



SIMCERE PHARMACEUTICAL GROUP LIMITED

2022 R&D DAY

STOCK CODE: 2096.HK

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AGENDA



01 Welcome Speech

Ren Jingsheng
Chairman of the Board & CEO

5min



02 Company Overview Strategy

Zhou Gaobo
CIO

10min



03 Pre-clinical R&D Update

EVP

20min



04 Late-stage Oncology Pipeline

Bijoyesh Mookerjee, MD
CMO, Oncology

20min



05 Late-stage Non-oncology Pipeline

Danny Chen, PhD
SVP, neuroscience

20min



06 Strengthening BD, M&A and Investments within a Global Strategy

SVP, PhD
SVP, Global Head of BD&L

10min



07 Q&A - ALL

HOST : Jason Bao
Secretary of the Board

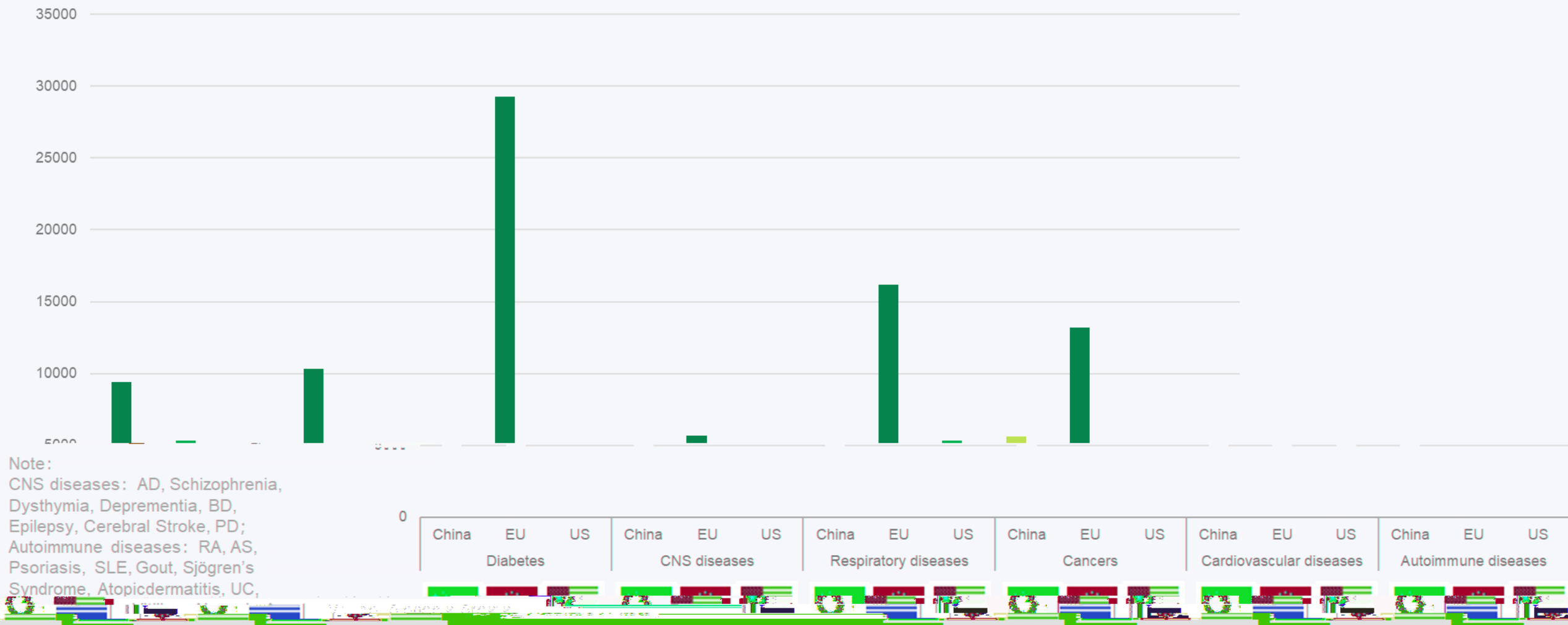


Company Overview Strategy

Zhou Gaobo
CIO

Fundamentals of our business driven by extensive unmet clinical needs in China and beyond

Forecast of global patient population in 2030: China, EU, US (10,000 people)



bottlenecks also emerging — industry entering innovation 2.0 era

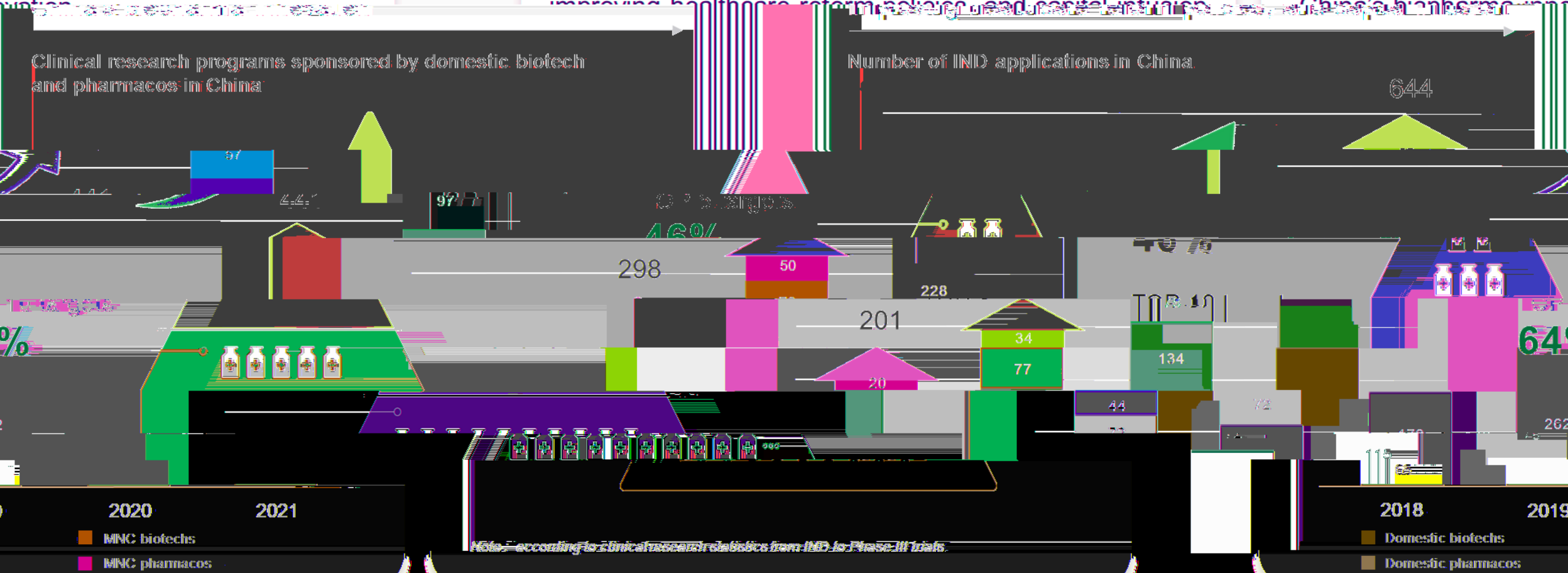
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Clinical research programs sponsored by domestic biotech and pharma in China

Biopharma innovation driven by growth patient needs, improving healthcare reform policies and capital infusion

Intense competition and China's high performance

Number of IND applications in China



Note: according to clinical research statistics from IIBD to Phase III trials

pharmaceutical company

2021

- Innovative drugs account for more than half of total revenue

- ENWEIDA® approved for marketing

2016-2020

- Listed on the Hong Kong Stock Exchange

- Iremed® approved for marketing
- Established State Key Laboratory

2006-2010

- Launched the company's first innovative drug Endostar®
- Listed on the New York Stock Exchange

Innovative research capability equipped

Innovative and competitively differentiated products contribute to 60%+ of Sincern's revenue

Share of innovative products in total revenue

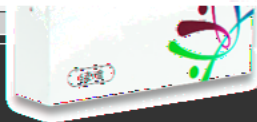
Sanbexin®

The only newly approved stroke drug globally since 2015

62.4%



Entered 2,400 hospitals in first year of launch
100+% growth annually, major contributor to CNS portfolio



ENWEIDA (Envafolimab)
Global first subcutaneous PD-L1

COSELA (Trilaciclib)
First-in-class comprehensive
myelo-protective therapy

32.9%

2021.11.25
Approved

2,000 patients treated

2021.11.29
NDA priority review
by NMPA



Full value chain capabilities enable Sincere's innovation aspiration

R&D capabilities

Products in the core therapeutic areas of Oncology, CNS, Autoimmune, Endocrinology, and others. Products in the pipeline include 40+ products included in NPD and Essential drug list



10+ products included in clinical guidelines

State Key Laboratory of Translational Medicine and innovative drugs



950 strong R&D organization including nearly 300 clinical team members

Differentiated product portfolio

Three core TAs:

Oncology, CNS, Autoimmune

with focus on areas of

significant therapeutic impact

500 professional sales staff

Reaching approximately 3,000 level-A municipal hospitals nationwide

37,000 other hospitals and medical institutions

200 national and regional pharmacies

International Standards

5 GMP manufacturing sites

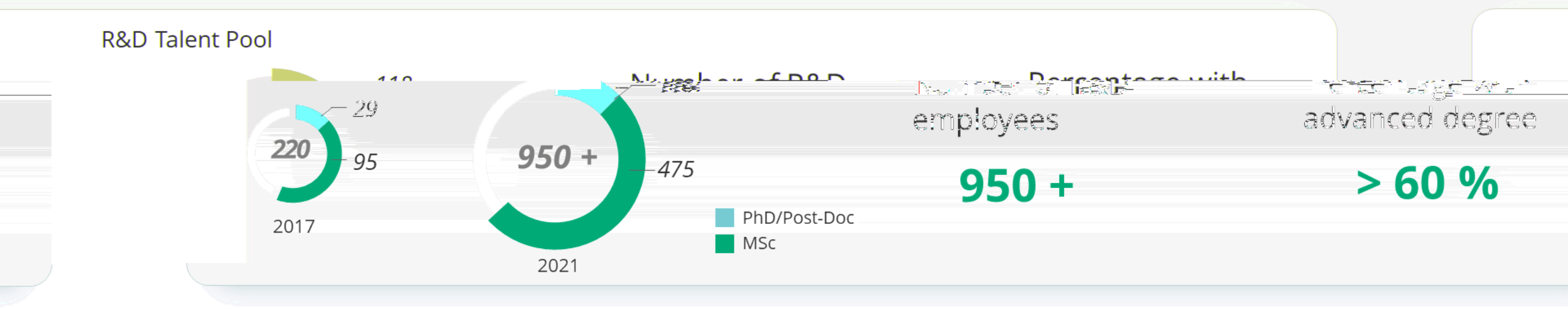
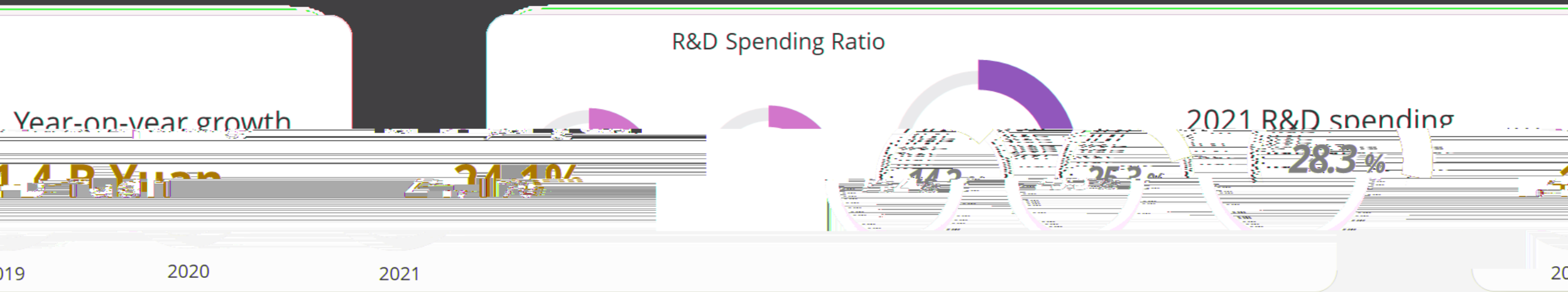


Various dosage forms of small and large molecules, prokaryotic and eukaryotic protein production capability

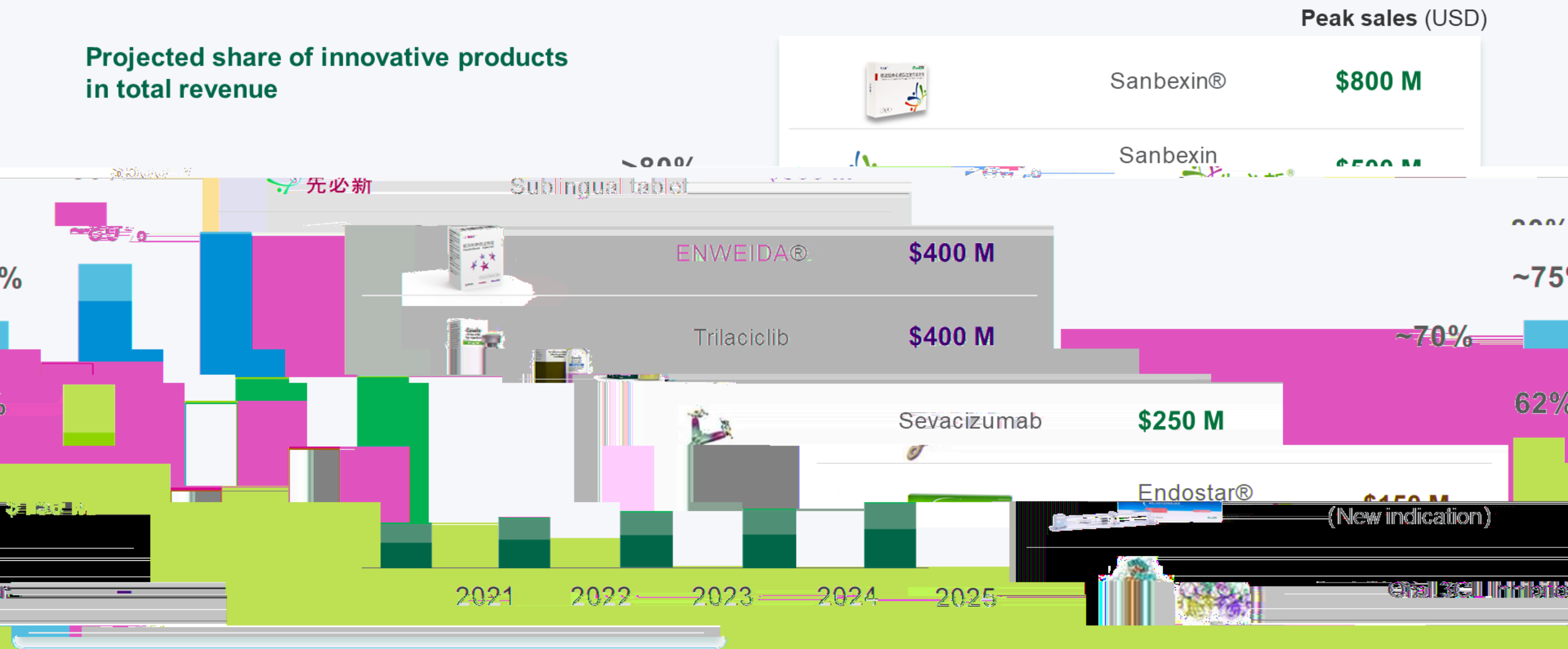
Select products exported to US and EU markets

Over 40

Sustained R&D investment for future growth



Sustained high quality growth driven by key innovative products



Key developments expected in 2022



continue to ramp up rapidly

Highlights

Sanbaxin[®] is expected to be launched in China in 2023. Targeting large Chinese patient population receiving chemotherapy, the product has the potential of gaining huge market share and attention.

Sanbaxin[®] achieved annual sales of RMB 1.5 billion in its first year. The rapid clinical development of Sanbaxin[®] strongly reflects its differentiated innovative therapeutic approach.

