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Simcere

SIMCERE PHARMACEUTICAL GROUP LIMITED

2022 R&D DAY

STOCK CODE: 2096.HK

DISCLAIMER

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information only. It should be understood th
representatives shall not be obligated to
regarding the securities of the Co
The information contained in th
these presentation mat
affiliates, directors, su
be accurate

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

Tang Kennong, PhD
EVP

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 Global Strategy

[illegible] Oliver, PhD
SVP, Global Head of BD&L

07 Q&A - ALL

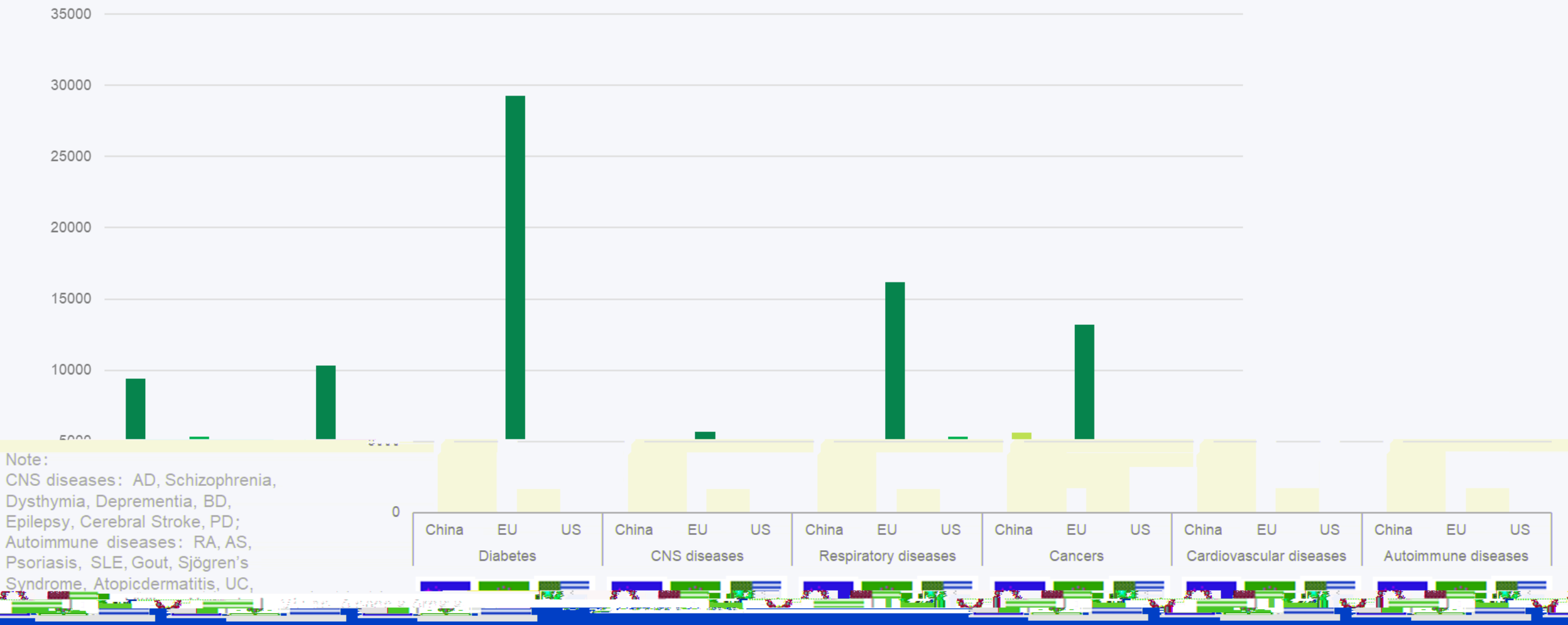
HOST : Jason Bao
Secretary of the Board

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)



Note:
CNS diseases: AD, Schizophrenia, Dysthymia, Deprementia, BD, Epilepsy, Cerebral Stroke, PD;
Autoimmune diseases: RA, AS, Psoriasis, SLE, Gout, Sjögren's Syndrome, Atopicdermatitis, UC,

Source: analysis of World Bank and Silicon Valley Bank, data of GD and CCI

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Biopharma innovation flourishing in China while bottlenecks also emerging —— industry entering innovation 2.0 era

and crowding limit quality of

Biopharma innovation driven by growth patient needs,

Intense competition

Clinical research programs sponsored by domestic biotech and pharmacos in China

644

57

97

298

50

201

34

20

262

2019

2020

2021

MNC biotechs

MNC pharmacos

Number of IND applications in China

64%

134

77

44

72

65

2018

Domestic biotechs

Domestic pharmacos

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

rmaceutical company

phar

half of total revenue

arketing

• ENWEIDA ® approved for m

2016-2020

Innovation Center

• Sanbexin® approved for marketing

• Listed on the Hong Kong Stock Exchange

• Iremod® 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 Simcere's revenue

Share of innovative products in total revenue

32.9%

45.1%

62.4%

ke drug globally since 2015

first year of launch

major contributor to CNS portfolio

Sanbexin®

The only newly approved stro

Entered 2,400 hospitals in

100+% growth annually, m

afolimab)

eous PD-L1

2021.11.25

Approved

2,000 patients treated

COSELA (Trilaciclib)

First-in-class comprehensive myelo-protective therapy

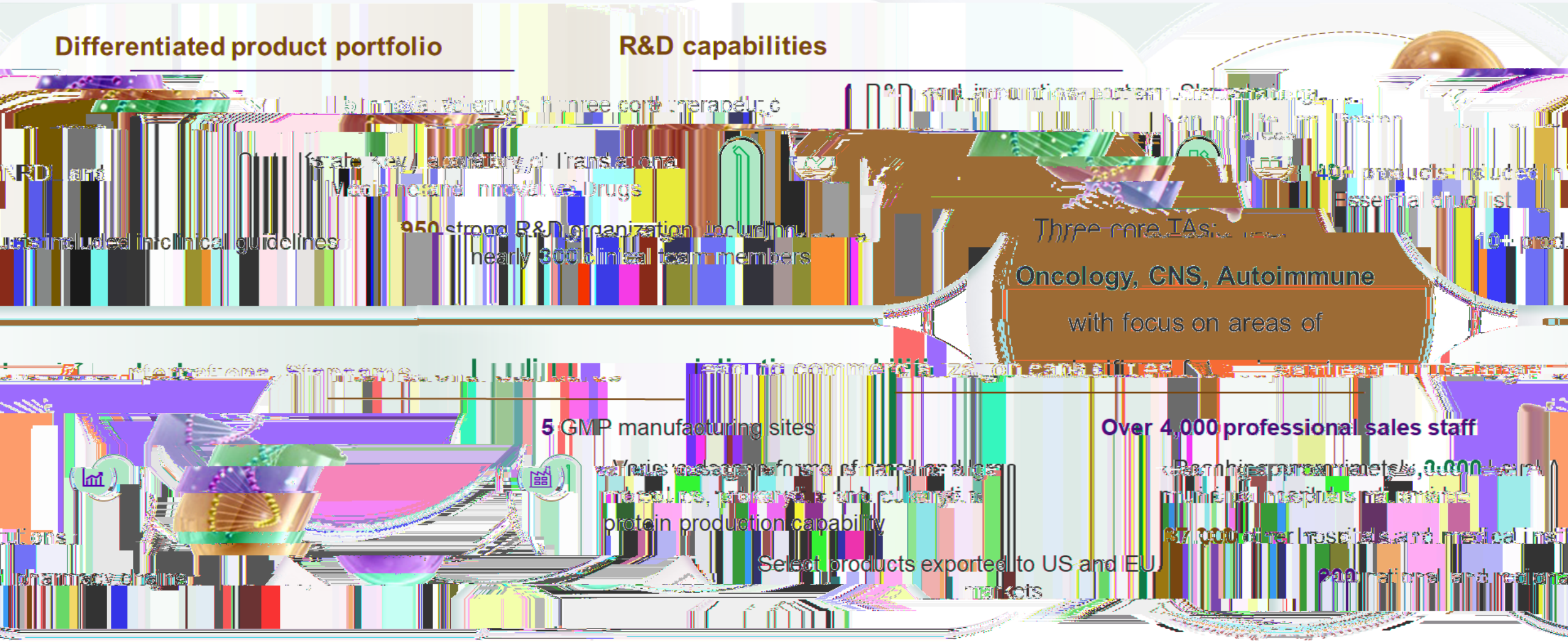
2021.11.29

NDA priority review by NMPA

ENWEIDA (Enva

Global first subcutane

Full value chain capabilities enable Simcere's innovation aspiration



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Accelerating towards innovation through in-house R&D and partner collaboration

Local innovation capabilities

Innovation Center Boston

- Global clinical Development
- BD Development
- New opportunity with breakthrough potentials

Innovation Center Shanghai

Oncology & Immunology,
Pre-/clinical capability

Innovation Center Beijing

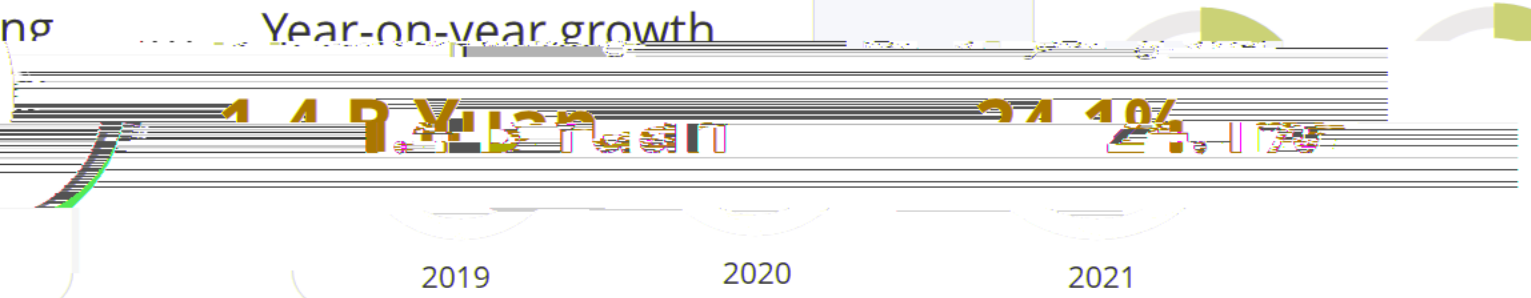
Neuroscience & Transl Sci
Clinical Dev, Registration, IP

