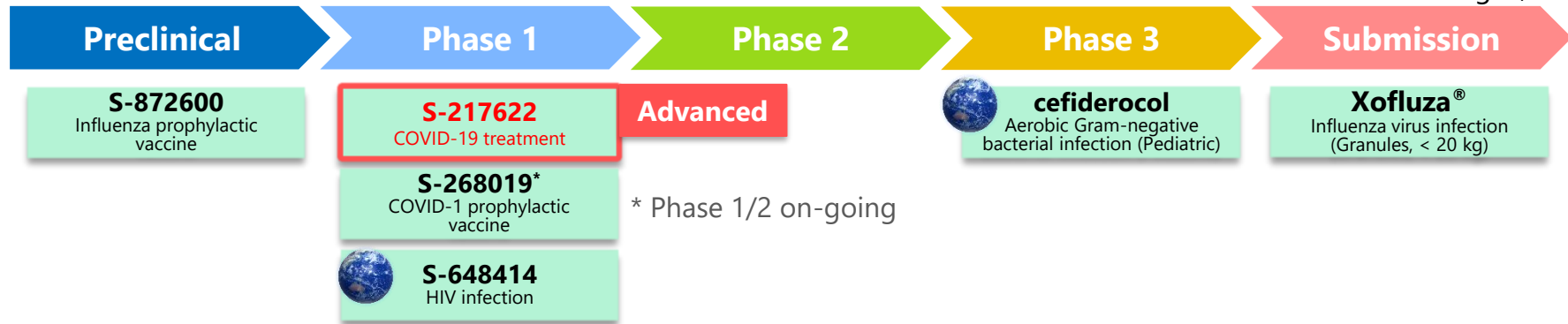
	Pipeline	Indication	Status
Infectious disease	S-540956	HIV infection, cancer	Preparing Phase 1 study
Psycho-neurological diseases	S-600918 [sivopixant]	①Refractory chronic cough ②sleep apnea syndrome	①Phase 2b study in progress ②Phase 2a study in progress
	S-637880	Neuropathic low back pain	Phase 2a study in progress
	S-812217 [zuranolone]	Depression	Phase 2b study in progress
	BPN14770 [zatolmilast]	①Alzheimer's disease ②Fragile X Syndrome	①Phase 2 study in progress ②Preparing Phase 2b and Phase 3 study (US)
	S-874713	Psycho-neurological diseases	Preparing Phase 1 study
New growth areas	S-531011	Solid tumor	Preparing Phase 1b/2 study
	S-005151 [redasemtide]	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)