Sanbaxin[®] is the first anti-CD47 inhibitor approved for clinical trial in China. The first public search result in relation to Sanbaxin[®] in early April.

Innovation

Simcere has formed a new drug R&D pipeline of nearly 60 projects, with 20 projects in clinical stage involving 17 potential innovative drugs.

Globalization

Simcere has established a global R&D network, including a highly internationalized organization and talent pool etc.



Preclinical Drug R&D

Tang Renhong, PhD
EVP

The background features a stylized DNA double helix in light blue and pink, set against a backdrop of colorful, wavy, and striped patterns in shades of blue, pink, and yellow. The overall aesthetic is modern and scientific.

Preclinical R&D Strategy and Drug Discovery Engines

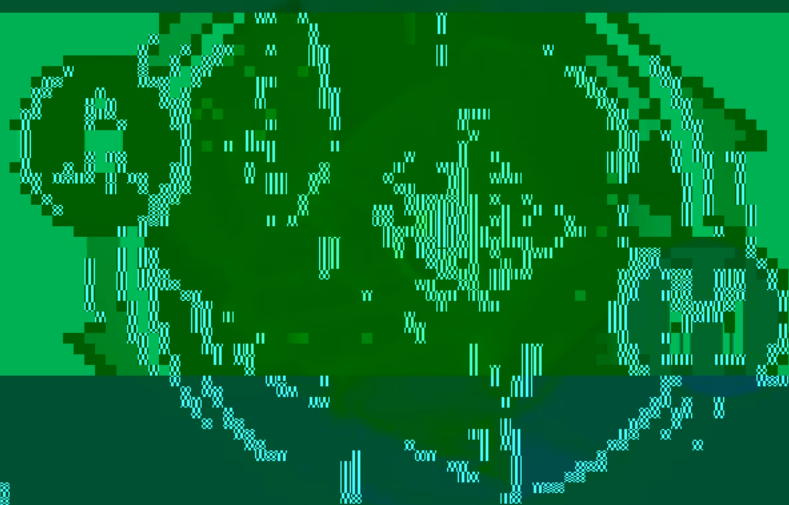
Patient-Centric Drug Discovery Strategy

100% Patient-Centric

100% Patient-Centric

100% Patient-Centric
100% Patient-Centric
100% Patient-Centric

100% Patient-Centric



100% Patient-Centric
100% Patient-Centric
100% Patient-Centric

100% Patient-Centric

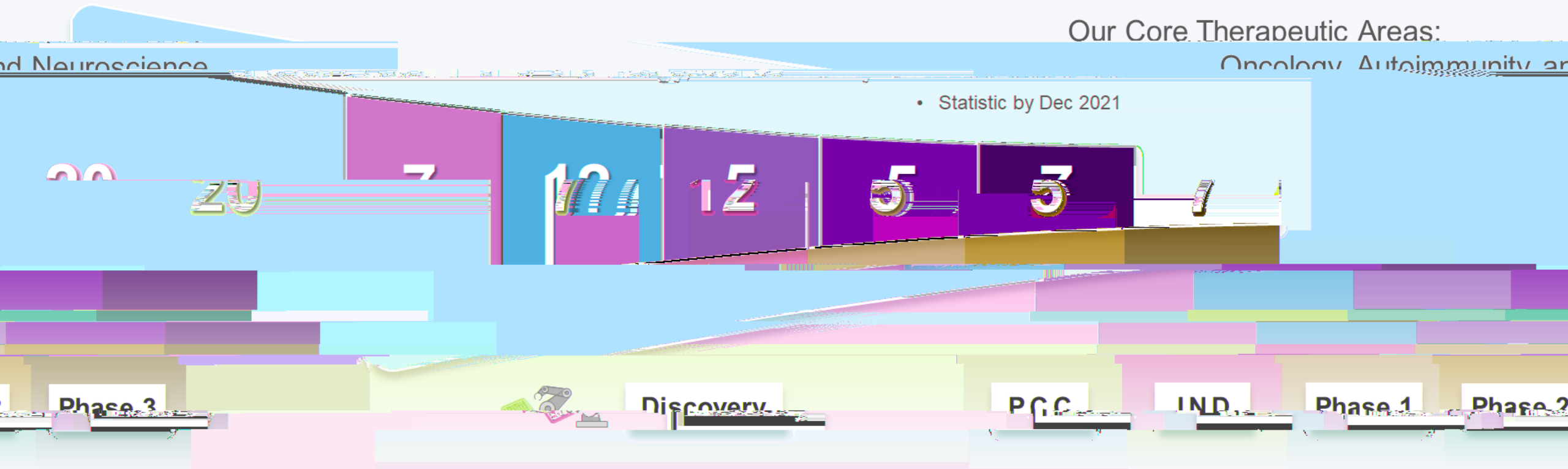
100% Patient-Centric
100% Patient-Centric
100% Patient-Centric

100% Patient-Centric

100% Patient-Centric
100% Patient-Centric
100% Patient-Centric

100%

Growing Portfolio with Strong long-term Potential



- Research Delivered 17 Molecules to the Clinical in less than 5 years

Majority from internal R&D, the remainder from our internal Discovery

Proprietary platform



- Focus on the application in early stage drug discovery, such as hit generation and optimization

- Establishing data science infrastructure and capability internally
- Collaborating with external partner for agile development



Project Y Our Path to the Future



...to attract and unite a group of young talents in life science and fill the gap during the transformation of research hypothesis to therapeutics development

focusing on exploring and creating

th either high treatment needs or



drug discovery



10 directions/technologies with breakthrough potential

PROJECT Y

fill the gap during the transformation of research hypothesis to therapeutics development



Building the true innovative research engine

Diseases-Specific Strategies and key Assets

© 2005-2010 World Bank

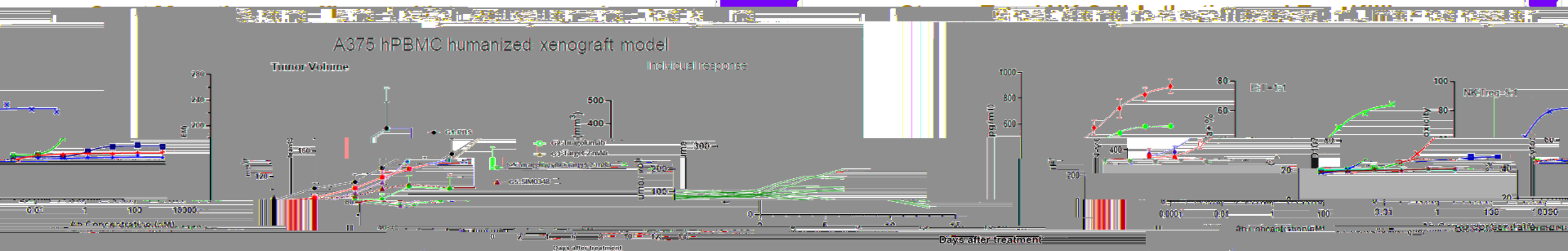
, Female reproductive, Hematological malignancy

Building Depth on prioritized tumor types: Lung, Breast, GI



SIM0340: TIGIT/CD96/2B4 Bimodal Antagonist

Dual Checkpoint targeting for enhanced T cell stimulation

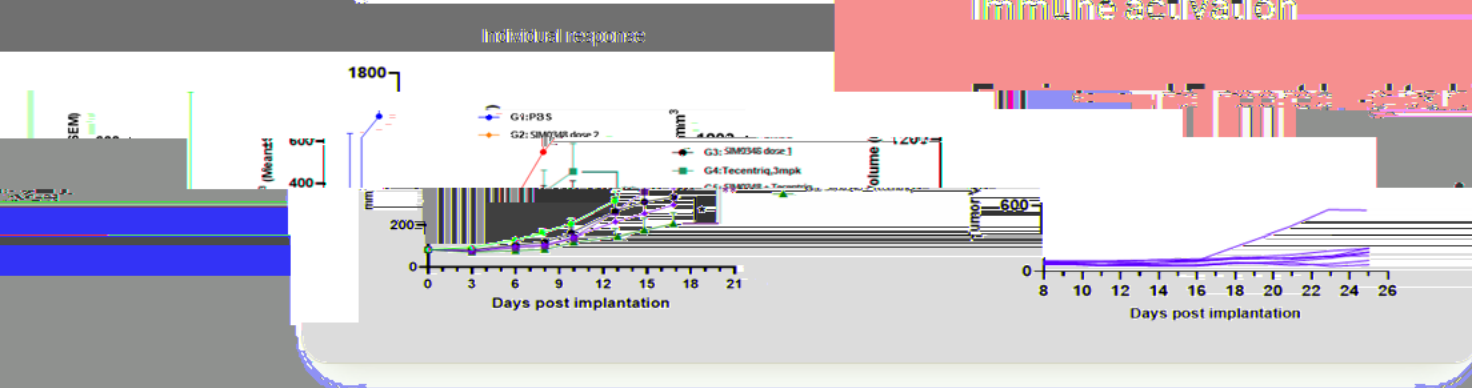


Effect With Tecentriq

- Simultaneously targeting two checkpoints for improved immune activation

Significant Synergy

A375 hPBMC humanized xenograft model



50% Tumor growth inhibition achieved in PD-1 blocker insensitive model.

SIM0237: PD-L1/IL15v Bifunctional Fusion Protein

Best-in-Class potential with Improved tumor control and low safety risk

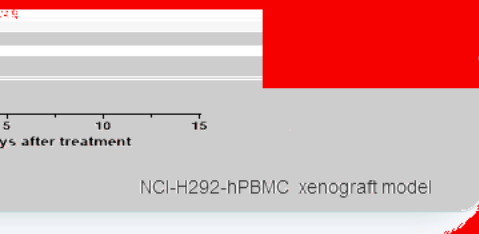
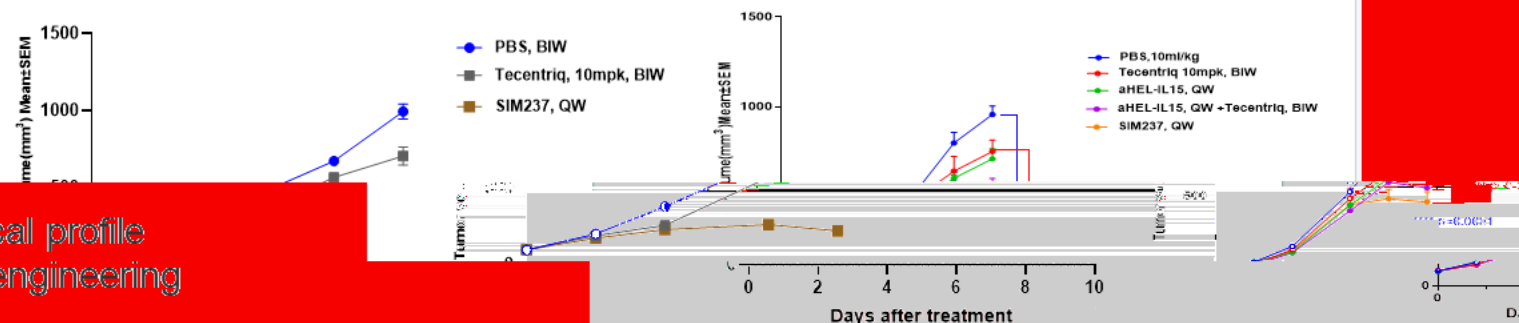


Rationale:

- Blocking PD-1/PD-L1 signaling and deliver IL-15 directly to TME for fully activation of CD8 T cells

- Fine tune IL-15 pharmacological profile through protein engineering

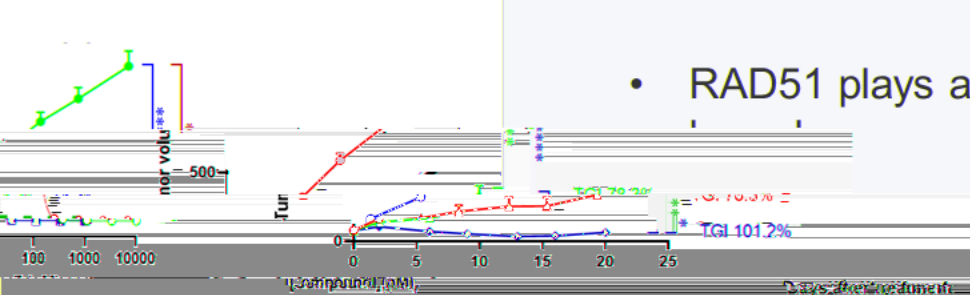
Significant Tumor Growth Inhibition



SIM0217: First in Class RAD51 inhibitor

Significant advantages on efficacy, safety , developability compared to current leading competitor

In Vivo Efficacy

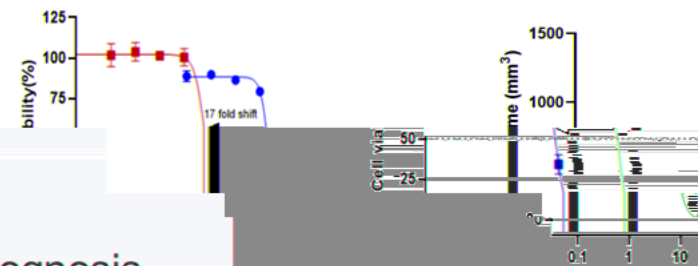


- RAD51 plays a central role in the homologous recombination pathway

Overexpressed in several human malignancies, correlates with poor prognosis

Synthetic lethality with ATRX

Superior In Vitro Activity And In Vivo



tumors

Multiple combination potential with chemotherapy and other DDR pathway

Broad combination opportunities for multiple tumor types

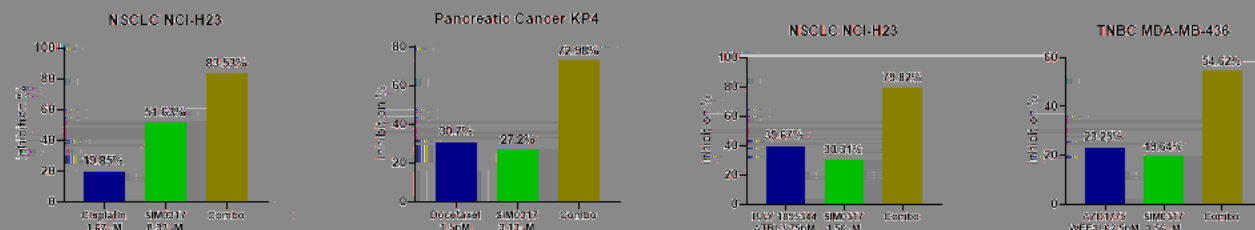
Combination with Gemtaz in MCF-7

Combination with Docetaxel in

Combination with ATRX in

Combination with W551i in

targeting therapeutics

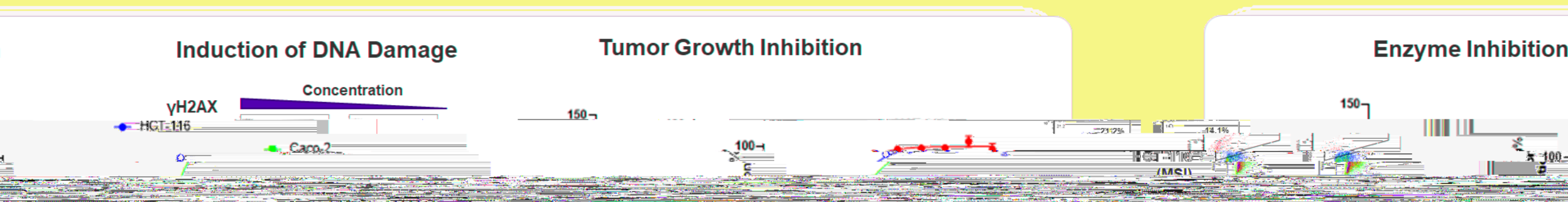


lethal potential to microsatellite instability (MSI)

ning supported by machine learning algorithm

- Target plays a pivot role in mismatch repair (MMR) with synthetic
- Current no publicly disclosed inhibitor yet
- Successful identification of Hit compound through virtual lib screen