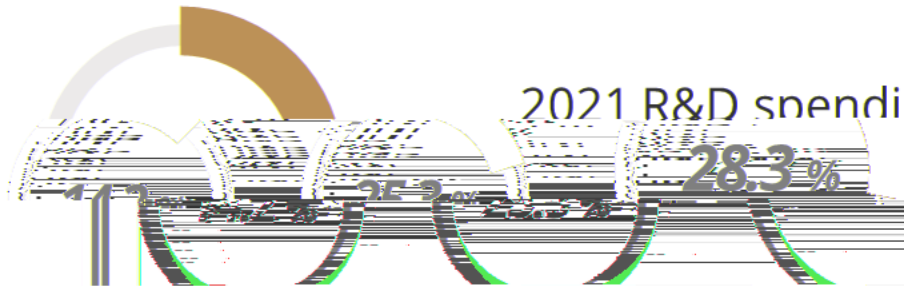
Track record as partner of choice

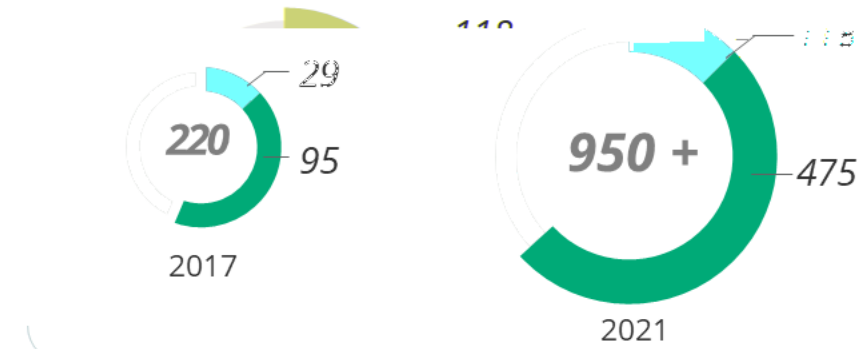
Bristol Myers Squibb · G1 Therapeutics · GT Innovation · JW Pharmaceutical · aeromics · Primary Peptides · Apexigen · HighTide Bio

National Key Lab Nanjing

Sustained R&D investment for future growth







> 60 %

950 +

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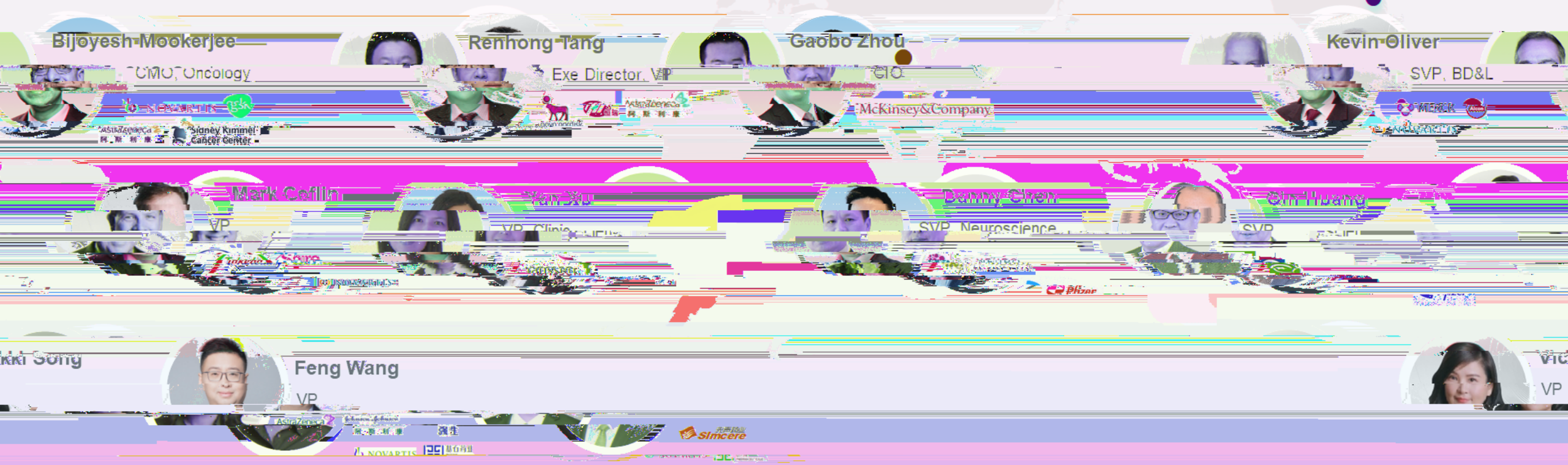
Seasoned Leadership with Global Vision



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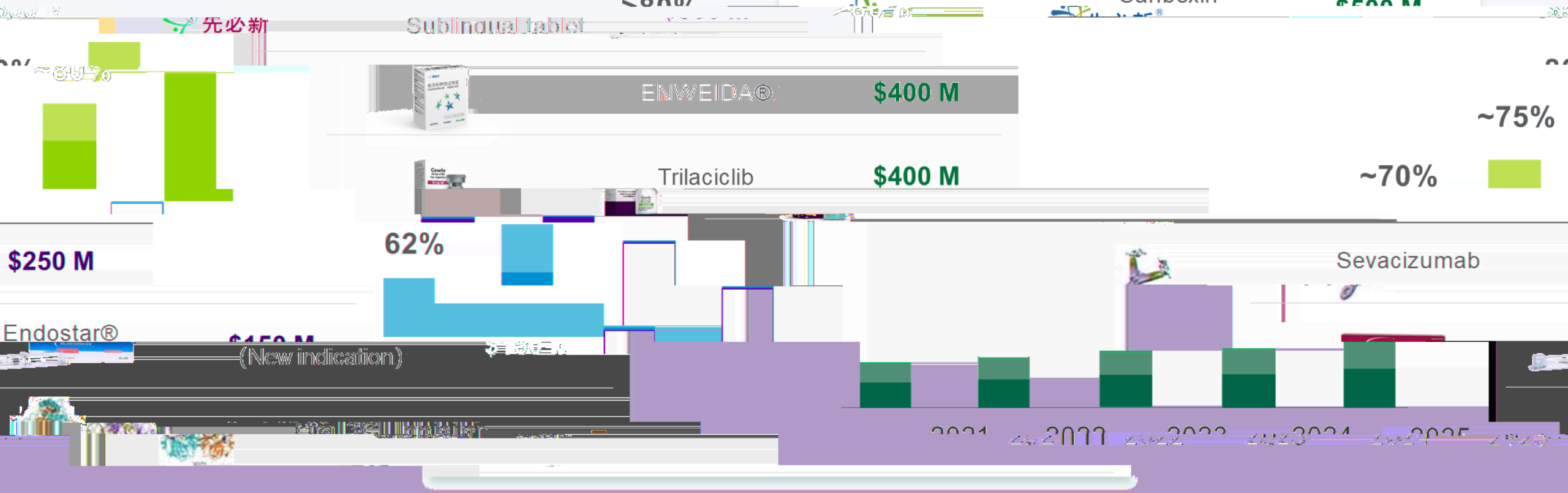
Sustained high quality growth driven by key innovative products

Projected share of innovative products in total revenue



Peak sales (USD)

Sanbexin®	$800 M
Sanbexin	
Sublingual tablet	
ENWEIDA®	$400 M
Trilaciclib	$400 M
$250 M	
Sevacizumab	
Endostar®	
(New indication)	

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Key developments expected in 2022

Joining the fight against COVID-19

Oral 3CL inhibitor

Rapid clinical advancement in China and abroad

New Product Launch

Trilaciclib (ES-SCLC)

First-in-class new drug expect to be launched in China in 2022

Expansion of key product

Sanbexin sublingual tablet

China phase III clinical trial to be completed in H1 2022

Sanbexin®, ENWEIDA®

Innovative drugs sales continue to ramp up rapidly

Highlights

ention.

chemotherapy, the product has the potential of gaining huge market share and att

rapid clinical development of Sanbaxin

achieved annual sales of RMB 1.5 billion in its first year. The

full-course therapeutic approach.

a multi-mechanism

in early April.

cts in clinical stage,

Innovation Simcere has formed **a new drug R&D pipeline of nearly 60 projects**, with 20 proje involving 17 potential innovative drugs.

pool etc.

Globalization internationalized organization and talent

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Preclinical Drug R&D

Tang Renhong, PhD
EVP

Preclinical R&D Strategy and Drug Discovery Engines

Patient-Centric Drug Discovery Strategy

- Fulfilling the clinical needs of patients as the core R&D goals
- Developing a diversified portfolio through both internal R&D and external collaboration

- Taking lead in competition with technology competence and execution for high-value projects
- Delivering value to global patients and stakeholders

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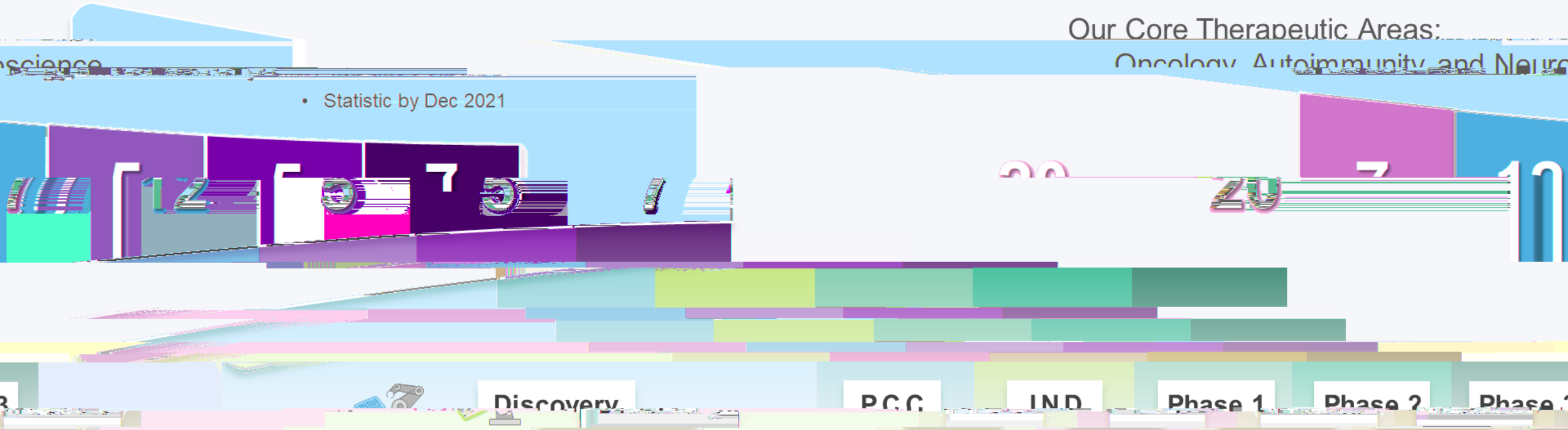
Growing Portfolio with Strong long-term Potential

Our Core Therapeutic Areas:

Oncology, Autoimmunity and Neuro



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

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Proprietary platforms support differentiated drug modalities