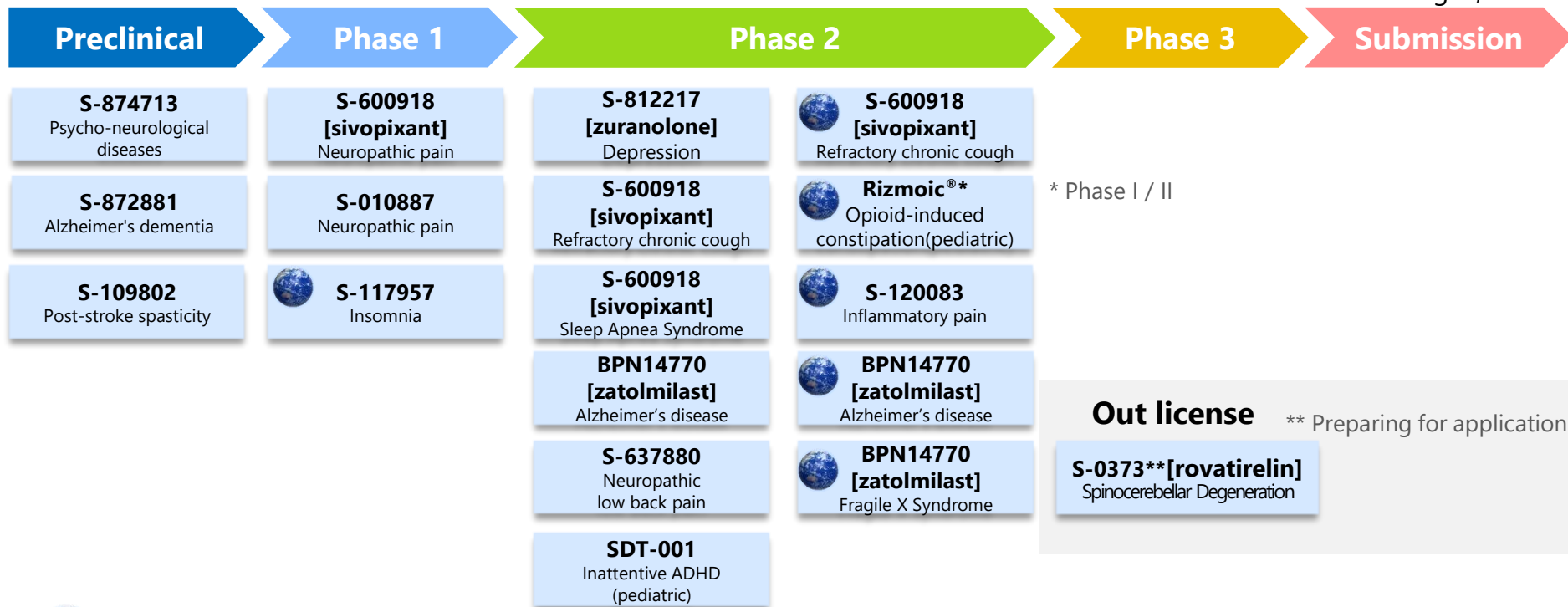
Xofluza®

Influenza virus infection (Transmission)

Pipeline: Psychological and Neurological Disease



as of Aug. 2, 2021

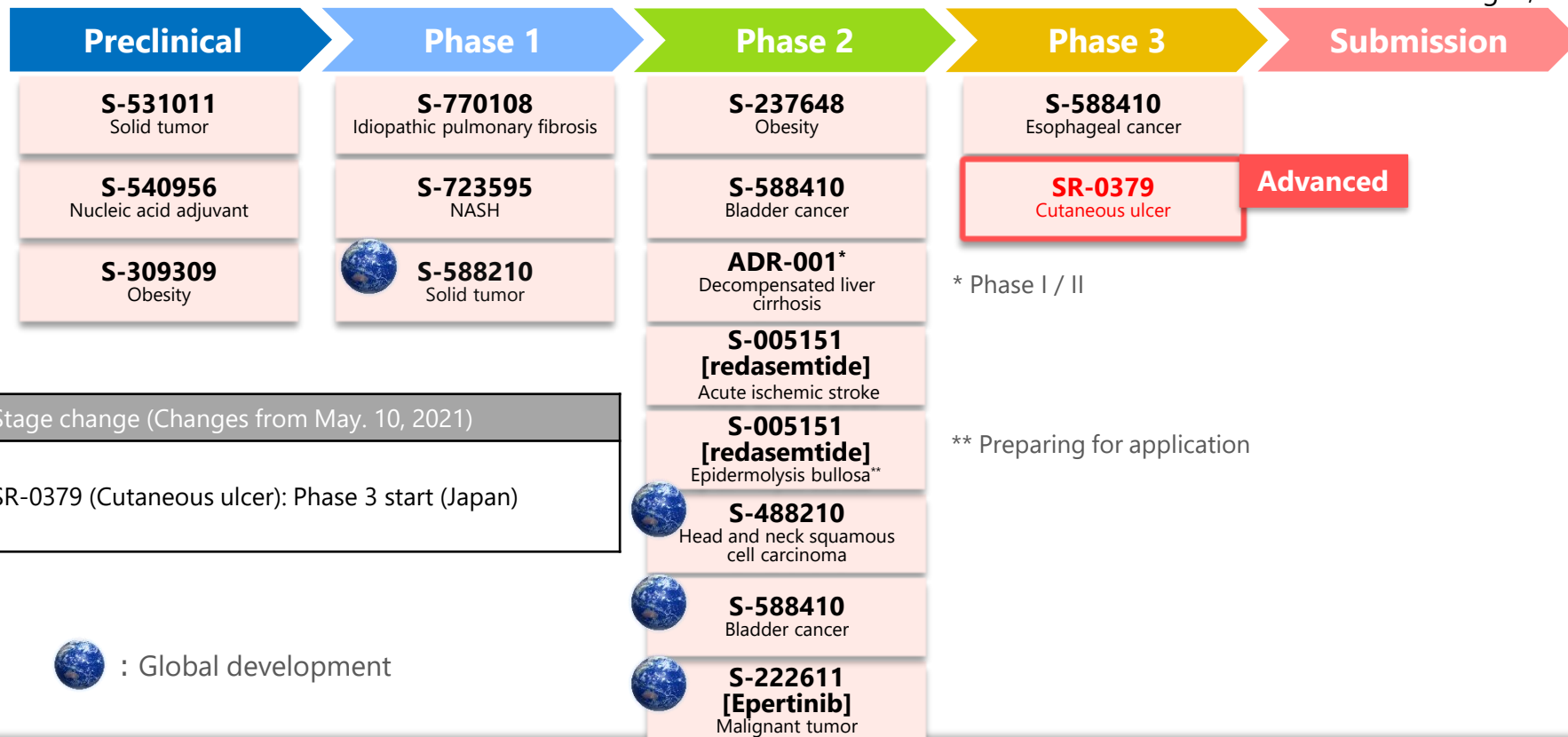


 : Global development

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

Infrastructure building

iii. Management Foundation Strategy



Building framework for new value creation