Identifying Inhibitors of MMR in Cancer Cells



Autoimmunity

Targeted Delivery of

Immunosuppressive
agents

02

- Profound immuno-suppression in disease

- Re-establish Treg/Teffs balance

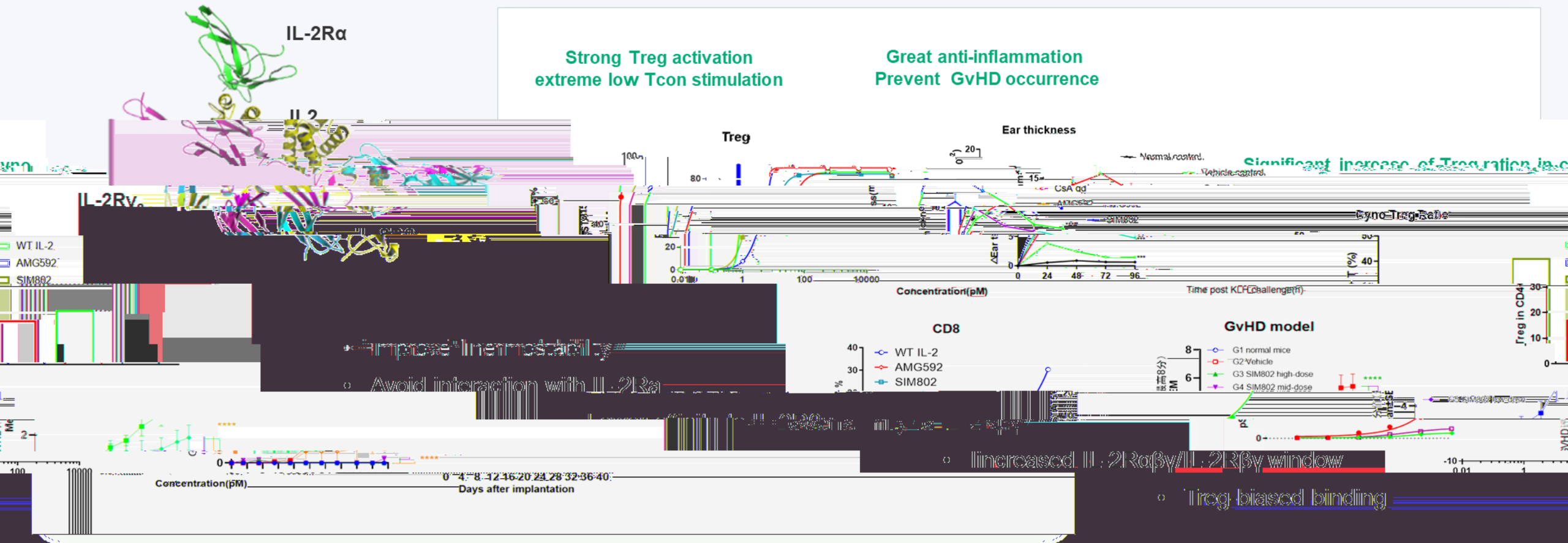
Treg Biology

- Selectively stimulate cell proliferation

- Minimizing the systemic side-effects

SIM0278: IL-2 mutein specifically Promote Treg Function

Differentiation through protein engineering



Ab-Steroid conjugate for Th2 suppression

Significant decrease of IgE production and inflammatory cell infiltration bring great histological improvement

Figure 1. Inhibition of IgE production

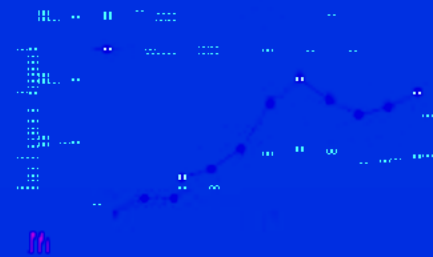


Figure 1

Figure 1

Figure 2. Inhibition of lymphocyte infiltration



Figure 3. Histological improvement



Neuroscience

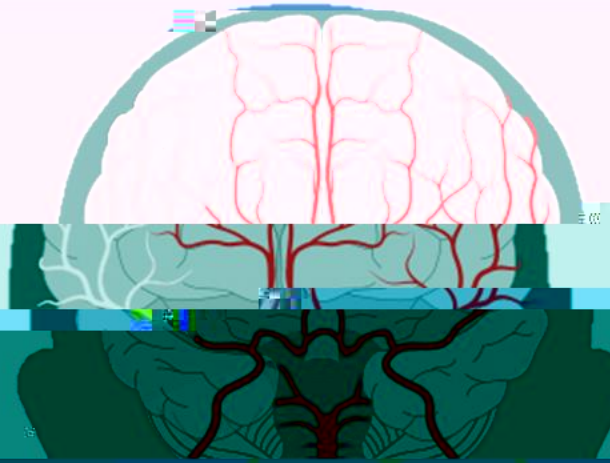
Strengthening our core competence **in stroke**,
expand to **neurodegenerative Diseases**

Stroke

- Whole disease course management
- co-morbidities control through new MoA/Modalities
- Hemorrhagic Stroke expansion

Neurodegenerative Diseases

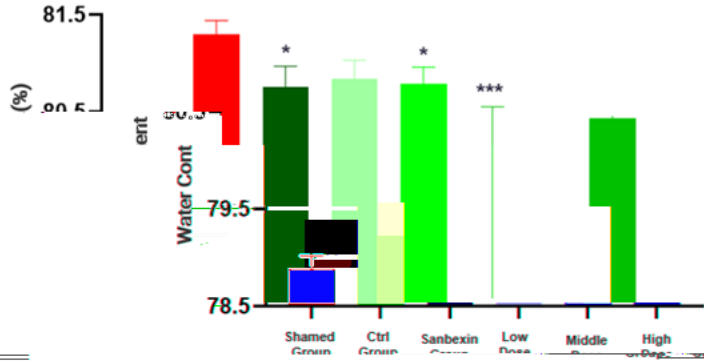
- Combination of multiple mechanisms for early intervention
- Inhibit neurocytotoxic protein aggregation
- Neuroimm...



Expand Sanbexin[®] to Hemorrhagic Stroke

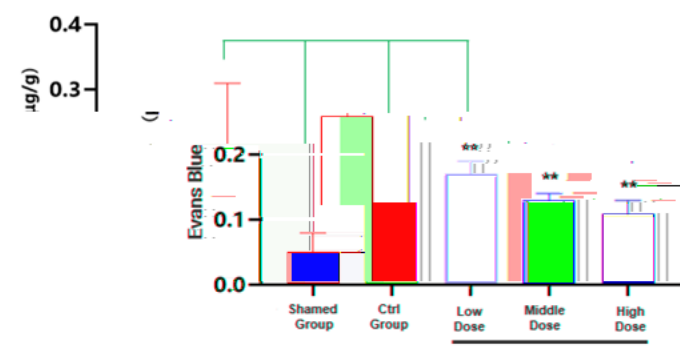
Collagenase-induced intracerebral hemorrhage Model

Reduce Cerebral Edema

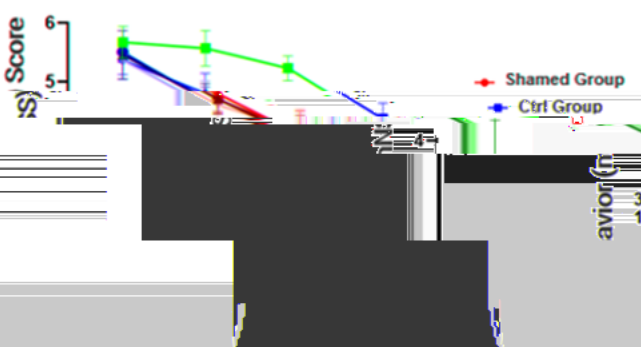


Subarachnoid Hemorrhage Model

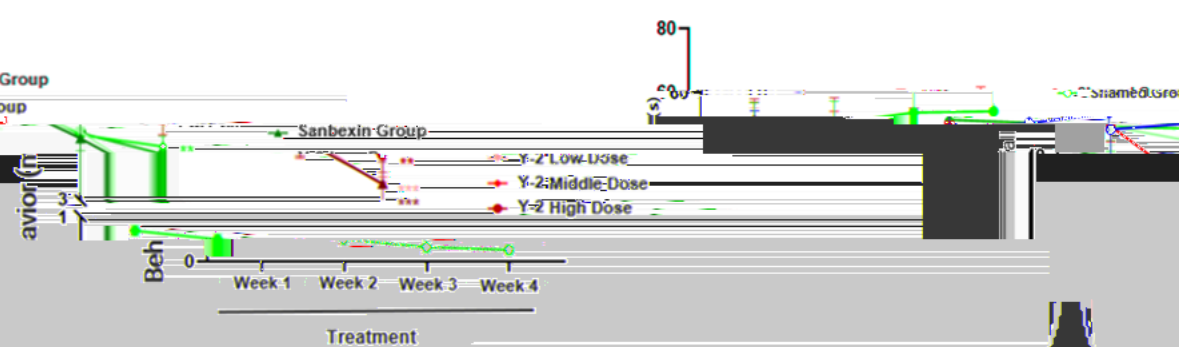
Protect Blood-Brain Barrier Integrity



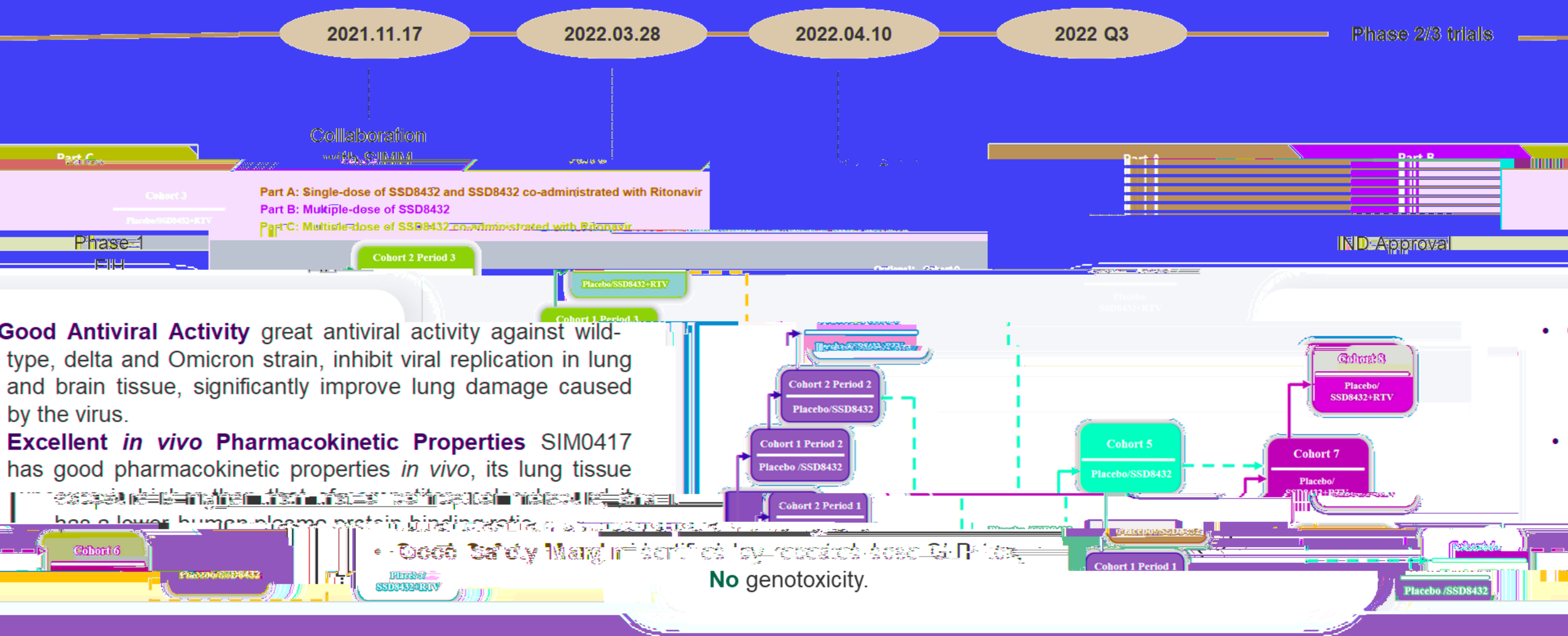
Improve Neuron Function



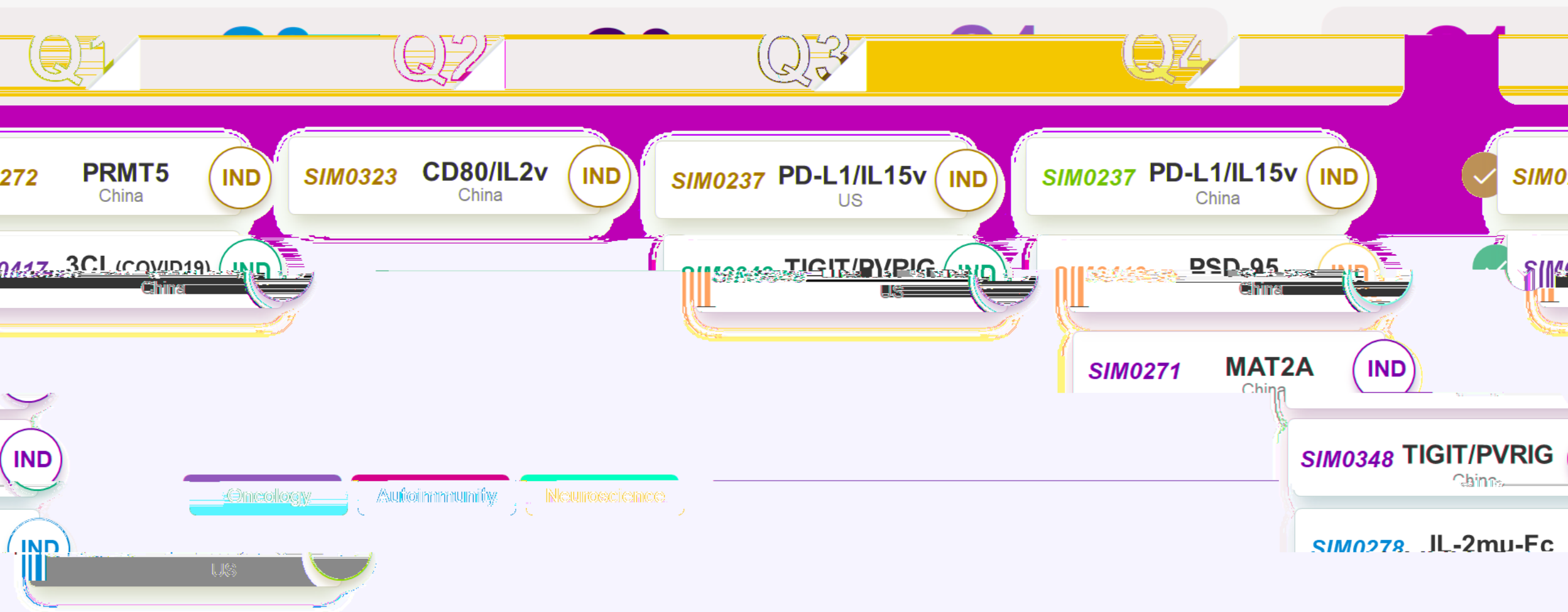
Ameliorate Dyskinesia



Oral 3CL protease inhibitor jointly developed with Shanghai Institute of Materia Medica



Expected submissions in 2022



Key Takeaways for Today

1

Patient-centered principle is core of our drug R&D efforts

2

Build competence in platform technology to create competitive advantages

3

Improve TA-focused strategy through deeper understanding of disease biology

4

Quick and agile execution of high potential assets for clinical validation

5

Future

Link cell foundation of next gen innovation through Project V fast track growth



Late-stage Oncology Pipeline

| Bijoyesh Mookerjee, MD
| Chief Medical Officer

Oncology Clinical R&D Strategy

Focus on innovation to maximize impact on patients

- Focus on the highest unmet need

- Focused Internal and external collaboration

Inmet Medical

- Improve global R&D capabilities
- Prioritize international R&D strategies

- Operational excellence
 - Strategic decision-making
 - Expedited and high-quality clinical trials