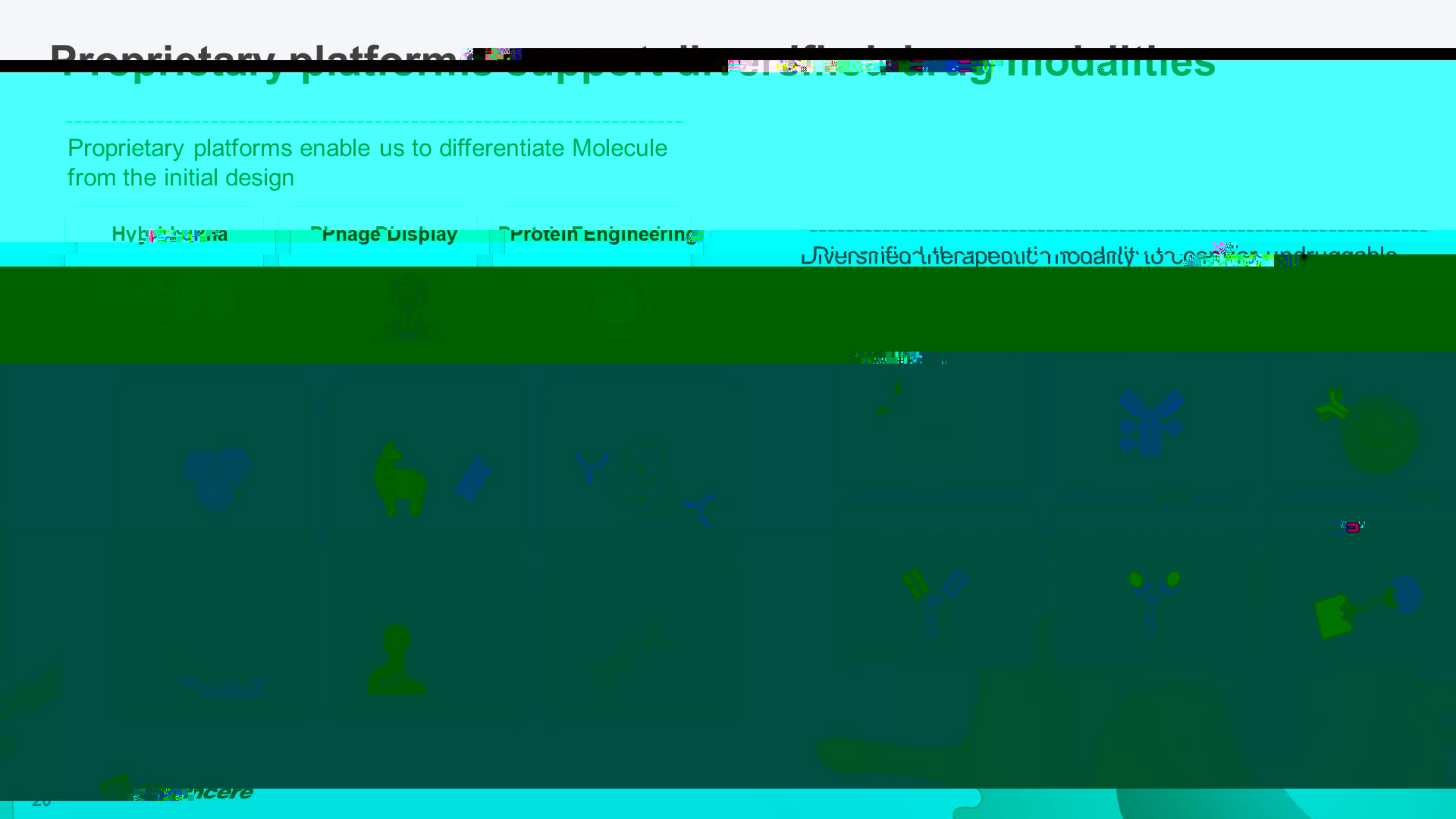
Proprietary platforms enable us to differentiate Molecule from the initial design

Hybridoma

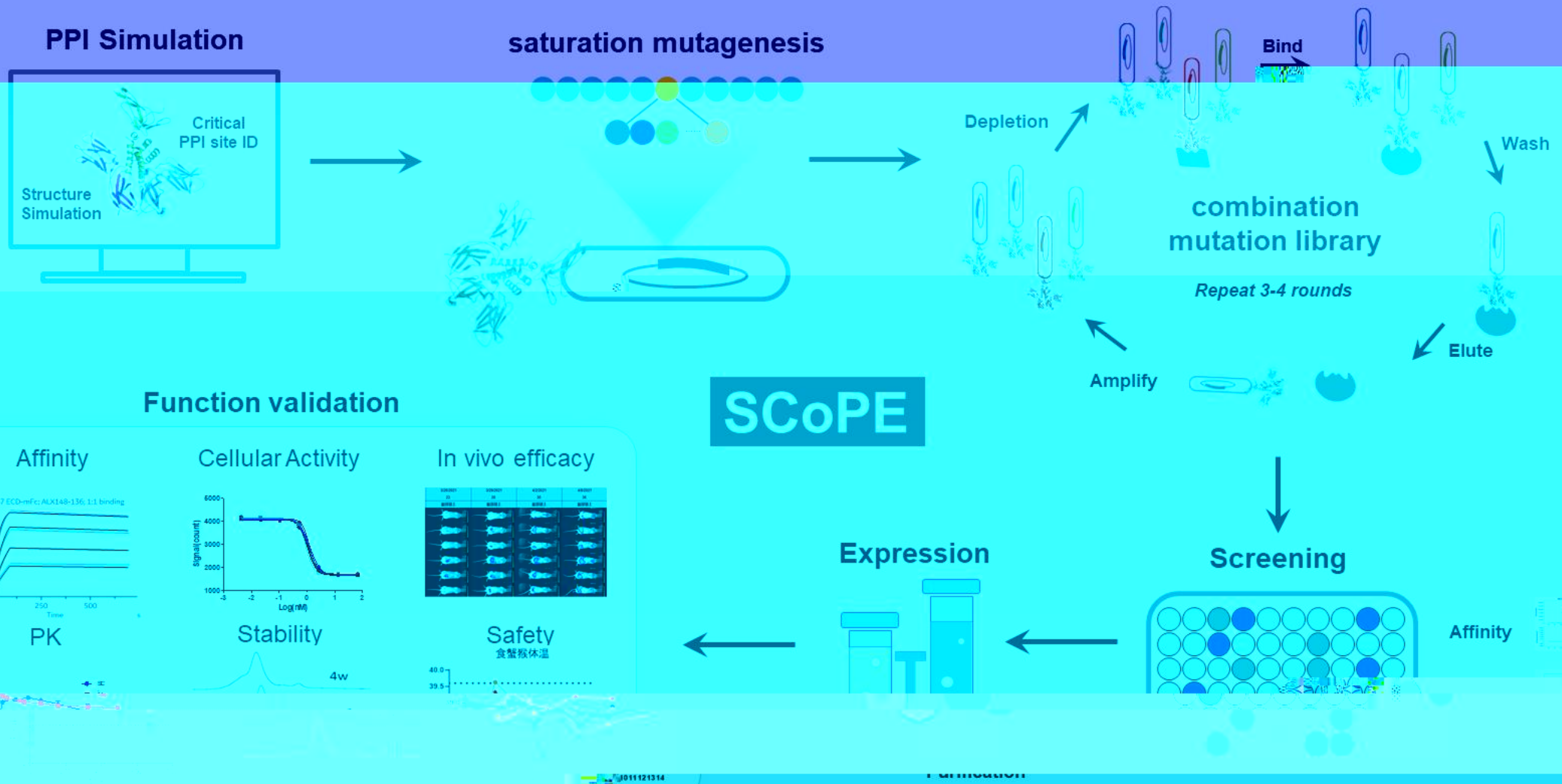
Phage Display

Protein Engineering

Diversified therapeutic modality to consider undruggable



Simcere Creative platform of Protein Engineering



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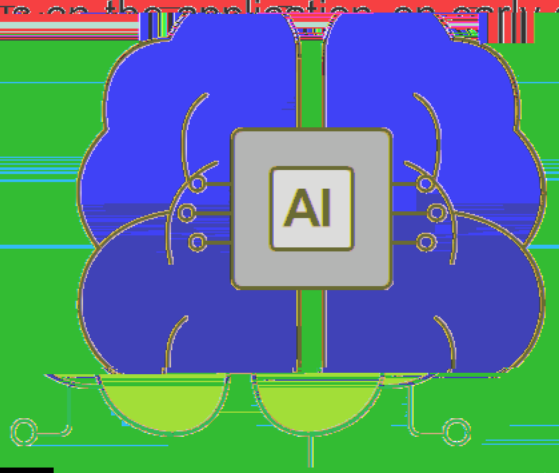
Adopting AI in Drug Discovery

- Focus on the application on early stage drug discovery, such as hit generation and optimization
- Establishing data science infrastructure and capability internally
- Collaborating with external partner for agile development



Internal Capability

Collaboration

Dynamics Simulation

ADMET Prediction

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Project X – Our Path to the Future

exploring and creating

…to attract and unite a group of young talents in life science and focusing on

high treatment needs or

drug discovery

10 directions/technologies with either breakthrough potential

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

Building the true innovative research engine

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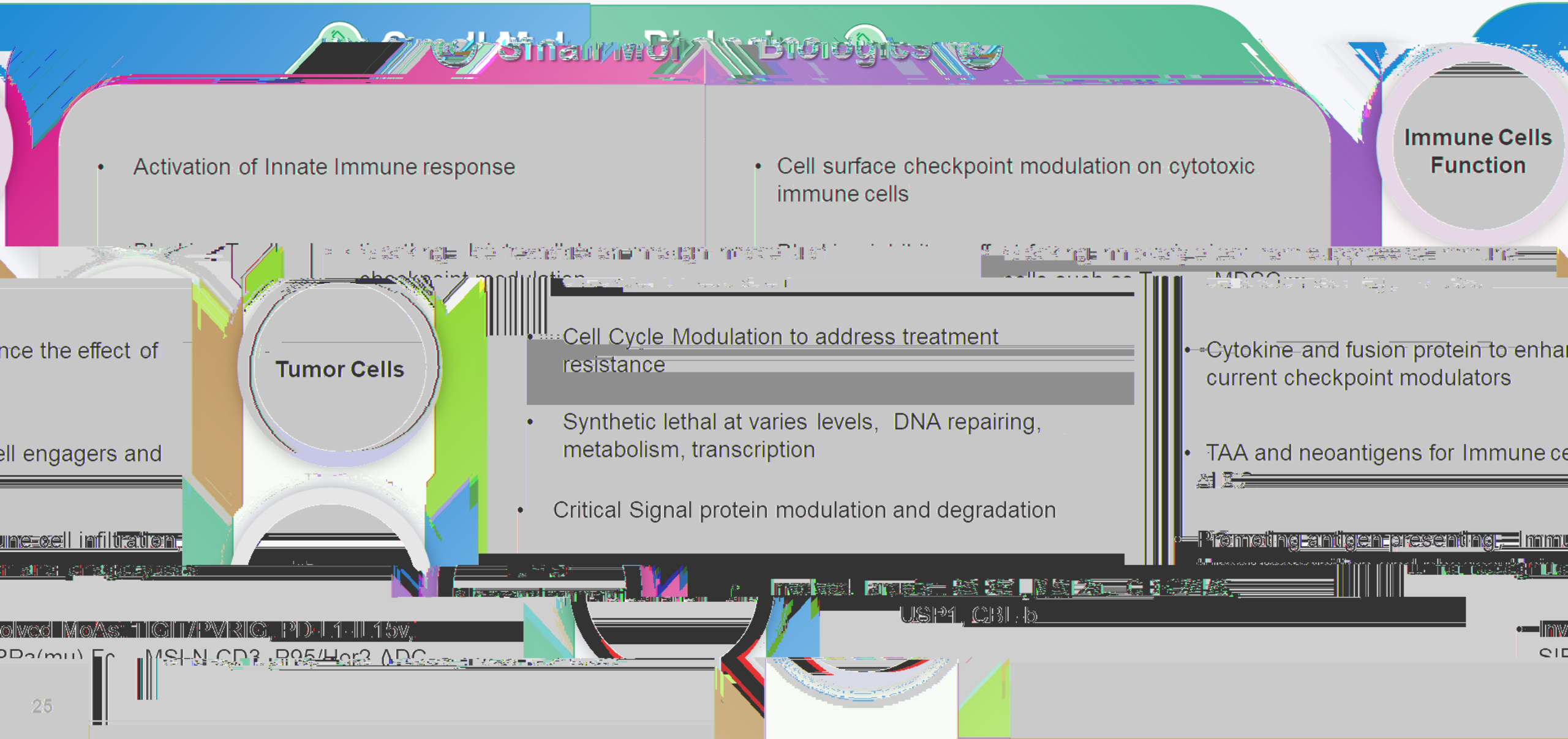
Diseases-Specific Strategies and key Assets