Need

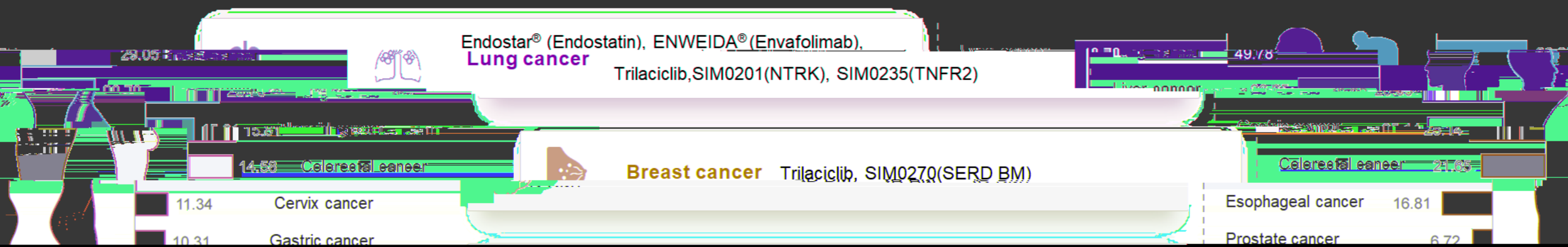
for cancer patients in China

therapeutic Area: Layoff

Clinical value-oriented medicines to provide greater efficacy

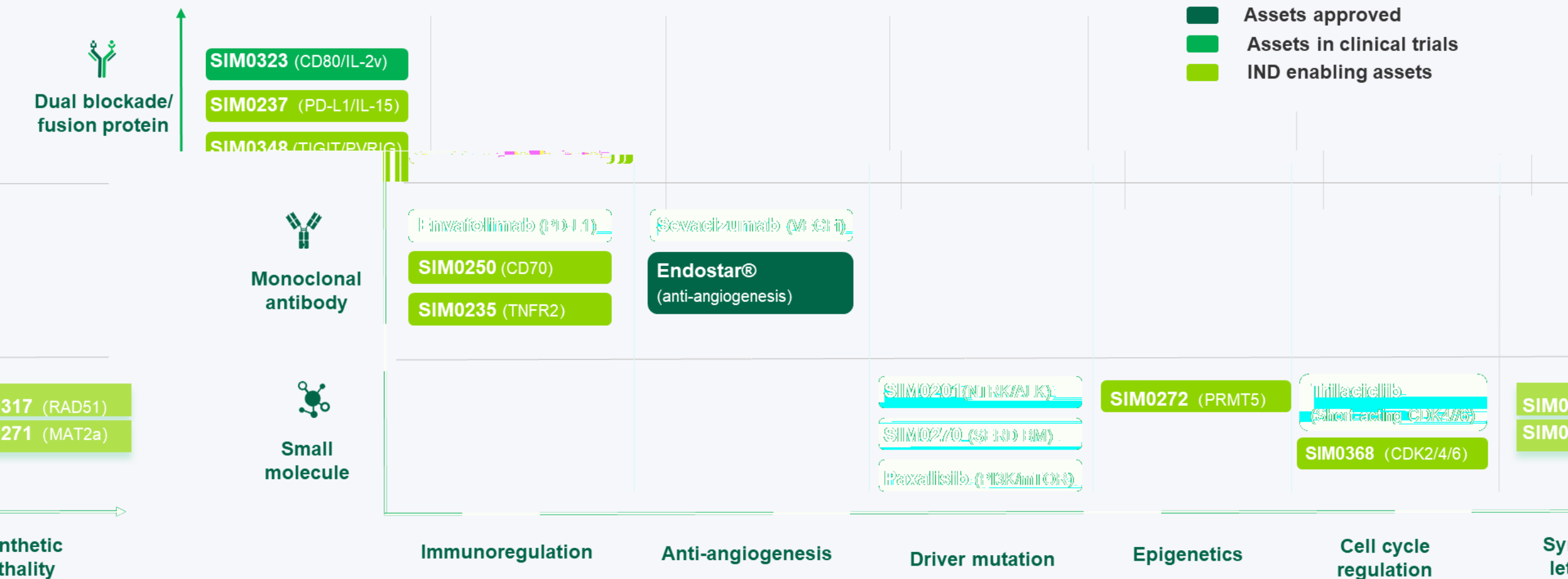
Simcere anti-tumor products approved for

Estimated incident rates of new cancers (China)



Oncology Pipeline Layout

Maximize existing, and accelerate new medicines and combinations



Differentiated Treatment for Patients

Providing novel medicines to cancer patients with greater efficacy



Key Project Introduction

Progress in Clinical Trials

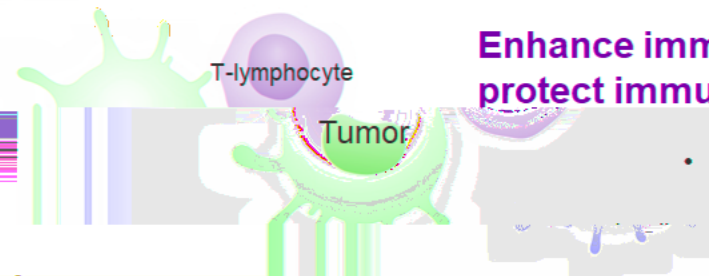
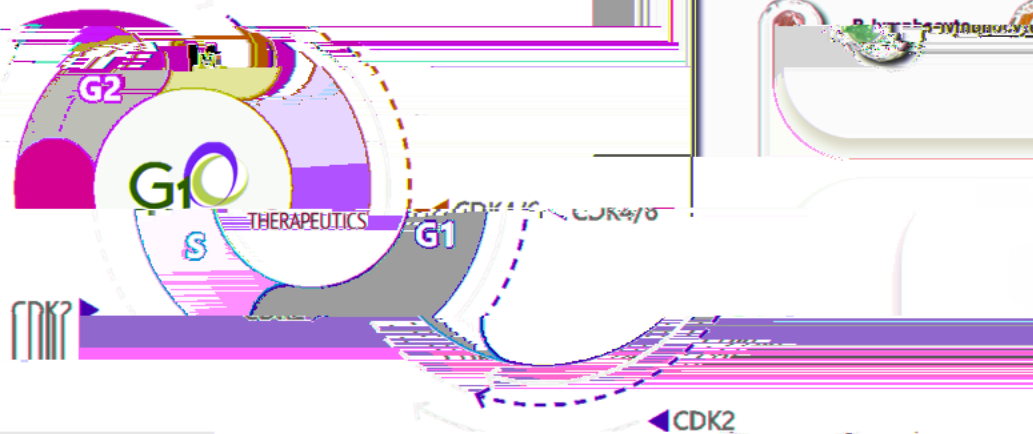
Trilaciclib: a CDK4/6 inhibitor that provides prophylactic bone marrow protection

Protects **hematopoietic stem/progenitor cells (HSPCs)** from chemotherapy and enhance the immune system through

Prevent multiple adverse events of myelosuppression through **multilineage bone marrow protection**¹⁻³

Mitigate neutropenia

avoid administration delay and



Enhance immune response and protect immune function

- Change the proliferation kinetics and composition of T cell subsets in tumors to enhance the number and function of effector T cells

 Journal of
 Management Education



Trilaciclib accelerating the indication process in China

Only FDA-approved therapy that proactively delivers multilineage myeloprotection to extensive stage SCLC patients being treated with chemotherapy

otherapy (N=92)

nSentro AG.

ding, primary analysis completed, PK and

overseas countries

ary endpoint met (DSN* in the first cycle).

ng application submitted to China NMPA in November

22

2021/11/29

Submission of Conditional Marketing

2021/2/12

On 12 February 2021, FDA fully approved

COSELA™ (Trilaciclib) for bone marrow

protection in ES-SCLC patients, which is **the world's first and only** bone marrow protection therapy that can reduce the incidence of chemotherapy-induced myelosuppression

TRACES study in China:

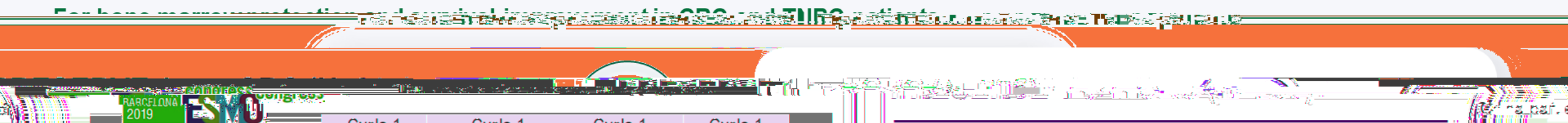
Phase III trial for ES-SCLC treated with 1-3L chemotherapy

- The 1st part: safety lead-in and PK bridging study, to establish the safety and benefit trend consistent with those in other studies
- The 2nd part: placebo controlled, primary endpoint: duration of severe neutropenia (DSN)
- Conditional marketing application submitted to NMPA

2021 Priority Review/Cer. granted, expected to be approved in 2022

*DSN; duration of severe neutropenia

Trilaciclib: PRESERVE trials

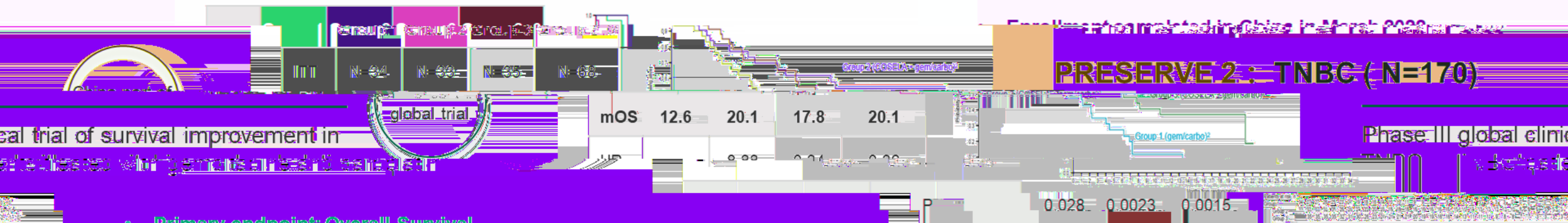


Phase III global clinical trial for bone marrow protection in CRC patients treated with FOLFOXIRI & Bevacizumab (N=296)

- Primary Endpoint: Duration of severe neutropenia in cycle 1 and occurrence of severe neutropenia during Induction
- FPI worldwide: 16 October 2020
- FPI in China: 24 September 2021

Enrollment met in China in March 2022

PRESERVE 2: TNBC (N=170)



- Primary endpoint: Overall Survival
- FPI worldwide: 15 April 2021
- FPI in China: 7 January 2022

Approval by the FDA.

Enrollment ongoing

Trilaciclib showed strong OS improvement in the TNBC randomized controlled phase II trial.

In July 2021, TNBC indication was granted Fast Track designation

gemt/carbo plus one of two agents (gemt/carbo or gemt/carbo plus one of two agents)

Endostar® New Indication: malignant thoracoabdominal effusions

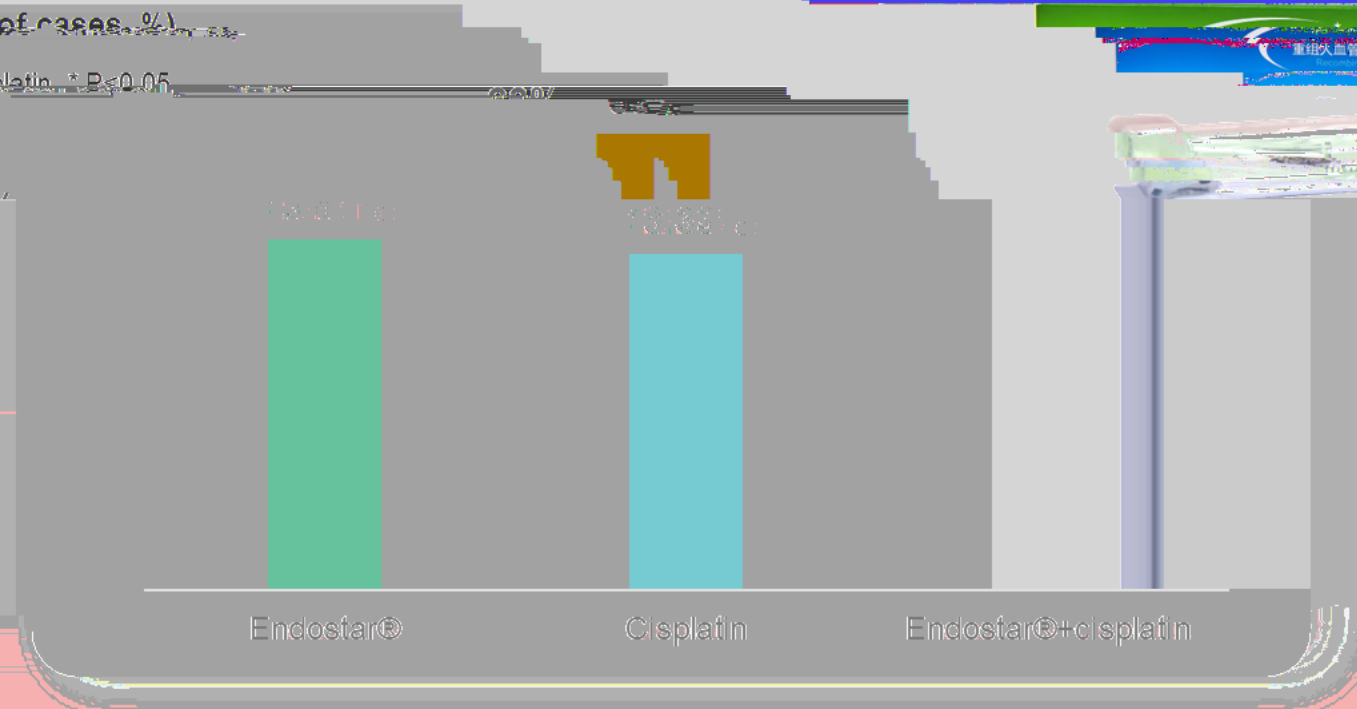
Endostar® also has a
positive therapeutic effect on malignant

effusions¹

Early studies have shown that Endostar® has a
positive therapeutic effect on malignant

ORR comparison in 3 groups / number of cases (%)
compared with cisplatin. * P<0.05

Endostar® is a recombinant human endostatin injection
first-line treatment of advanced NSCLC in China



Endostar® is
approved for first

Endostar® New Indication: COREMAP study

minal effusions

To address the urgent need of patients with malignant thoracoabdo

- Among patients with incurable tumors whose expected survival is longer than two weeks, the proportion of abdominal distension caused by ascites and other reasons is as high as 29% (meta analysis).
- According to Frost & Sullivan data, the incidence of intracavitary malignancy reached 707,900 in 2019 and is estimated to increase to 756,900 by 2030.