Oncology

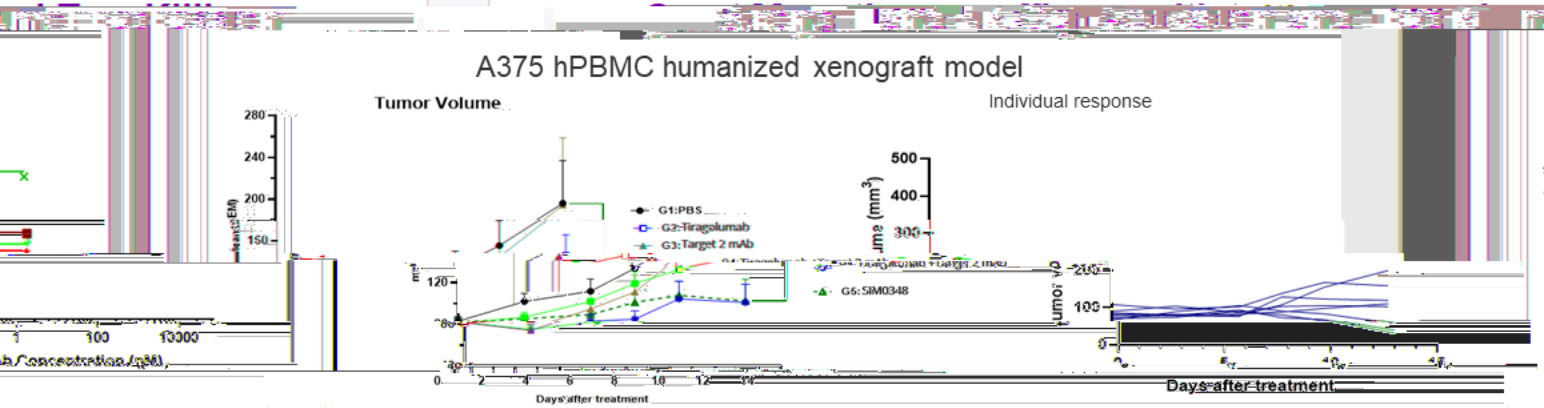
natological malignancy

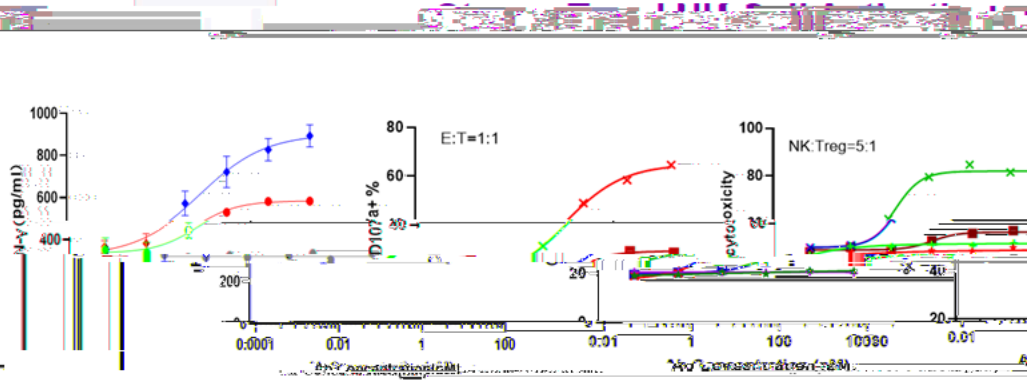
Building Depth on prioritized tumor types: Lung, Breast, GI, Female reproductive, Hem



SIM0348 - TIGIT/PVRIG Bi-specific Antibody

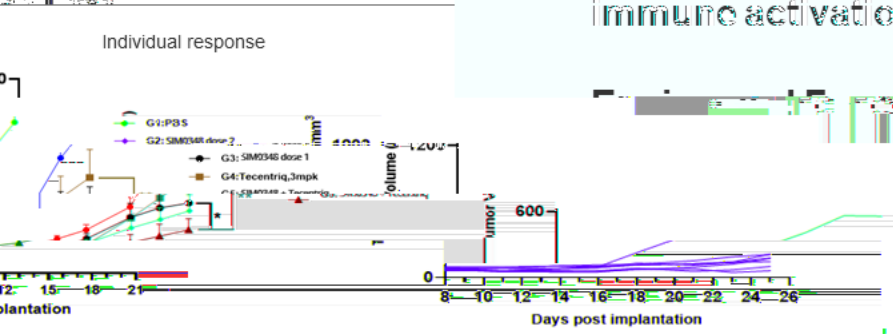
Dual Checkpoint targeting for enhanced T cells stimulation



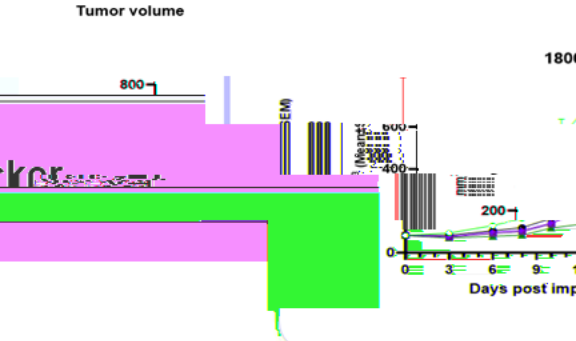


riq

- Simultaneously targeting two checkpoints for improved immuno activation



Significant Synergy Effect With Tecentr



- 60% Tumor growth inhibition achieved in PD-L1 blocker-insensitive model

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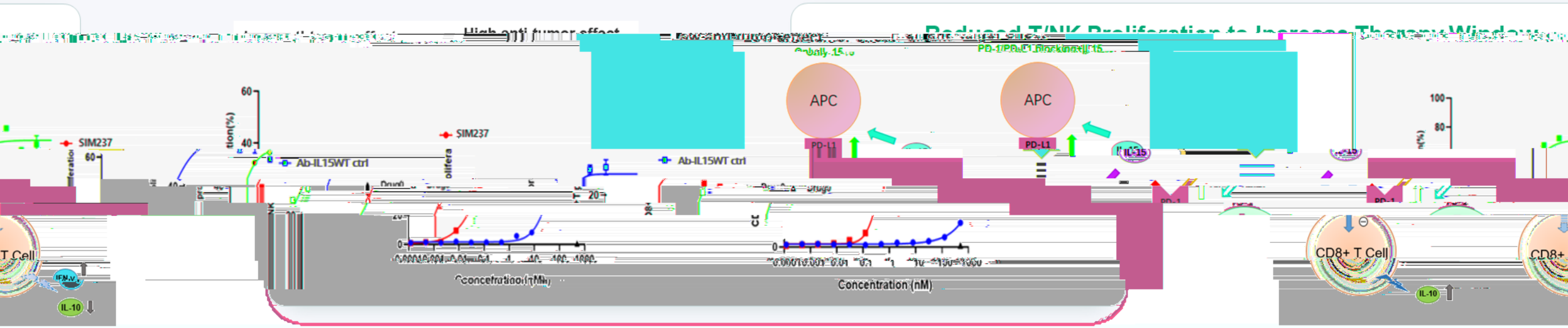
SIM0237: PD-L1/IL15v Bifunctional Fusion Protein

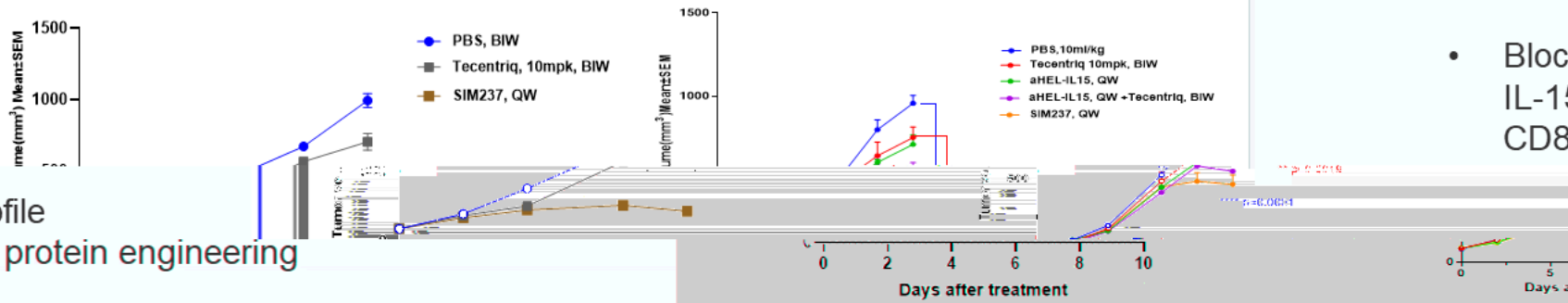
Best-in-Class potential with Improved tumor control and low safety risk



aling and deliver
ully activation of

tune IL-15 pharmacological profile
through protein engineering

Significant Tumor Growth Inhibition



Rationale:

- Blocking PD-1/PD-L1 sign
  IL-15 directly to TME for fu
  CD8 T cells
- Fine

model

NCI-H292-hPBMC xenograft

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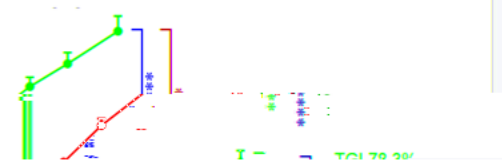
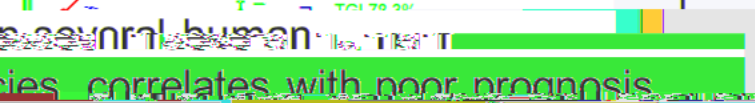
SIM0317: First-in-Class RAD51 inhibitor

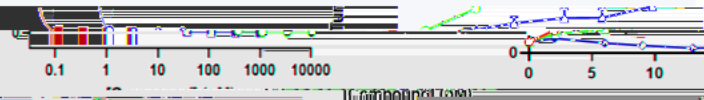
Significant advantages on efficacy, safety , developability compared to current leading competitor