COREMAP : Endostar® for treatment of malignant thoracoabdominal effusions, phase III

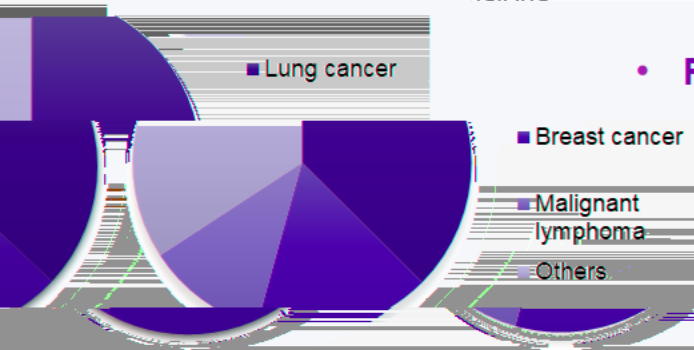
CHINA

Intra-pleural injection of recombinant human endostatin/placebo with cisplatin in treatment of malignant thoracoabdominal effusions: a multicenter, randomized,

controlled, double-blind, phase III study

Tumors causing malignant thoracoabdominal effusions

Tumors causing malignant thoracoabdominal effusions



• FPI: 28 July 2021

- Recruitment: 105 subjects enrolled as of March 30, 2022
- Interim results analysis expected in H2 2022

■ Ovarian

■ Hepato-Pancreatic

■ Biliary cancer

■ Gastric cancer

■ Esophageal cancer

■ Colorectal cancer

■ Others

12-15 months

average survival with treatment ~65%

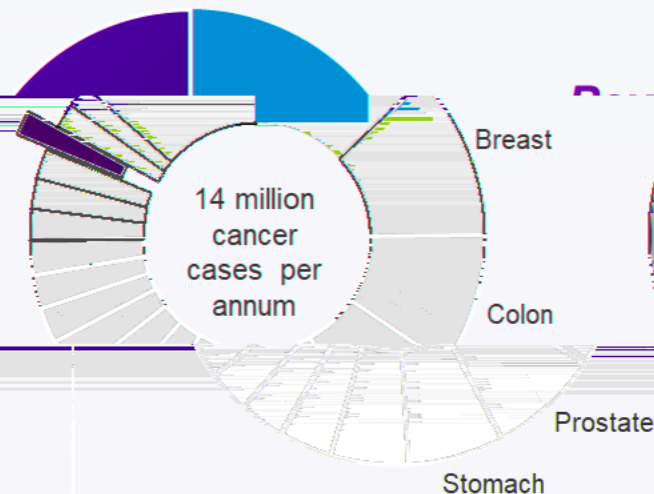
main treatment drug is temozolomide

China's annual market size for temozolomide is about 2B yuan

temozolomide almost ineffective for 35% of the patients (those with unmethylated MGMT status)

great potential²

- Clinical trials underway in other forms of brain cancer beyond GBM: DIPG, primary CNS lymphoma, brain metastases.
- Potential to combine with chemotherapy, radiotherapy and targeted drugs (e.g., EGFR inhibitors).
- Potential to target non-brain cancers: Breast cancer, NSCLC, CRC, endometrial cancer, GIST, pancreatic cancer, RCC, TCC, HNSCCs, GBM, leukemia, melanoma, and NHL



Glioblastoma (GBM)

133,000 cases per annum worldwide

- The main treatment drug is temozolomide
- China's annual market size for temozolomide is about 2B yuan
- temozolomide almost ineffective for 35% of the patients (those with unmethylated MGMT status)



KAZIA
THERAPEUTICS

PARALISIB

BM indication, Orphan Drug designation was granted

GBM AGILE: A trial of Paralysib in GBM

- For the G

Envafolimab

Envafolimab

康宁木瑞

subcutaneous Injection

First PD-L1 Antibody Approved For S

camel
PDL1



dAb blocking

PDL1-PD1

interaction

Envafolimab has a good safety profile, as a single agent

• Envafolimab phase II trial for advanced MSI-H/dMMR solid tumor showed it

was effective in PD-L1 expression was exhausted in NMBA in Dose cohort

2020 and approved in November 2021

Immunize
with

2020 CSCO

N

ORR

DCR

12moPFS

12mo

Total

Treatment

Advanced 3 drugs

Treatment
failure after

2-drugs

Advanced SC

Advanced SC

~80kDa

• Novel humanized dAb against PDL1

• Low immunogenicity

• Putative binding site for PDL1

• Stable

Envafoлимab and Anti-andiodenic Combinations

Envafoлимab + Sevdulizumab

Phase II trial of Envafoлимab combination therapy in solid tumor patients

Envafo

CHINA



SIM0235: Humanized anti-TNFR2 monoclonal antibody

New targets for tumor immunity

Approved (1st in same target)



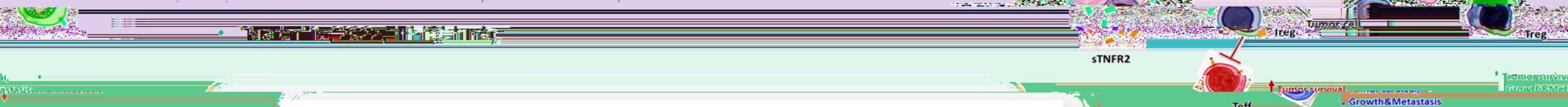
US IND approved



China IND approved

Exploring the development potential of single agents in solid tumors and

Exploring the development potential of single agents in solid tumors and



cell surface:

endogenous TNF, it

TNFR2-mediated immunosuppression and tumor cell

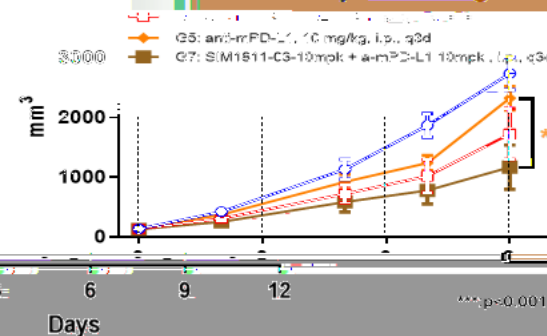
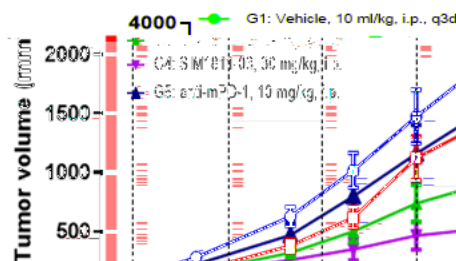
ADCC mediated
terminal has a direct killing effect on immunosuppressive
including tumor cells expressing TNFR2, regulatory T cells
and bone marrow-derived suppressor cells (MDSCs).

TNFR2 Humanized Animal Model:
Single Drug Efficacy

2500
G1: Vehicle
G2: SIM1811-03, 3 mg/kg, i.p.

TNFR2-mediated immunosuppression and tumor cell

Animal Model Data: Combination
with Anti-PD-L1 Antibody



It can specifically recognize TNFR2^{1,2,3} on the

• By blocking the activation of TNFR2 by e

affects

proliferation
• Antibody
by Fc to
cells, in
(Tregs)

SIM0270: BBB permeable, tumor tissue-enriched,

BBB permeable, tumor tissue-enriched, tumor tissue-enriched

Brain-to-blood ratio

2

3

4

5

6

Name	R&D company	Clinical phase	Oral	BBB permeability
Simvastatin	Abbott	Phase III	Yes	High
Atorvastatin	Pfizer	Phase III	Yes	High
Fluvastatin	Schering-Plough	Phase III	Yes	High
Pravastatin	Bristol-Myers Squibb	Phase III	Yes	High
Simvastatin	Abbott	Phase III	Yes	High
Atorvastatin	Pfizer	Phase III	Yes	High
Fluvastatin	Schering-Plough	Phase III	Yes	High
Pravastatin	Bristol-Myers Squibb	Phase III	Yes	High

Approved SERD compound

Annual sales exceeding 1 billion US dollars

SCR-6106 rat

D-0502 rat

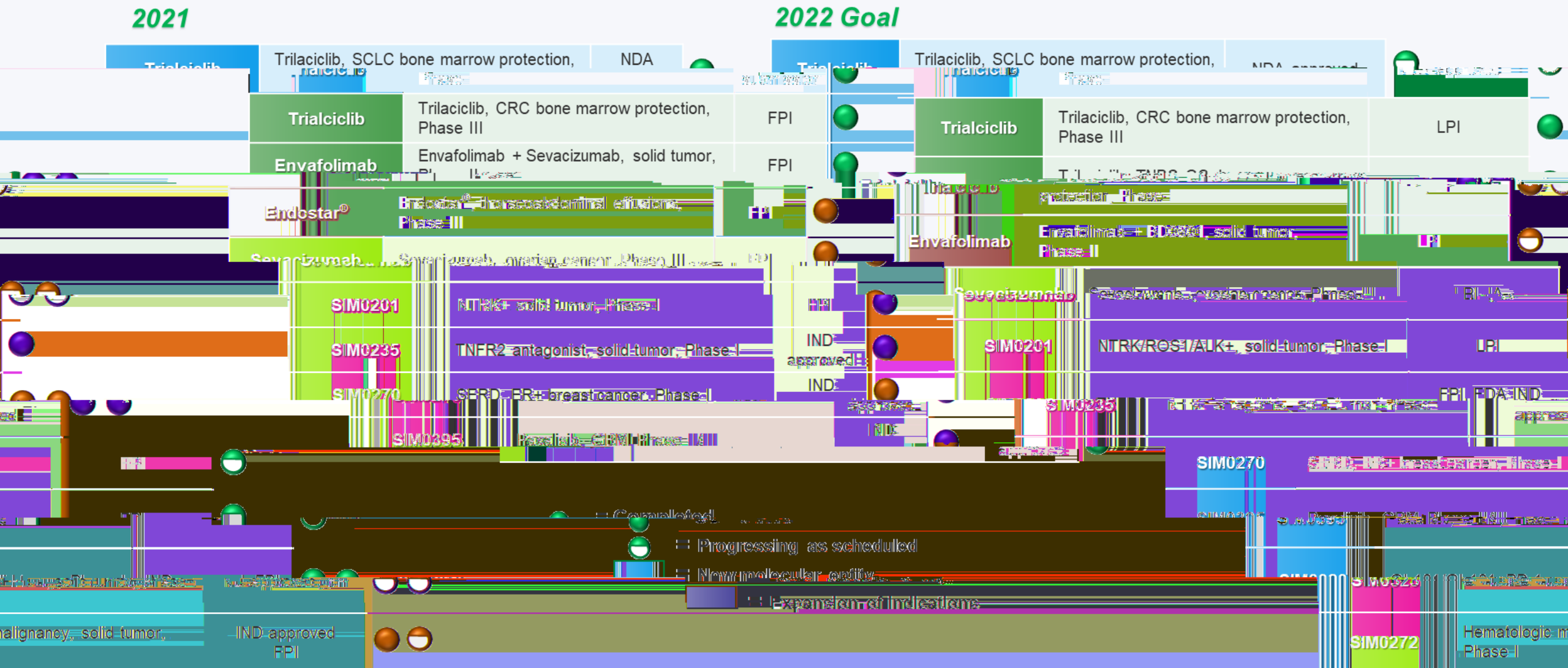
SCR-6106 mouse

SAR-439859 mouse

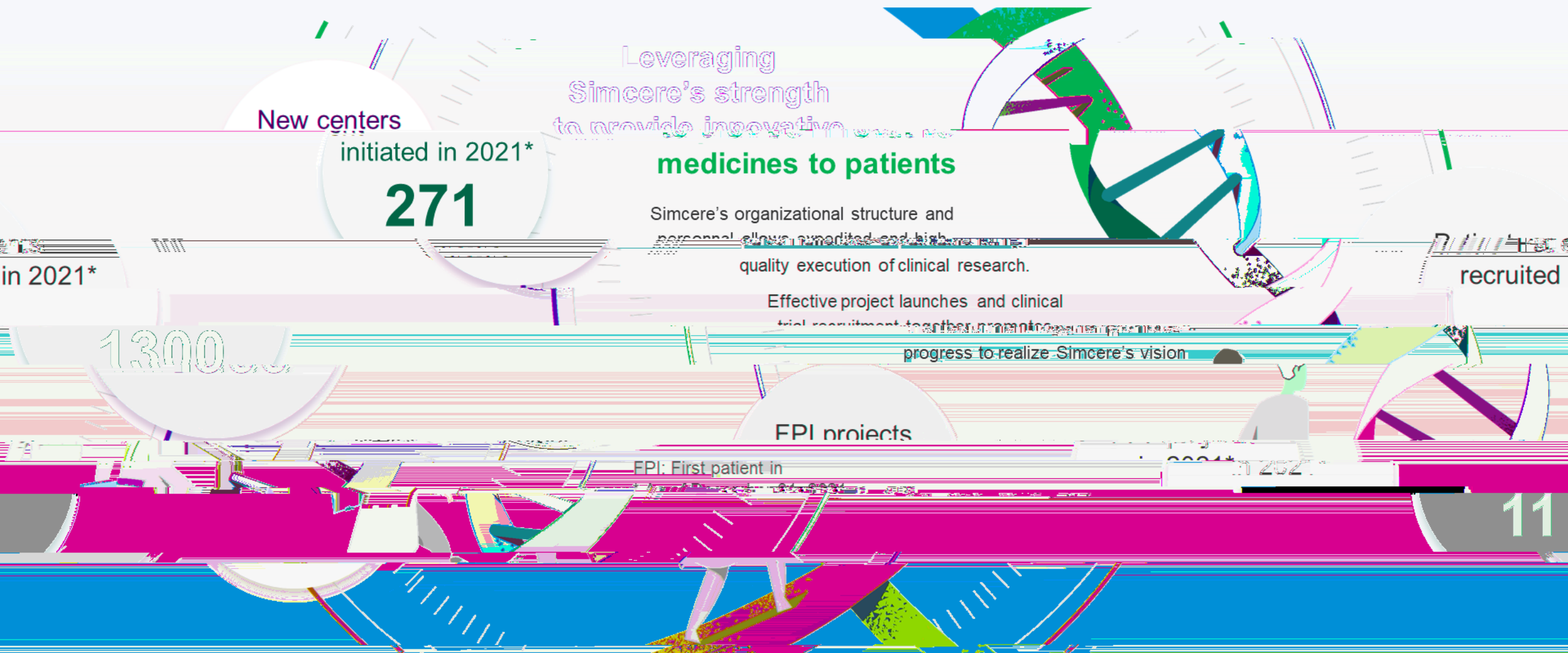
GDC-9545 mouse

Core Advantages

Milestones 2021-2022



Operational Excellence Driving Simcere's Purpose and R&D Vision



Operational Excellence— New Asset Development

Operational Excellence— New Asset Development

EP in China (SCIC)

126d

2021.5.25

Globalization to Further Extend Asset Value



Providing Today's Patients with Medicines of the Future





Late-stage

Non-oncology Pipeline

| Danny Chen, PhD
| SVP

Overall Strategy

Manufacturing and Distribution of Pharmaceuticals

Overall Strategy (2020)

- Manufacturing and Distribution of Pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

in manufacturing and distribution of pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

- Manufacturing and Distribution of Pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

- Manufacturing and Distribution of Pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

Manufacturing and Distribution of Pharmaceuticals

- Manufacturing and Distribution of Pharmaceuticals

Summary

CNS/Autoimmune clinical strategies and highlights – clinical value and differentiation

Focus on

WTB II

II

WTB

WTB

WTB

WTB

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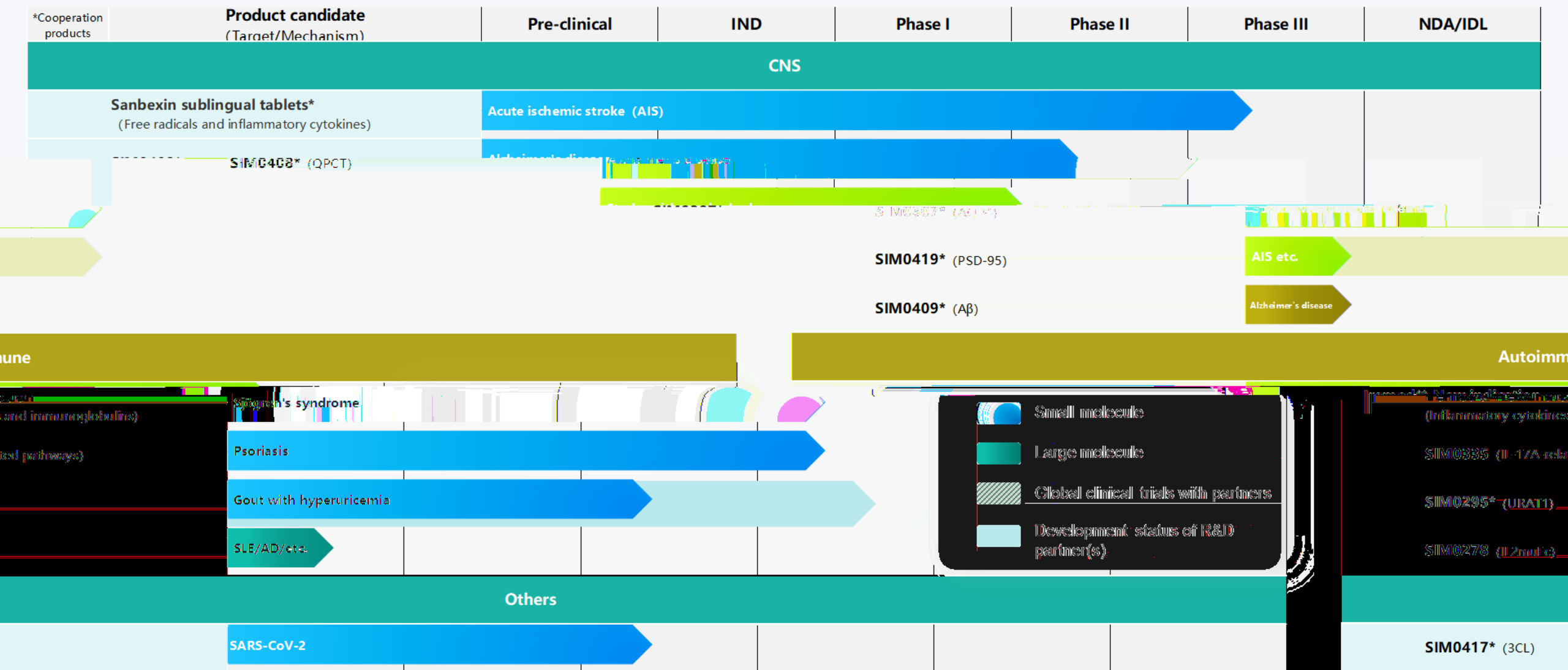
WTB