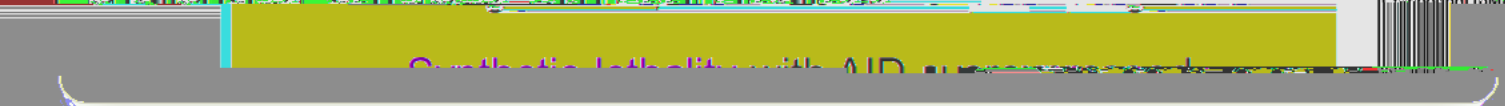
o Efficacy



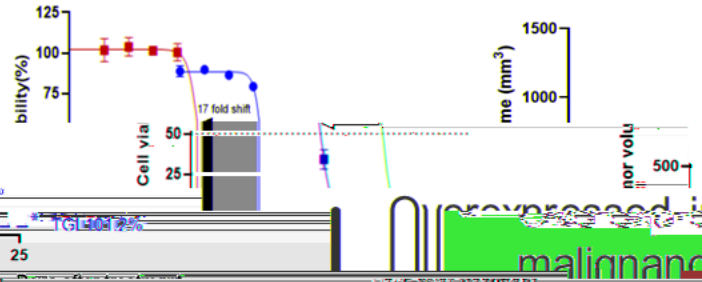
- RAD51 plays a central role in the homologous recombination pathway







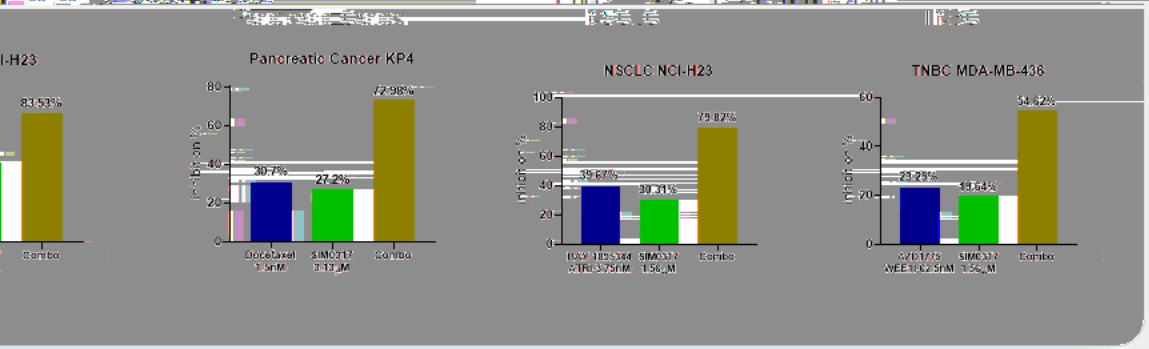
Superior In Vitro Activity And In Vivo

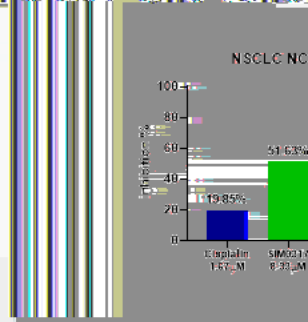


tumors

- Multiple combination potential with chemotherapy and other DDR pathway targeting therapeutics

Broad combination opportunities for multiple tumor types





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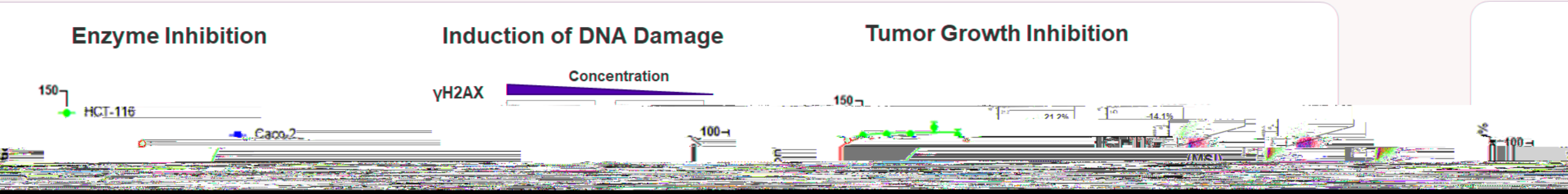
ays a pivot role in mismatch repair (MMR) with synthetic lethal potential to microsatellite instability (MSI)

o publicly disclosed inhibitor yet

ul identification of Hit compound through virtual lib screening supported by machine learning algorithm

- Target pla
- Current n
- Successfu



Autoimmunity

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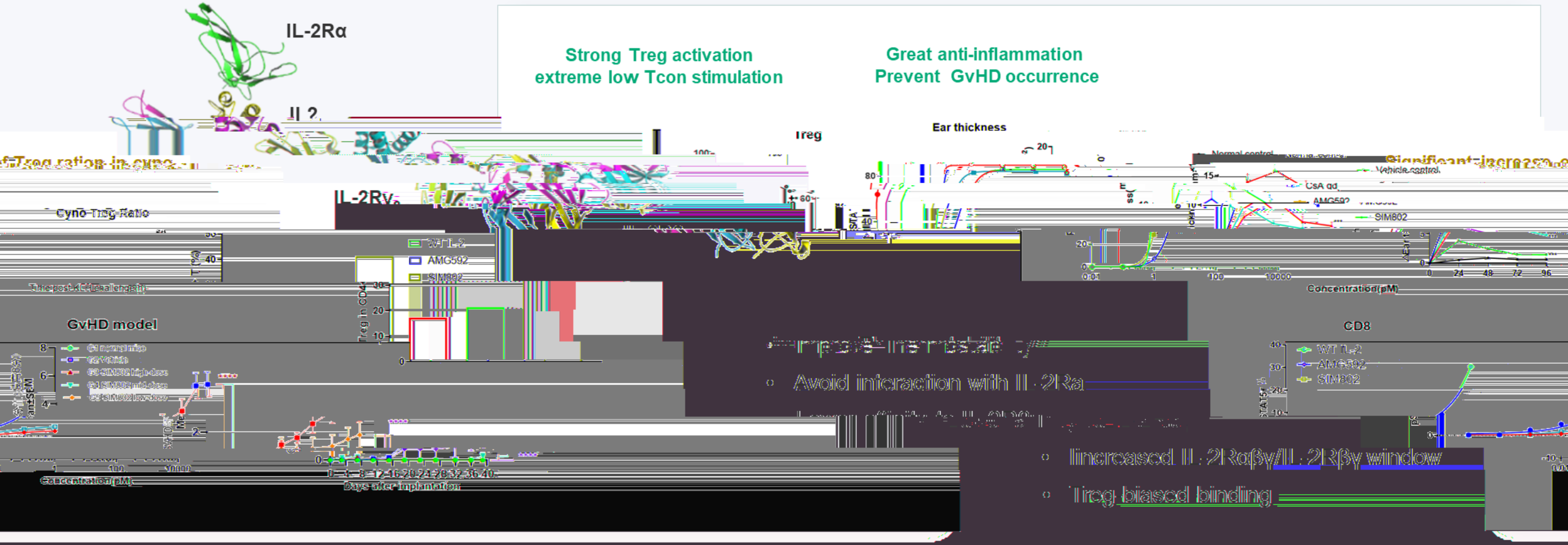
SIM0278：IL-2 mutein specifically Promote Treg Function

Differentiation through protein engineering



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Ab-Steroid conjugate for Th2 suppression

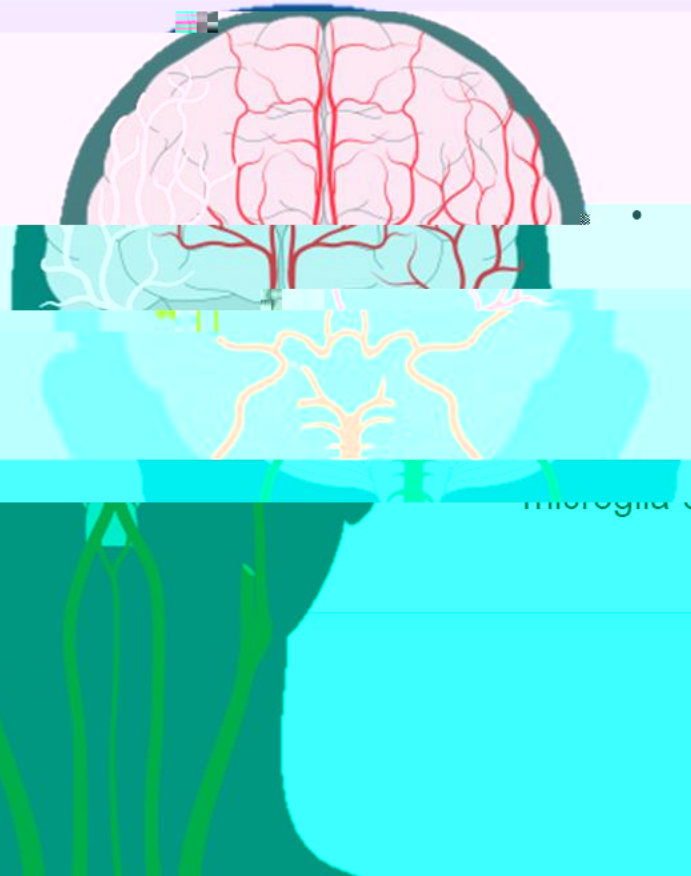
Significant decrease of IgE production and inflammatory cell infiltration bring great histological improvement

Neuroscience

Strengthening our core competence in stroke, expand to neurodegenerative Diseases