WTB



Non-oncology Pipeline

CNS, Autoimmune, and the disease areas that have significant clinical needs in the future



Key Project Introduction

CNS

CNS Clinical Focus

Subsegments of nervous system disease

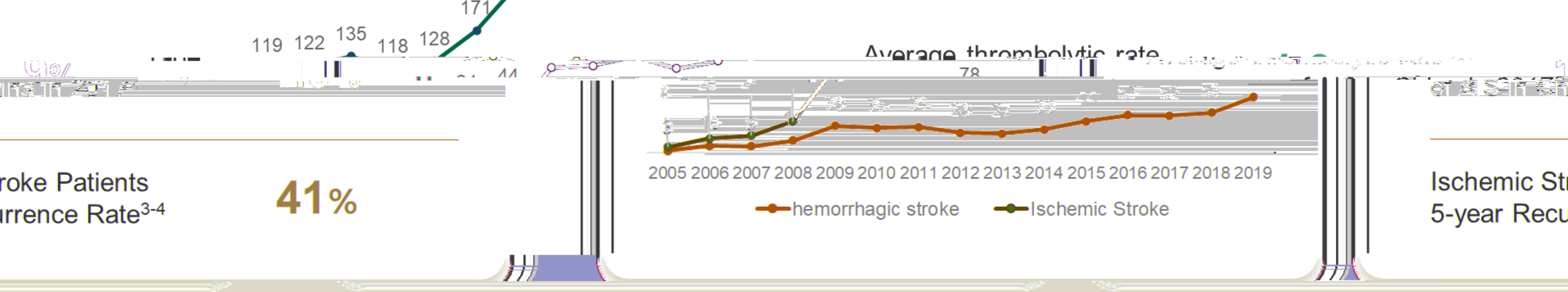
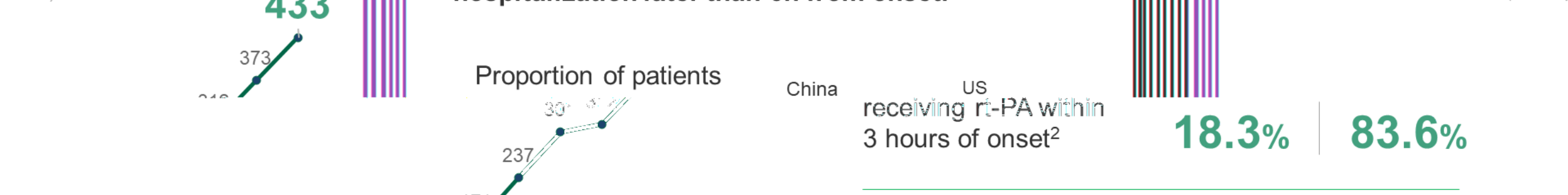
Neurological drug R&D success	Few domestic	Both China unique and
-------------------------------	--------------	-----------------------

China's Stroke Treatments Still Have Huge Challenge

Large Number Patients And Low Thrombolytic R

About 60% ischemic stroke patients missed IV thrombolysis treatment window due to hospitalization later than 6h from onset.

Number of Discharged Patients with Ischemic and Hemorrhagic Stroke (10000 person)



Sanbexin in acute ischemic stroke

48 clinical centers across the country participated in the trial, including ~1200 subjects, and the data were

of patients with
treatment

Primary efficacy endpoint: Proportion of
mRS score ≤ 1 on day 90 of treatment

Sanbexin 50.93%

Sanbexin 67.48%

OR:1.42, 95%CI:1.12~1.81, $P = 0.0004$

avone

20.9

38.1

17.2

11.9

8.6

3.0

Edara

0-point

44.4

12.8

10.9

6.3 2.7

Sanbexin

22.7

0%

20%

40%

60%

80%

100%

Sanbexin[®]: TASTE II Ischemic Stroke Reperfusion Study

Phase IV study to evaluate the efficacy and safety of Sanbexin combined with early endovascular recanalization therapy in patients with Acute Ischemic Stroke (AIS)

- A phase IV study to evaluate the efficacy and safety of Sanbexin combined with early endovascular recanalization therapy in patients with Acute Ischemic Stroke (AIS)
- March 18, 2022: FPI
- Complete 80% enrollment expected in 2023

TASTE-2

After vascular recanalization, Sanbexin can directly enter the ischemic site to promote the recovery of ischemic damaged brain tissue.

Protect the brain tissue from re-injury caused by ischemia-reperfusion injury.



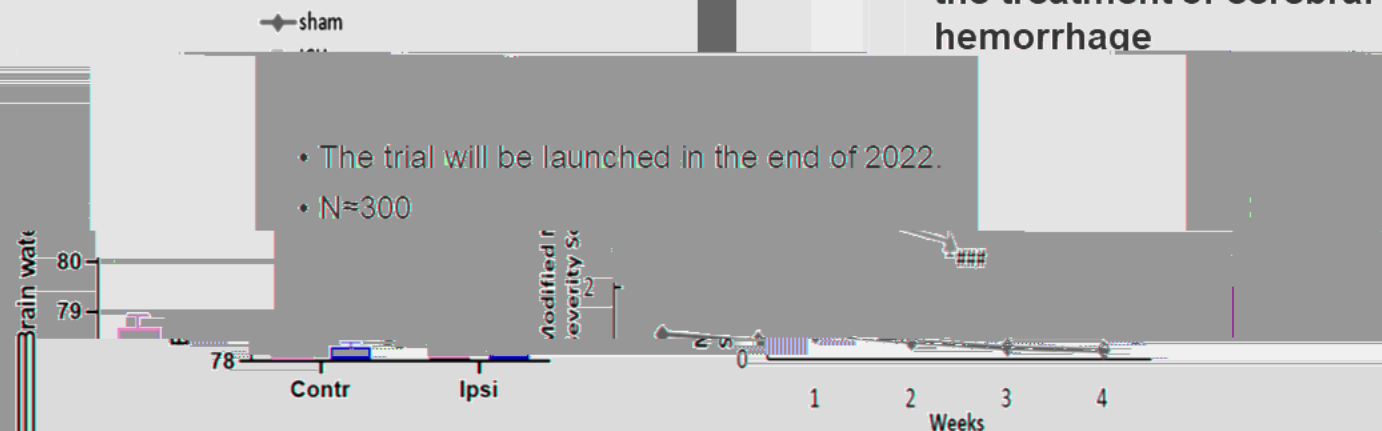
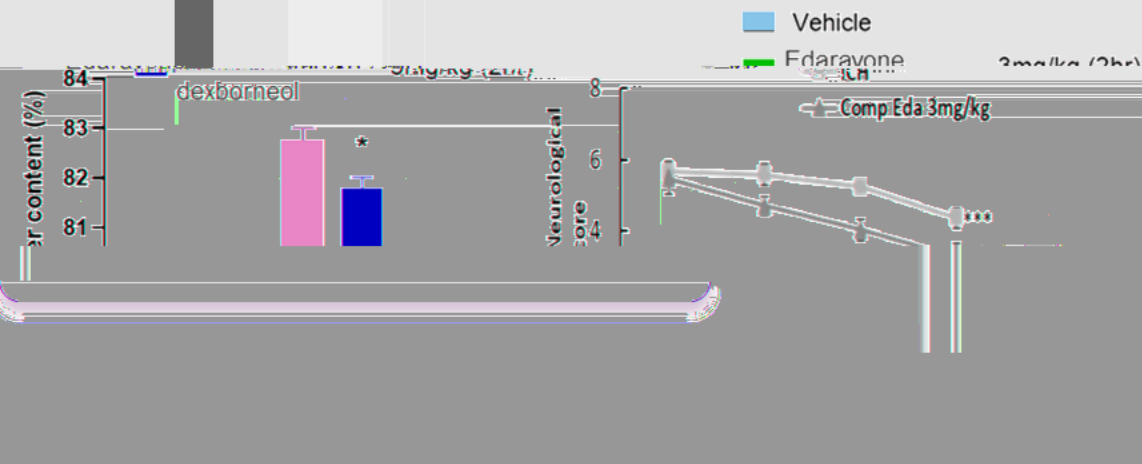
The efficacy of new neuroprotective agent edaravone dextroborneol combined with alteplase on AIS

Sanbexin®: Hemorrhagic Stroke Indication

Preclinical study

Animal experiments showed that Sanbexin® could significantly improve the prognosis of cerebral hemorrhage.

- Sanbexin® administration two hours after the onset of collagenase-induced ICH could significantly relieve the cerebral edema caused by hemorrhagic stroke.
- Sanbexin® could significantly improve the permeability of blood brain barrier after cerebral hemorrhage.

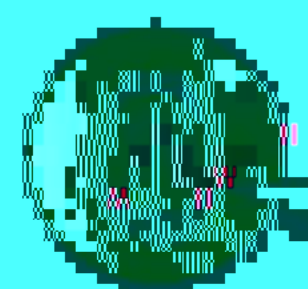
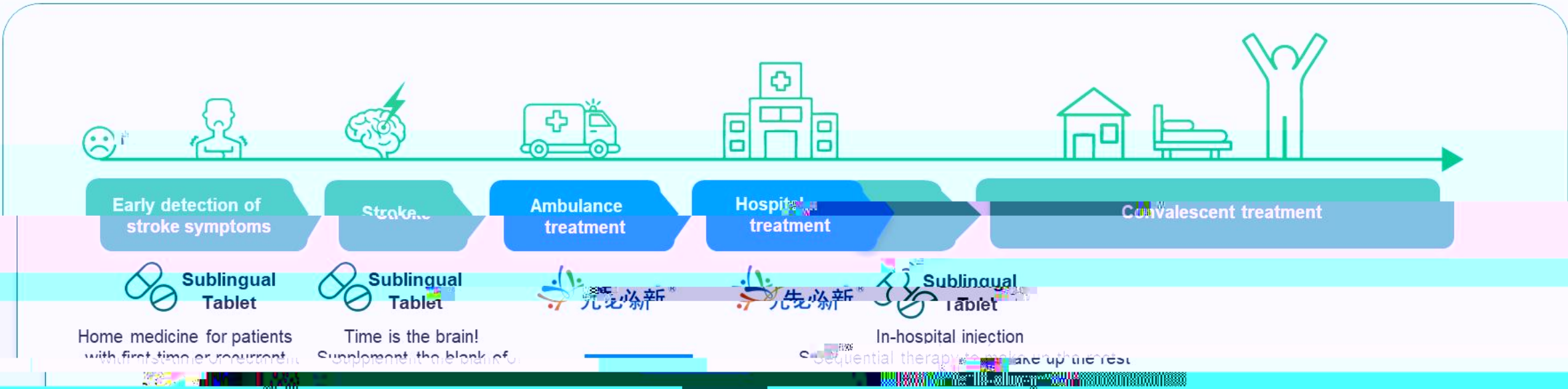


- The trial will be launched in the end of 2022.
- N≈300

the treatment of cerebral hemorrhage

Sanbexin Sublingual Tablet

Further expand the effectiveness of Sanbexin in stroke treatment and recovery



Sanbexin Sublingual Tablet is a new type of stroke treatment and recovery drug. It is a sublingual tablet that can be taken at any time and place. It is a home medicine for patients with first-time or recurrent stroke. It is a time-saving drug that can be taken at any time and place. It is a sequential therapy drug that can be taken at any time and place. It is a make-up drug that can be taken at any time and place.

Phase	Indication	Research Institution
Phase I	Stroke	Phase I
Phase II	Stroke	Phase II
Phase III	Stroke	Phase III

Sanbexin Sublingual Tablet is a new type of stroke treatment and recovery drug. It is a sublingual tablet that can be taken at any time and place. It is a home medicine for patients with first-time or recurrent stroke. It is a time-saving drug that can be taken at any time and place. It is a sequential therapy drug that can be taken at any time and place. It is a make-up drug that can be taken at any time and place.

Sanbexin Sublingual Tablet

Phase III clinical study in the treatment of acute ischemic stroke

Primary endpoint: proportion of participants with mRS≤1 on day 90 of treatment

Sanbexin Sublingual tablet

Randomized
1:1
double-blinded
parallel control

placing a tablet under the tongue to obtain the sublingual administration, every 12 ± 1 h, for 14 days (28 times) in a consecutive manner

Placebo Sublingual tablet

Whole course management of stroke (N=914)

- June 28, 2021, the first case of the subject's delivery
- December 31, 2021, achieving the enrollment of 519 subjects, exceeding expectations
- March 12, 2022, 783 subjects were enrolled
- Interim analysis expected in 2022H1 and complete recruitment of all subjects, lock

Phase I clinical trial in China

Phase I clinical trial in China



- IND approval: April 2021
- FIH: December 2021
- Phase I completion: Q3 2022

“Schering and Bristol-Myers Squibb are pleased to announce the completion of the Phase I clinical trial in China.”