Stroke

- Whole disease course management
- co-morbidities control through new



Neurodegenerative Diseases

- Combination of multiple mechanisms for early intervention

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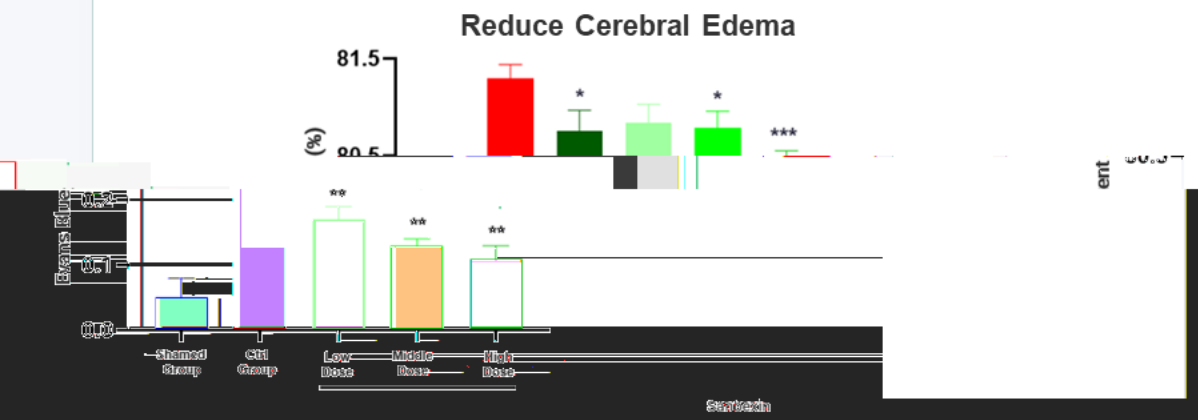
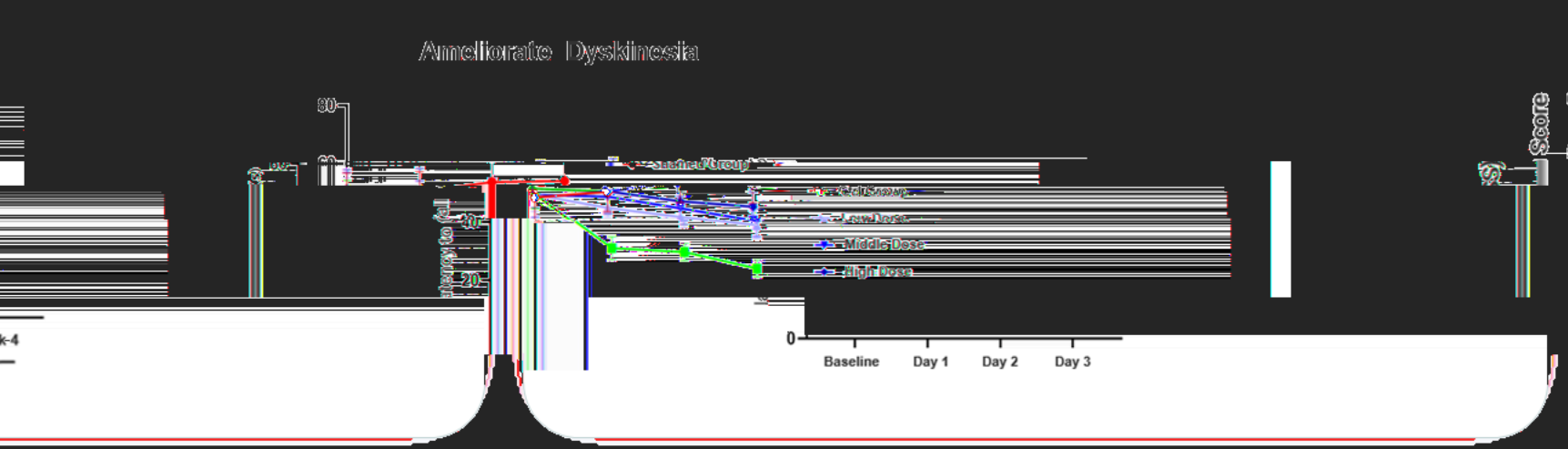
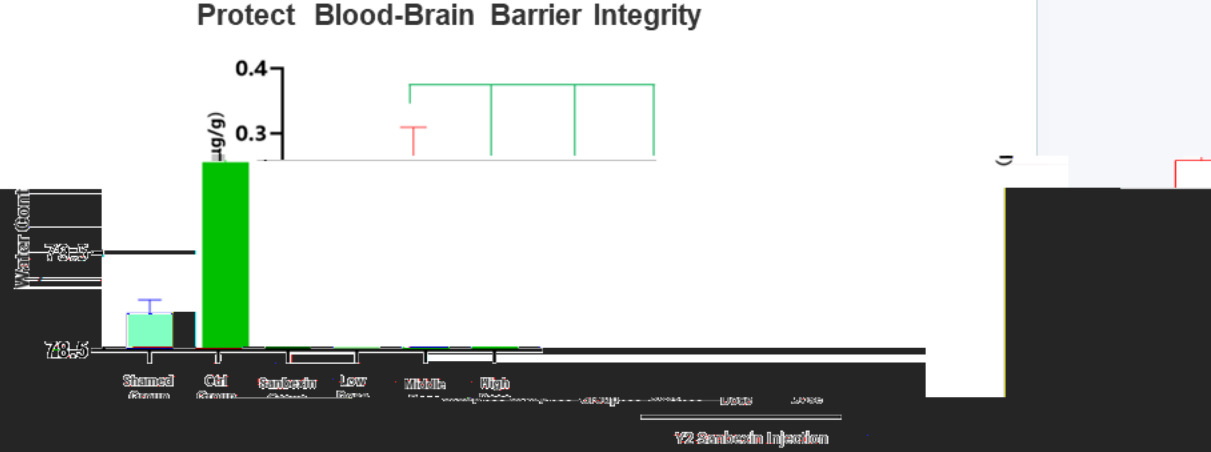
Expand Sanbexin® to Hemorrhagic Stroke

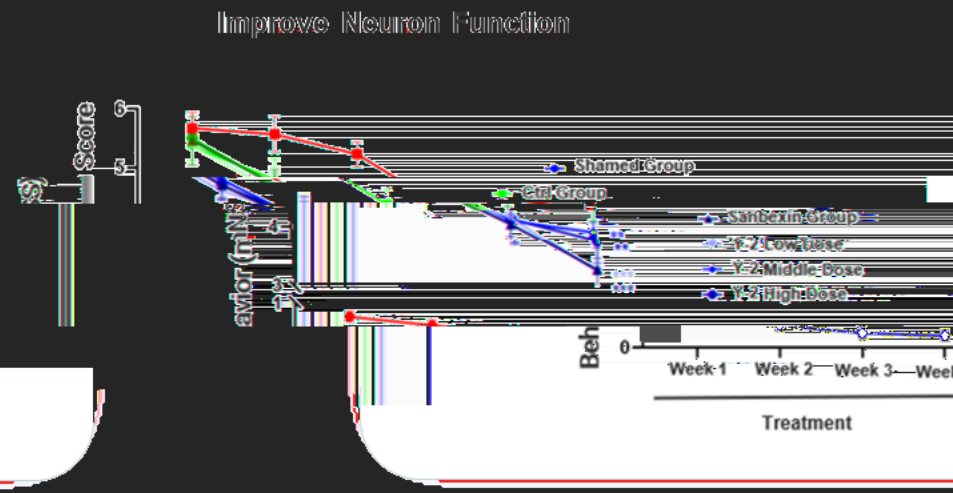
Collagenase-induced intracerebral hemorrhage Model





Subarachnoid Hemorrhage Model





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

2021.11.17 — Collaboration with SIMM

2022.03.28 — IND Approval

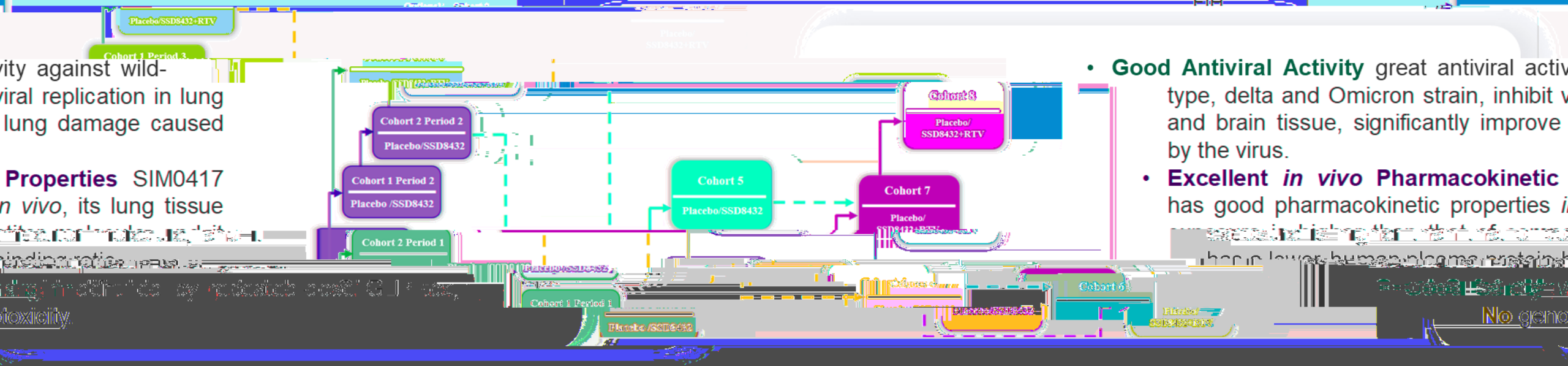
2022.04.10 — Phase 1 FIH

2022 Q3 — Phase 2/3 trials

Part A: Single-dose of SSD8432 and SSD8432 co-administrated with Ritonavir

Part B: Multiple-dose of SSD8432

Part C: Multiple-dose of SSD8432 co-administrated with Ritonavir



vity against wild-
viral replication in lung
lung damage caused

Properties SIM0417
n vivo, its lung tissue

oxicity

- **Good Antiviral Activity** great antiviral activ
  type, delta and Omicron strain, inhibit v
  and brain tissue, significantly improve
  by the virus.
- **Excellent *in vivo* Pharmacokinetic**
  has good pharmacokinetic properties *i*

No geno

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Expected submissions in 2022

Q3 Q4 Q1 Q2

M0237 PD-L1/IL15v IND
US

SIM0237 PD-L1/IL15v IND
China

SIM0272 PRMT5 IND
China

SIM0323 CD80/IL2v IND
China

SIM

SIM0348 TIGIT/PVRIG IND
US

SIM0419 PSD-95 IND
China

SIM0417 3CL(COVID19) IND
China

SIM0271 MAT2A IND
China

SIM0348 TIGIT/PVRIG IND
China

SIM0278 IL-2mu-Fc IND
US

cience

Oncology

Autoimmunity

Neurosc

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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 Establish solid foundation of next gen innovation through Project Y for long-term growth

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Late-stage Oncology Pipeline

Bijoyesh Mookerjee, MD
Chief Medical Officer

Oncology Clinical R&D Strategy

Focus on innovation to maximize impact on patients

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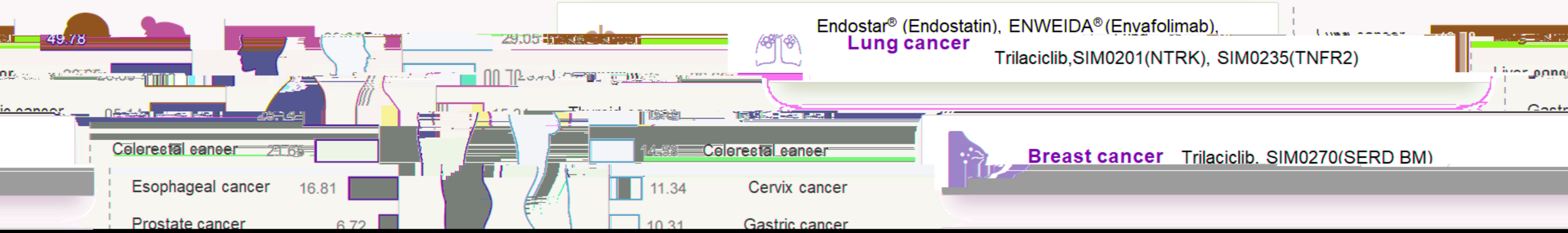
cy for cancer patients in China

Clinical value-oriented medicines to provide greater effica

Simcere anti-tumor products approved for

Estimated incident rates of new cancers (China)



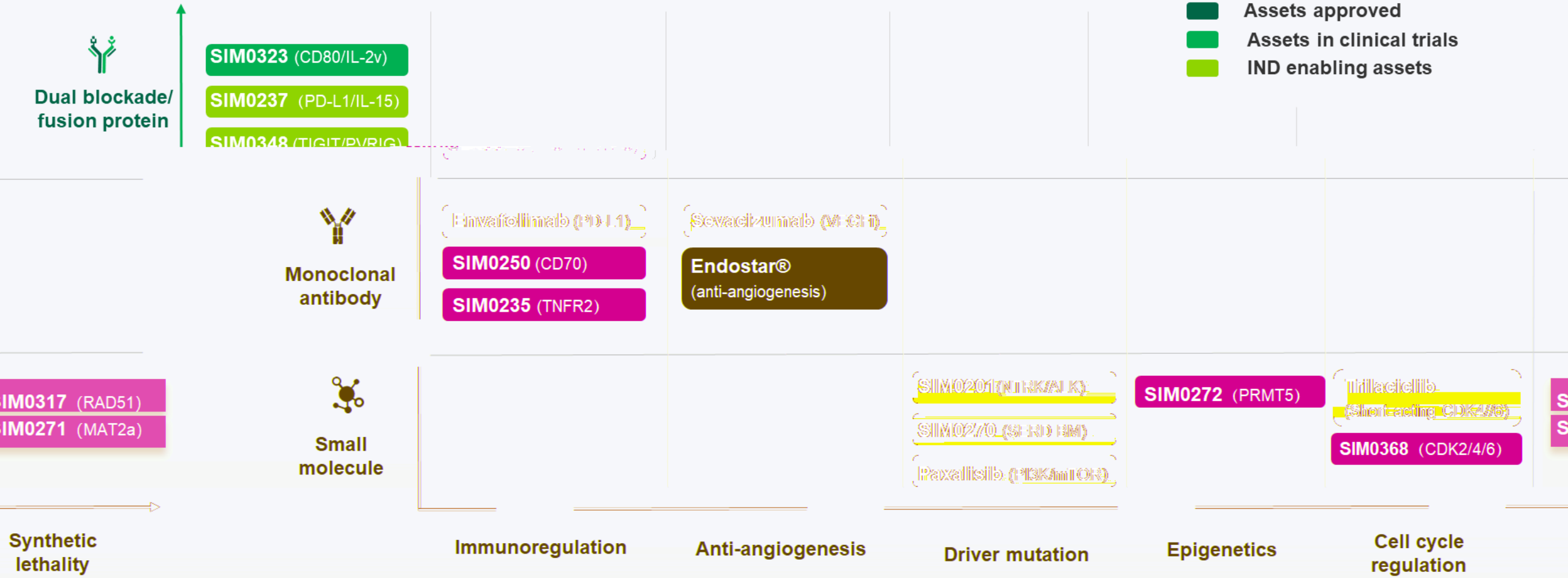
Endostar® (Endostatin), ENWEIDA® (Envafolimab),

Lung cancer Trilaciclib,SIM0201(NTRK), SIM0235(TNFR2)

Breast cancer Trilaciclib, SIM0270(SERD BM)

Oncology Pipeline Layout

Maximize existing, and accelerate new medicines and combinations



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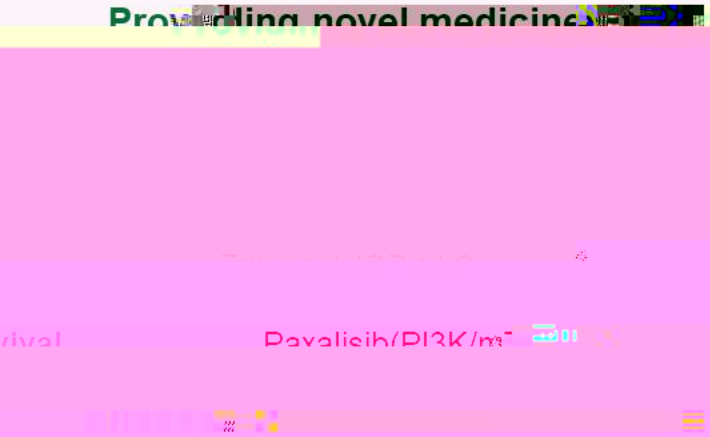
Differentiated Targets and Indications



Key Project Introduction

Progress in Clinical Trials

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

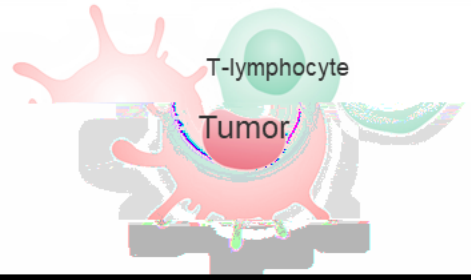
Protects **hematopoietic stem/progenitor cells (HSPCs)** from chemotherapy and enhance the immune system through

Prevent multiple adverse events of myelosuppression through multilineage bone marrow protection[1-3]

Mitigate neutropenia

avoid administration delay and

tion of T
and



Enhance immune response and protect immune function

- Change the proliferation kinetics and composit
cell subsets in tumors to enhance the number
unit on effector cells

Pipeline-in-a-Molecule Opportunity Beyond ES-SCLC Launch

Myeloprotection
Improved Survival (+ chemo)
Improved Survival (+ new combinations)

TBD

Other Chemo Combos TBD

1L NSCLC (PD-L1 Combo)
ISS Initiating 1H 2022

2L/3L TNBC (ADC Combo)
Data Readout[5]: 4Q 2022

Focused on transformational new Tx combos, pending MOA/preclinical studies.

Other Novel

(+/- chemo)

Current Registrational Trials

1L Bladder (PD-L1 Combo)
Data Readout[4]: 4Q 2022

Antitumor Agents

MOA in

TNBC
Data Readout[3]: 4Q 2022

Trilaciclib + TROP2-ADC (sacituzumab govitecan)

- Both Trilaciclib and TROP-2 ADC showed continuous, meaningful OS improvement
- The combination therapy is expected to improve the outcome and reduce the side effect of myelosuppression.
- CN Phase III trial initiated in Q4 2021 (anti-tumor efficacy and OS)

1L TNBC
Data Readout[2]: 2H 2023

COSELA trilaciclib for injection

1L CRC

ES-SCLC
Data Readout[1]: 1Q 2023

1. CRC data readout in 1Q 2023 expected to include results for myeloprotection and Objective Response Rate (ORR) endpoints

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Trilaciclib: accelerating the indication process in China

sive stage SCLC

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

with 1-3L chemotherapy (N=92)

and PK bridging, primary analysis completed, PK and

ith those in overseas countries

Conditional marketing application submitted to China NMPA in November

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

2021/11/29

Submission of Conditional Marketing

TRACES study in China:

Phase III trial for ES-SCLC treated

- The 1st part: safety lead-in
- benefit trend consistent w

*DSN; duration of severe neutropenia

Trilaciclib: PRESERVE trials

ne marrow protection in
XIRI & Bevacizumab

vere neutropenia in cycle 1
enia during Induction

=170)

	Cycle 1 Day 1	Cycle 1 Day 2	Cycle 1 Day 8	Cycle 1 Day 9
Group 1 n=34	GC		GC	
Group 2 n=33	GC + Trilaciclib		GC + Trilaciclib	
Group 3 n=35	Trilaciclib	GC + Trilaciclib	Trilaciclib	GC + Trilaciclib

ITT	N=34	N=33	N=35	N=68
mOS	12.6	20.1	17.8	20.1

Phase III global clinical trial for bo
CRC patients treated with FOLFO
(N=296)

- Primary Endpoint : Duration of se
and occurrence of severe neutrop
- FPI worldwide: 16 October 2020
- FPI in China: 24 September 2021

PRESERVE 2 : TNBC (N=

global trial

Phase III global clinical trial of survival improvement in

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

P	0.028	0.002

clib showed strong OS improvement
NBC randomized controlled phase II trial.
n July 2021, TNBC indication was granted Fast Track designation by the FDA.

Trilaci
in the TN

Patients randomized to receive gem/carbo chemotherapy only (Group 1) or gem/carbo plus one of two

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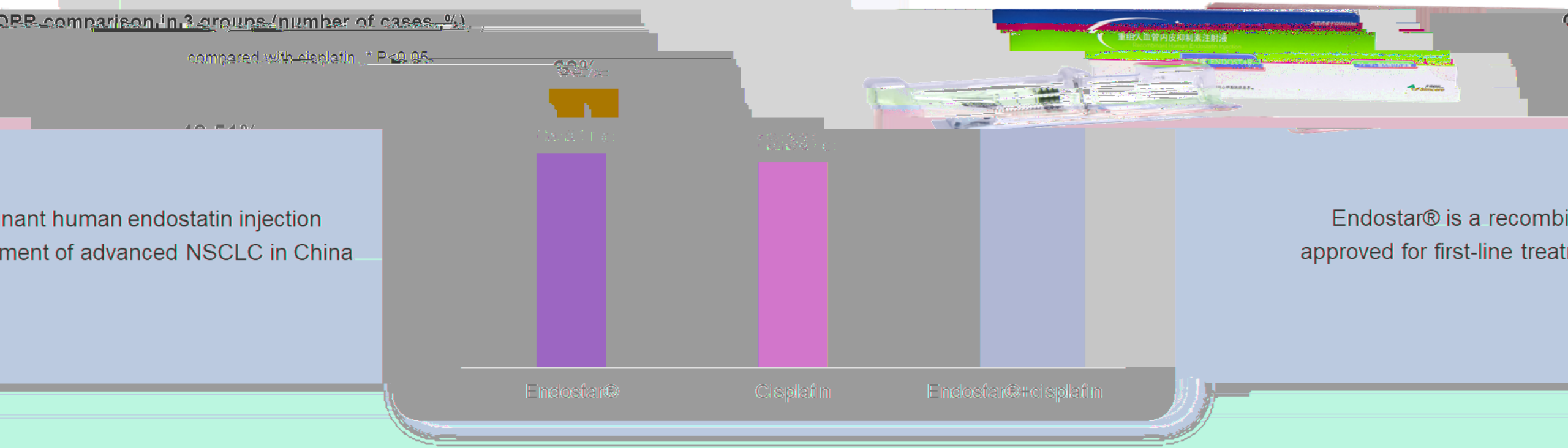
Endostar® New Indication: malignant [illegible] thoracoabdominal effusions

minal

effusions[1]

nant human endostatin injection
ment of advanced NSCLC in China

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



Endostar® is a recombi
approved for first-line treat

etc. Chinese Clinical Oncology, 2017

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.Shukui Qin,

Endostar® New Indication: COREMAP study

To address the urgent need of patients with malignant thoracoabdominal effusions

e tumors whose expected survival is
oportion of abdominal distension caused
s as high as 29% (meta analysis).

data, the incidence of intracavitary
in 2019 and is estimated to increase to

Tumors causing malignant
thoracoabdominal effusions

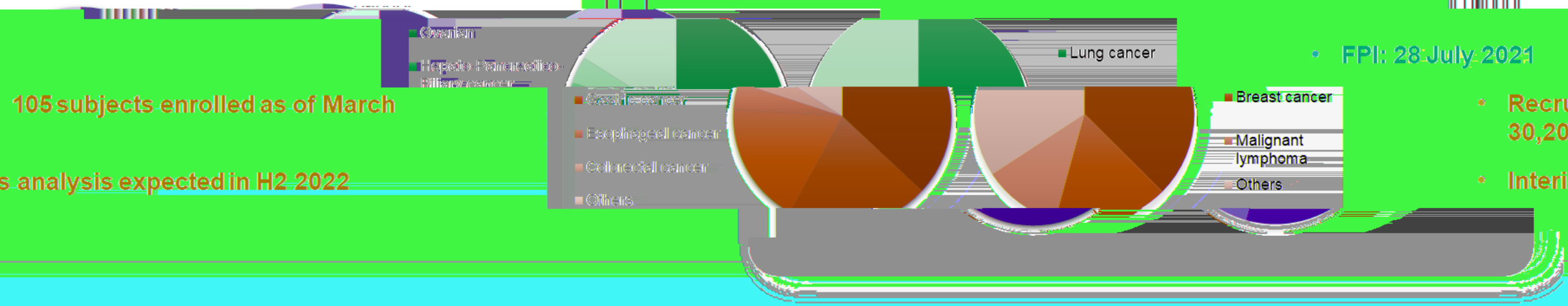
COREMAP ： Endostar® for treatment of malignant thoracoabdominal effusions, phase III

CHINA

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

- Among patients with incurable
  longer than two weeks, the pr
  by ascites and other reasons i
- According to Frost & Sullivan
  malignancy reached 707,900 i
  756,900 by 2030.