Stroke Pipeline Layout



Early/Long term intervention based on a combination of multiple mechanisms

01 Reduce neuroinflammation

02 Reduce BBB permeability

03 Prevent cerebral edema

04 Improve neuronal survival

Ischemic stroke

Hemorrhagic stroke

Cerebral edema

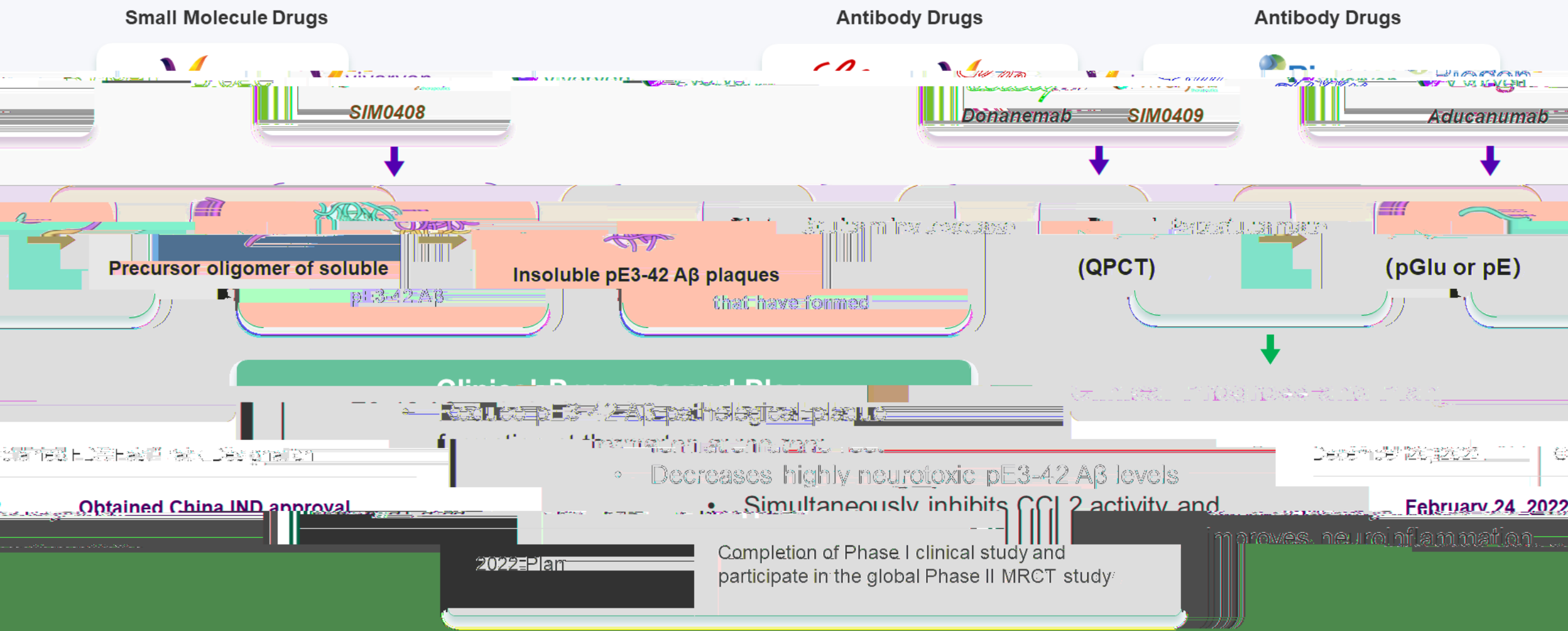
Sanbexin®
Sanbexin® Sublingual Tablet
PSD-95

Sanbexin®

SIM0307 (AQP4)

SIM0408: Targeting A Key Catalytic Enzyme in Neurotoxic A β Aggregate Formation

QPCT oral small molecule inhibitor



Decreases highly neurotoxic pE3-42 A β levels

Simultaneously inhibits γ 2 activity and

improves neuroinflammation

Completion of Phase I clinical study and participate in the global Phase II MRCT study

Key Project Introduction

Autoimmune

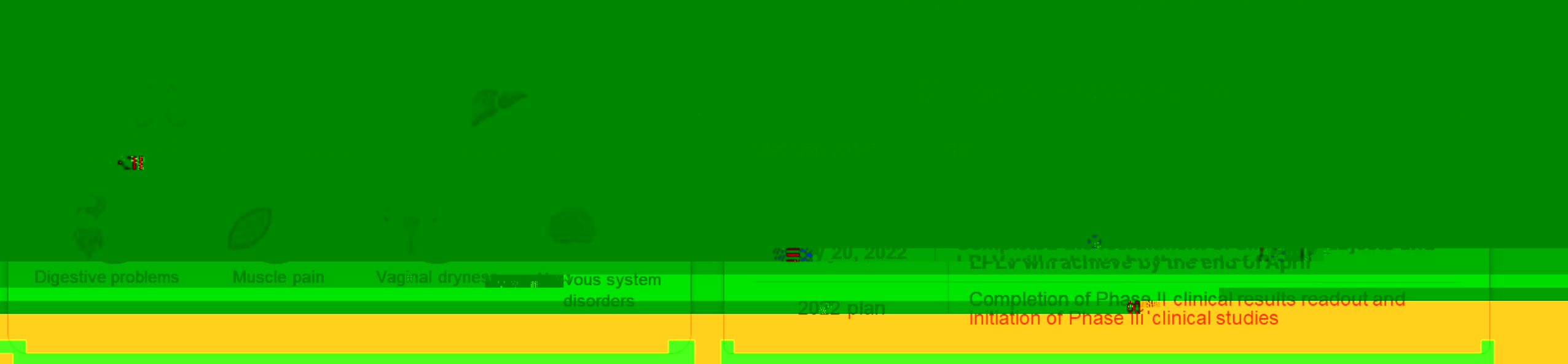
Iremod® New Indication: Sjogren's Syndrome

The efficacy and safety for RA have been verified for over 10 years

score, hypertriglyceridemia and ESR of the patients were significantly lower than those at baseline:



Iremed® New India: From Shingles to Shingles



LNK01001: Selective Jak1 Inhibitor

March 18, 2022, Simcere entered into a collaboration agreement with Lynk Pharmaceuticals to obtain the exclusive commercialization interest of LNK01001 for rheumatoid arthritis (RA) and Ankylosing spondylitis (AS) indications in China. Lynk Pharmaceuticals will be responsible for the clinical development of LNK01001.



Subjects and tolerability

TEAE above >2 or higher during the trial;
TEAE;
Death-causing TEAE;
TEAE leading to discontinuation;

No dose-related incidence of adverse events;
Metabolism and elimination of LNK01001;
Significantly with fasting or eating;
Relationship (pS1A1 Inhibition assay)

Phase 1 PK and PD summary:

SAD: PK increase proportionally in the range of 5 mg to 84 mg along with the dose. Exposure in vivo to LNK01001 AUC and Cmax are linearly kinetic.

MAD: AUCs with multiple administrations on D1 & D7: basically consistent; basically, no accumulation in the body

FE: AUC shows no significant change with fasting or eating state; postbrandi administration has no significant effect on the metabolism and elimination of half life period(11/2). Not change significantly
PD: good Pharmacokinetic and Pharmacodynamic relationship

Milestones Expected in 2022

SIM0417(3CI)

Orally Administered SSD8432 COVID-19
Treatment, phase I & phase II/III
Phase I, CSR
Phase II/III, FPI

SIM0408(QPCT)

Sanbexin®(Reperfusion)

Combined with reperfusion for AIS
treatment, phase IV
Achieve the enrollment goal

SIM0307 (AQP4)

Acute severe ischemic stroke
complicated with cerebral edema,
phase I CSR

Iremod® (Sjogren's syndrome)

Result summary of phase II: Regulatory communication
before phase III

Sanbexin®(Cerebral hemorrhage)

Hemorrhagic stroke as a newly added indication of
Sanbexin® phase II

Varicellulometal AD phase II in Europe
(international multicenter)
FPI

Sanbexin Sublingual Tablet

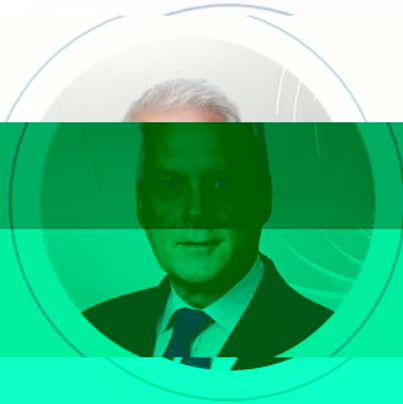
Y-2 for AIS treatment, phase III
IPIV, DRI

SIM0335

CKBA for treatment of mild to moderate
psoriasis, phase II
FPI, LPI

SIM0278

IL-2 for treatment of systemic lupus
Erythematosus
FDA IND



Strengthening BD, M&A and Investments within a Global Strategy

Kevin Oliver , PhD

SVP, Global Head of BD&L

Sincere's RD/M&A Team has high credibility, is diverse and has a deep reputation in the industry

50+

2018, 2019, 2020

30

20

10+ years of successful experience in strategic acquisitions integrated collective experience

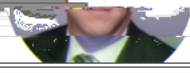
10+ years of successful experience in strategic acquisitions integrated collective experience
Professional (ASAIP) Excellence Awards

TRANSACTIONS



Caohe Zhou
CIO, Head of H&M AP

McKinsey
& Company



Michael Bayewitch
ED, US AP Transactions

teva



Kevin Oliver
SVP, Global Head of H&M

MERCK

Novartis

Alcon



Yuchua Gong
ED, Head of H&M, EU

Esai

POLYHERICS



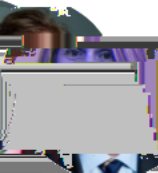
Yves McMullen
Head of US Transactions and
Global Invest

Shin

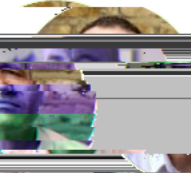
S&E

LEGAL

AM



Mark Coflin
VP Global Alliance Management



Catherine Abbadie
Global Head of CNS S&E



Matthias Höss
Global Head of Autoimmune

Novartis

Novartis



Markus Decker
Global Head, Oncology S&E

Novartis

Novartis



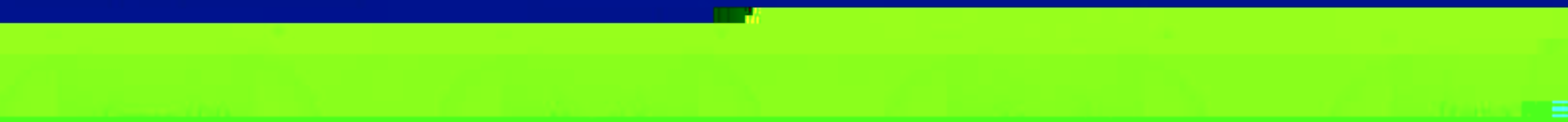
Ian Liu
Head of Legal & Gov't Affairs

FOSUN 复星

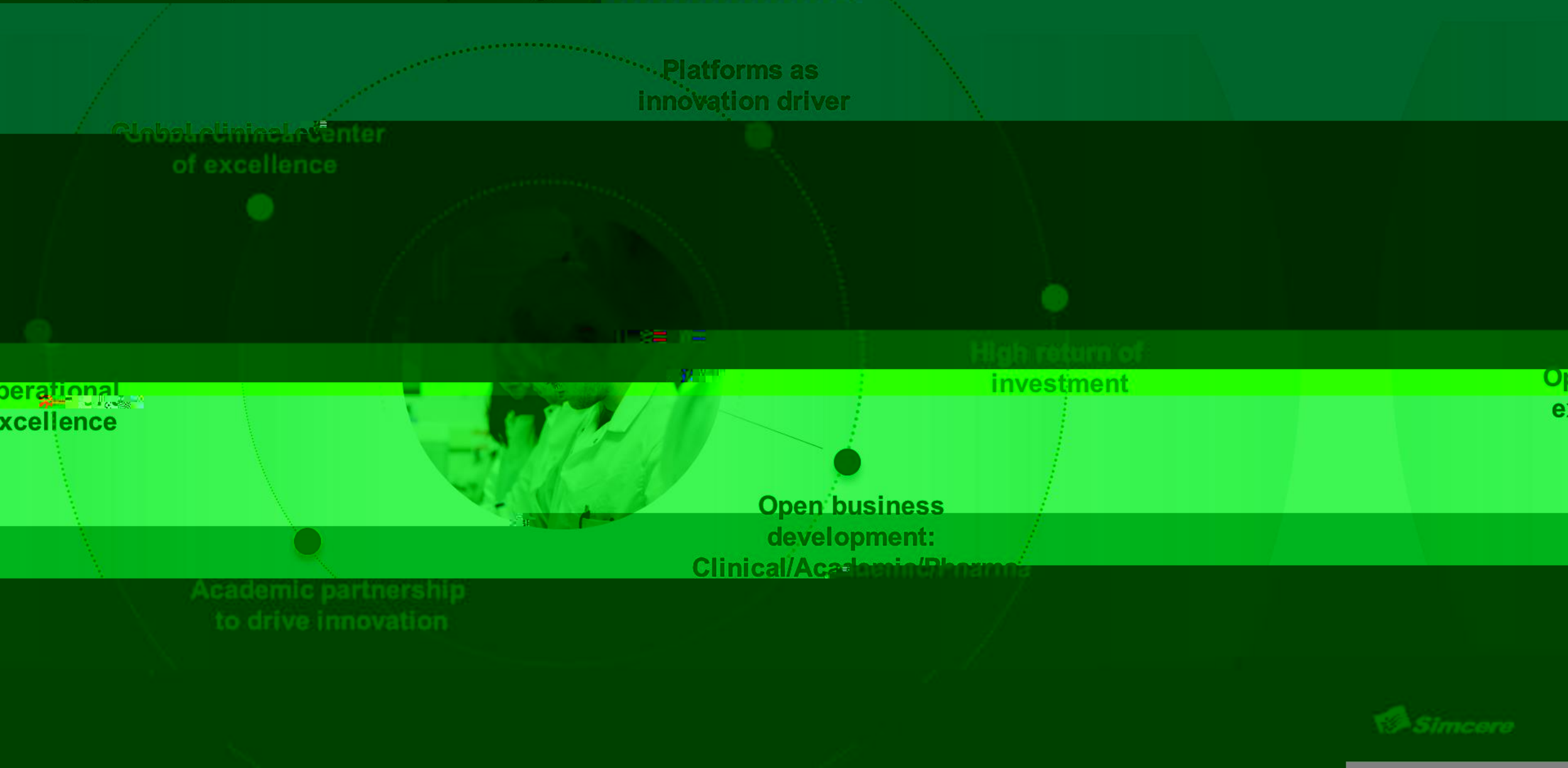
BREAS

S

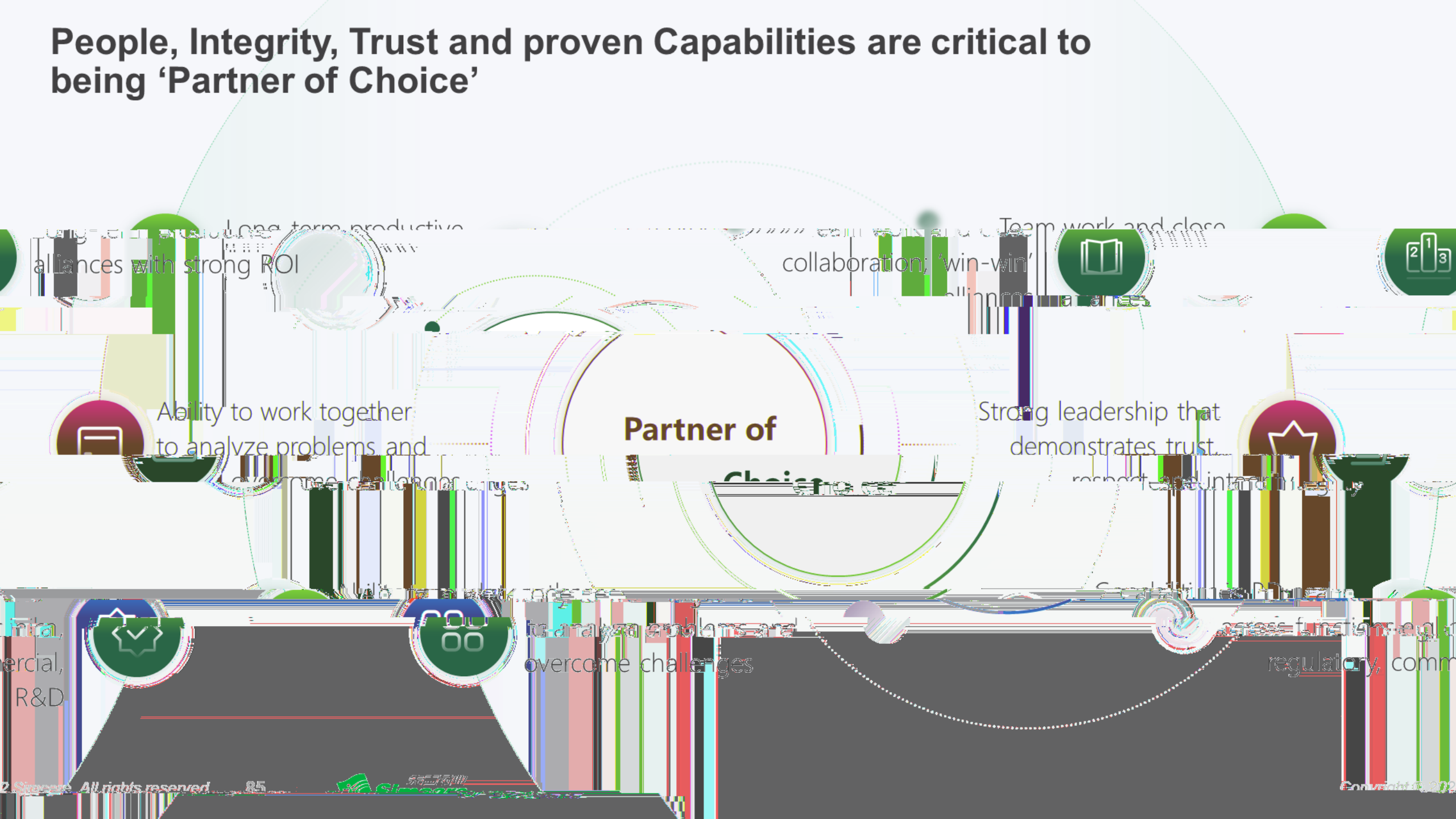
BD is geographically established to become ‘Partner of Choice’



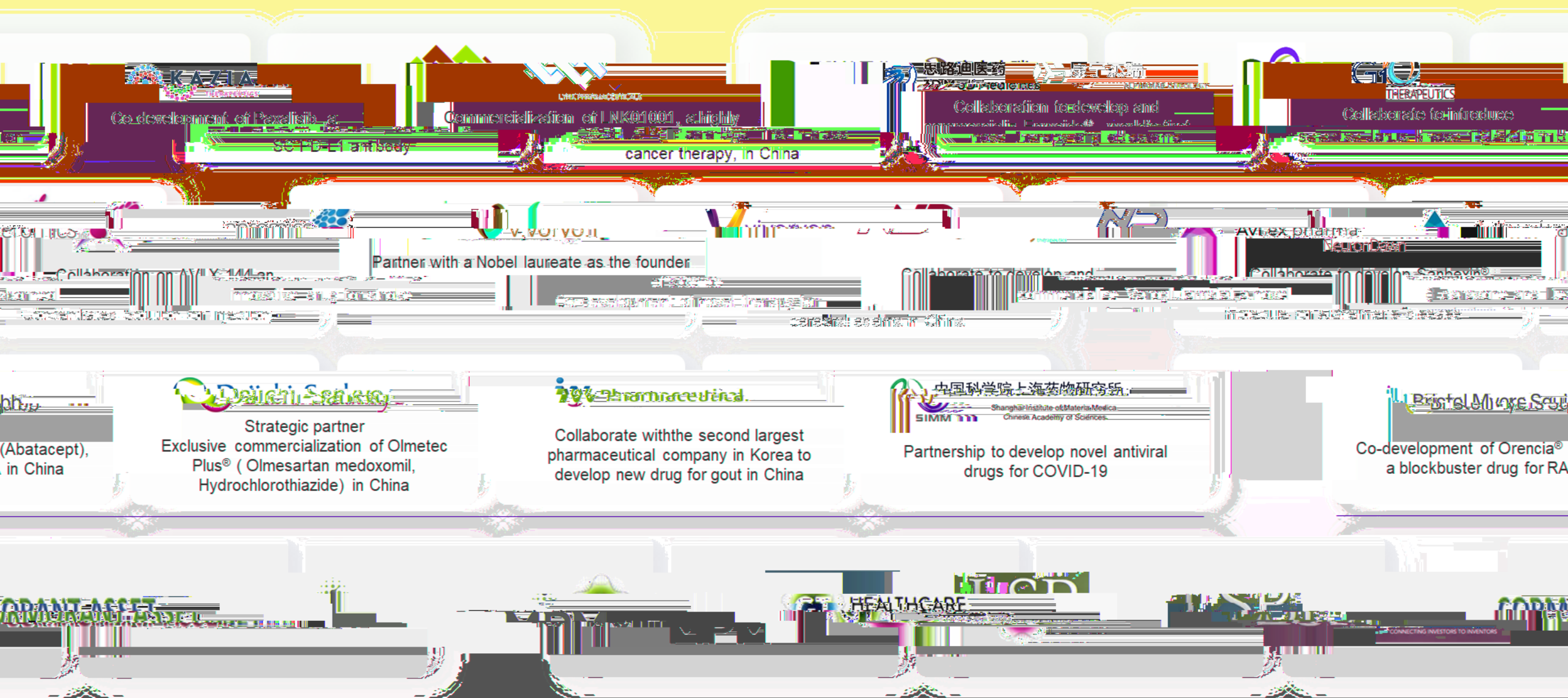
Global operations, centered in Boston, will focus on six key, global operational strategies



People, Integrity, Trust and proven Capabilities are critical to being 'Partner of Choice'



Simcere values its existing 35+ alliances and LP positions



Strategically driven R&D: In-licensing interests in Oncology

Small molecule and biologics

Focus on high unmet need indications that are TOP10 prevalent tumor types in China

Innovative modalities

High-throughput structure-based drug (Challenging Targets)

Novel drug targets

(preferred)

Earlier stage assets

Novel drug classes/modalities (RNA therapeutics, Tetra-

First-in-class

Novel ex-vivo functional screening platforms (types of SL interactions)

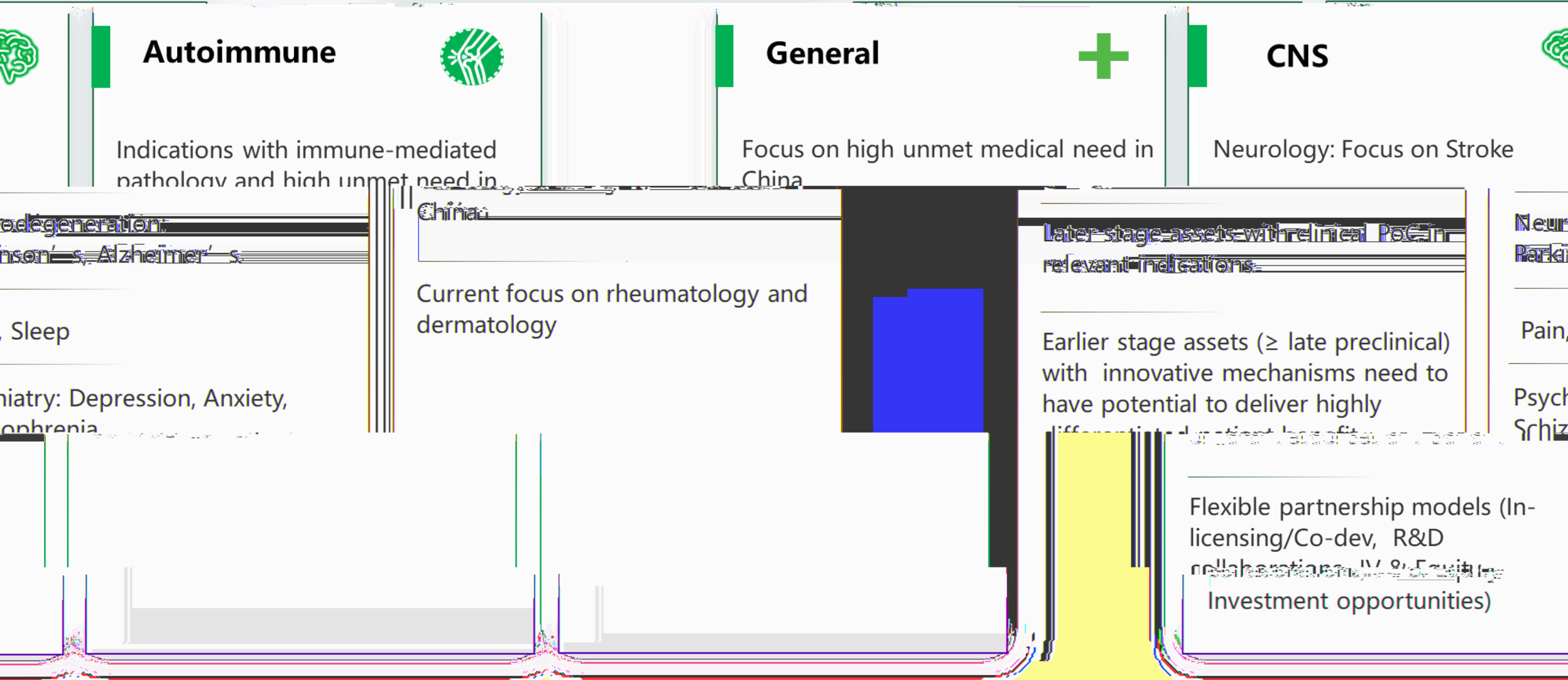
Novel platform capability partnering with academia –

relationships that lead to global licensing rights and an engine to feed the pipeline

Late / commercial stage M&A

Flexible partnership models (I collaborations, JV & Equity In

Strategically-driven BD: In-licensing interests in CNS and Autoimmune



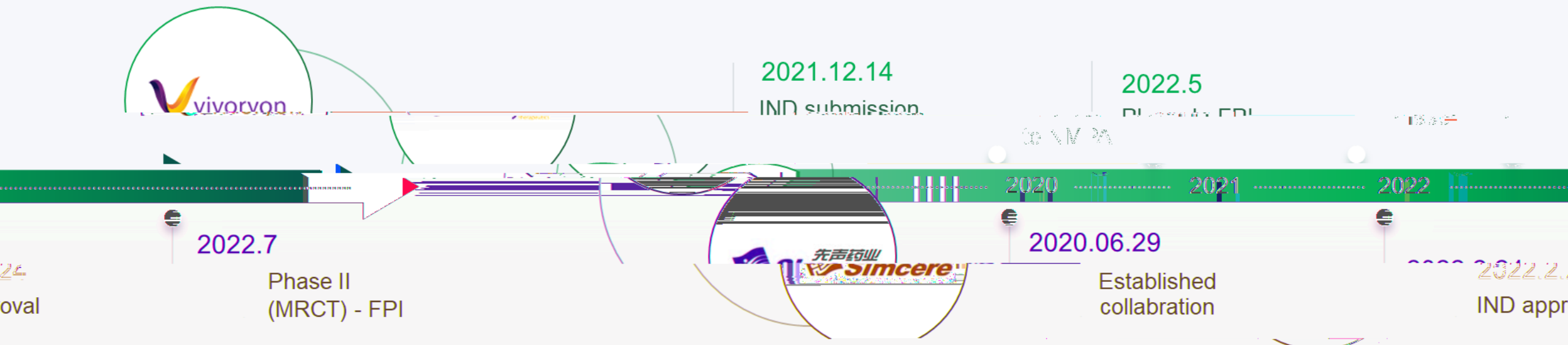
Exclusive License Agreement for Trilaciclib in Greater China

2020.11.18(SCLC)

IND for leading
indication

2021.11.29
(SCLC)

Exclusive License Agreement for small molecule, PQ912, and biologic in Greater China

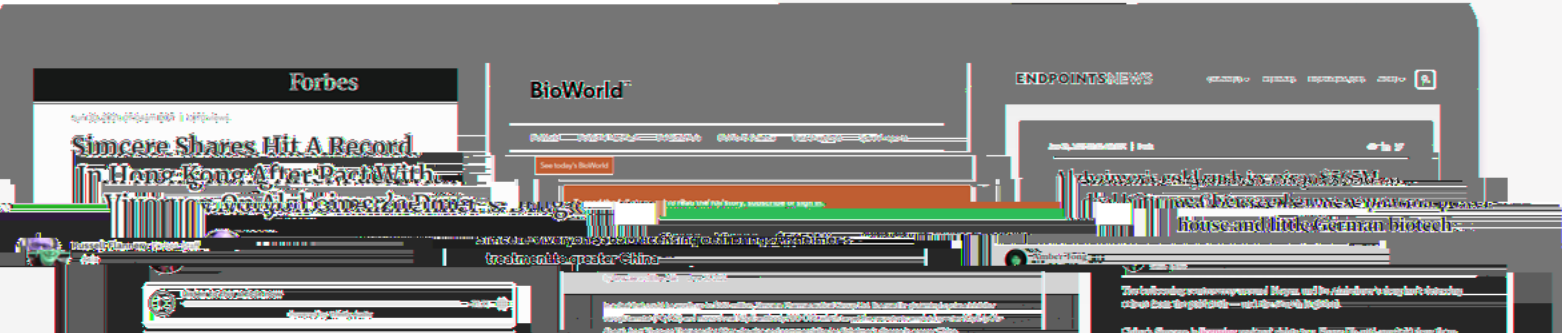


3pE Amyloid-Targeting Medicines to Treat
s Disease.

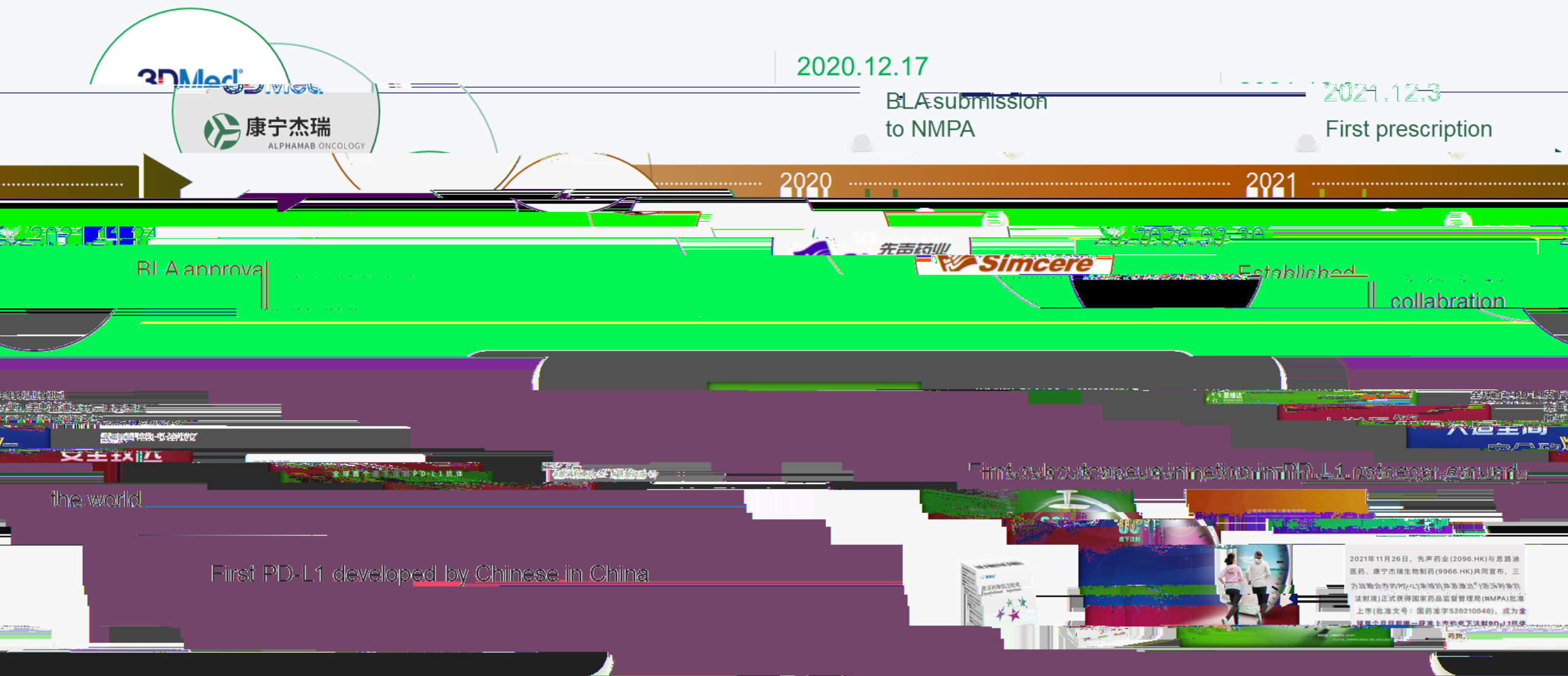
acy among available clinical opportunities

Phase 2 N3
Alzheimer's

Rest effi
patient



3DMed Alphamab Exclusive License Agreement for Envafolimab in Mainland China



Simcere as Partner of Choice in China... with global ambitions



ATTENDEES

HOST:





SINCERE PHARMACEUTICAL GROUP LIMITED

2022 R&D DAY

STOCK CODE: 2096.HK

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