Tumors causing malignant
thoracoabdominal effusions



- FPI: 28 July 2021
- Recruitment: 30,2022
- Interim results

105 subjects enrolled as of March

s analysis expected in H2 2022

Shukui Qin, etc. Chinese Clinical Oncology, 2017

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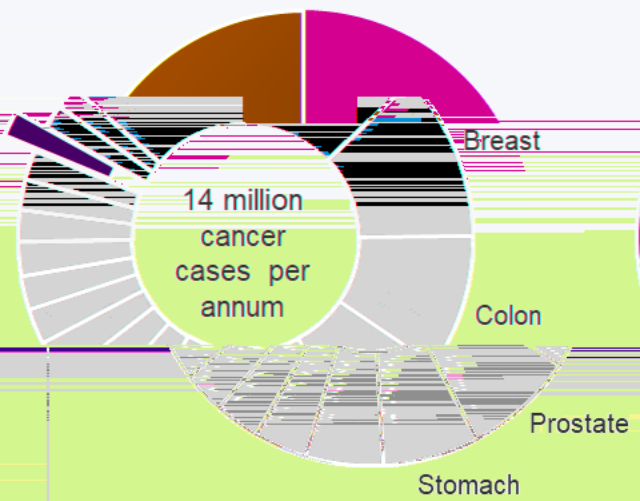
Rexalisib: a potent, oral, selective, BBB permeable [illegible] small molecule inhibitor targeting [illegible]



great potential[2]

- 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 GBM is about **2B yuan**
- Temozolomide **almost ineffect for 65%** of the patients (those v unmethylated MGMT status)

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- For the GBM indication, Orphan Drug designation was granted

Envafolimab

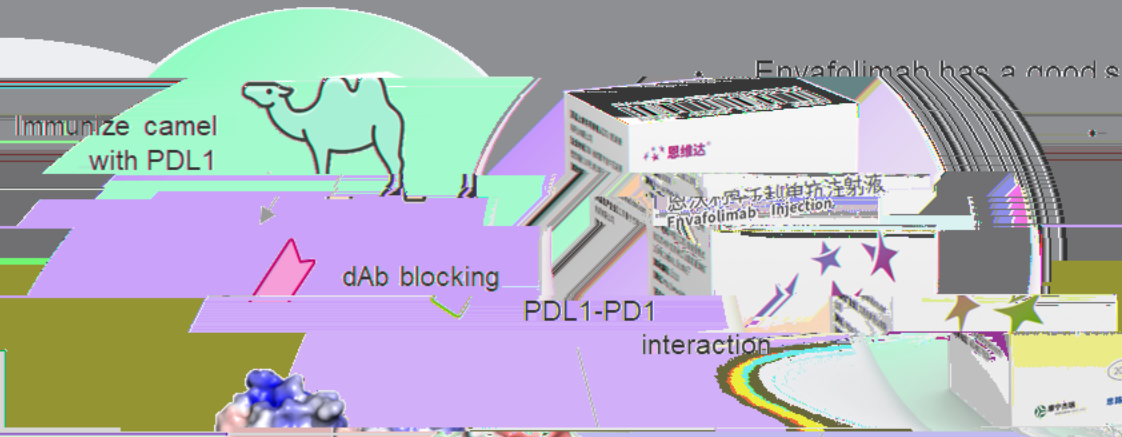
First PD-L1 Antibody Approved For Subcutaneous Injection

afety profile as a single agent

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

was efficacious. BLA application was submitted to NMPA in December

2020 and approved in November 2021



2020 CSCO	N	ORR	DCR	12moPFS	12mo OS
3 drugs					
2 drugs					
Advanced CC	19	44.4%	88.2%	58.8%	88.2%
Solid tumors	20	40.0%	65.0%	52.6%	75.0%

Treatment

Advanced

Treatn
failure

~80kDa

- Novel humanized dAb against PDL1
- Low immunogenicity
- Stable

Other so

1.2020 CSCO

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Envafolimab and Anti-angiogenic Combinations

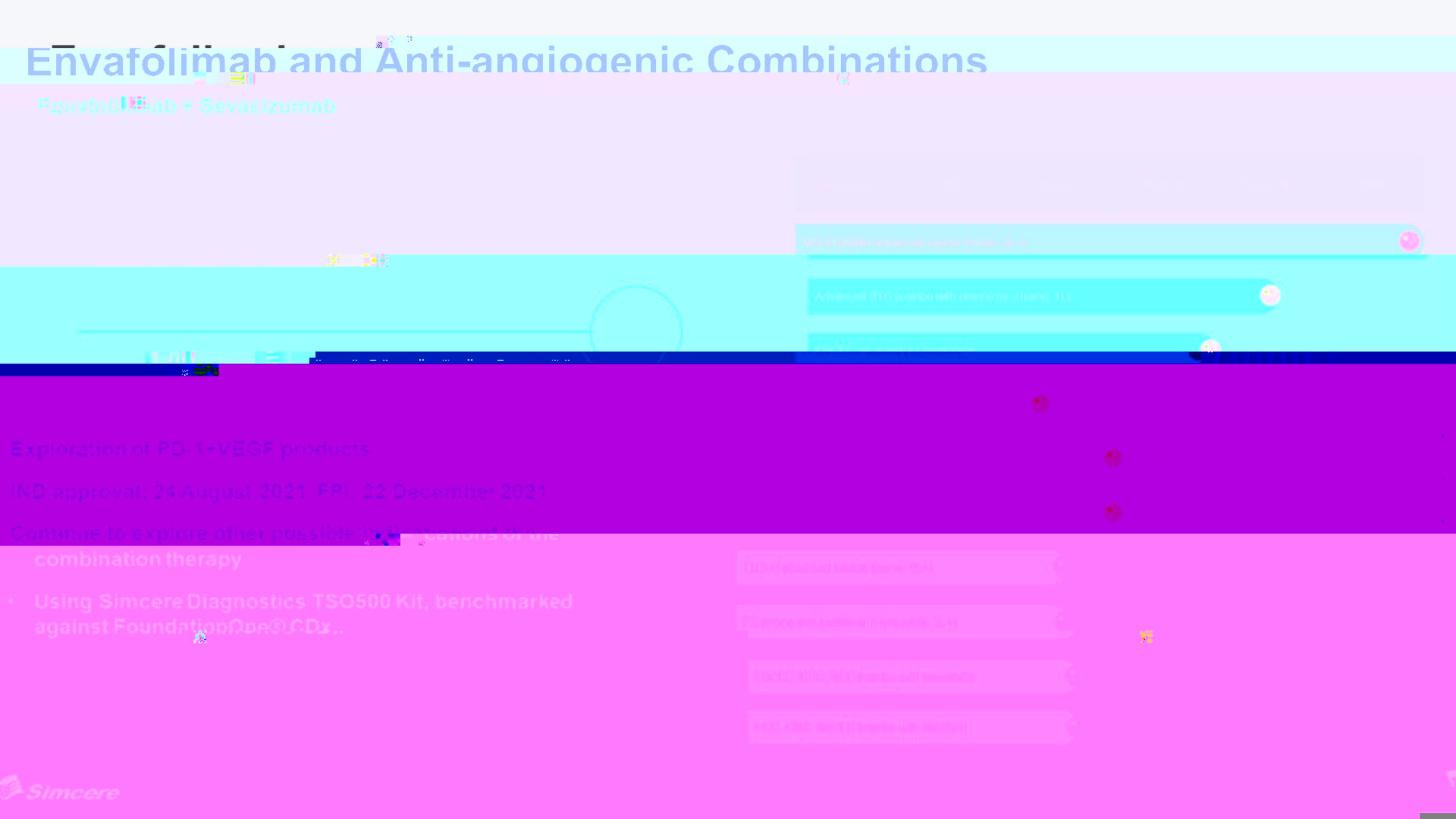
Envafolimab + Sevacizumab

Exploration of PD-1+VEGF products

IND approval: 24 August 2021 FPI: 22 December 2021

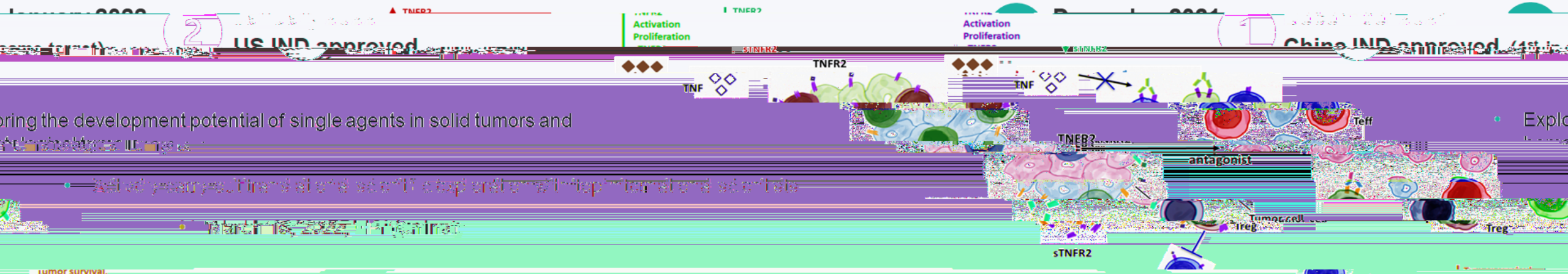
Continue to explore other possible indications of the combination therapy

- Using Simcere Diagnostics TSO500 Kit, benchmarked against FoundationOne®CDx..



SIM0235： Humanized anti-TNFR2 monoclonal antibody

New targets for tumor immunity



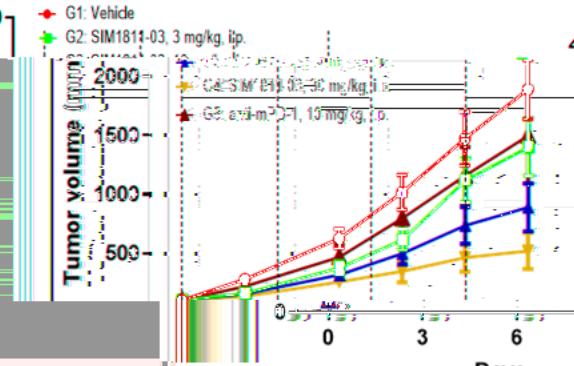
ring the development potential of single agents in solid tumors and

TNFR2[1,2,3] on the cell surface:

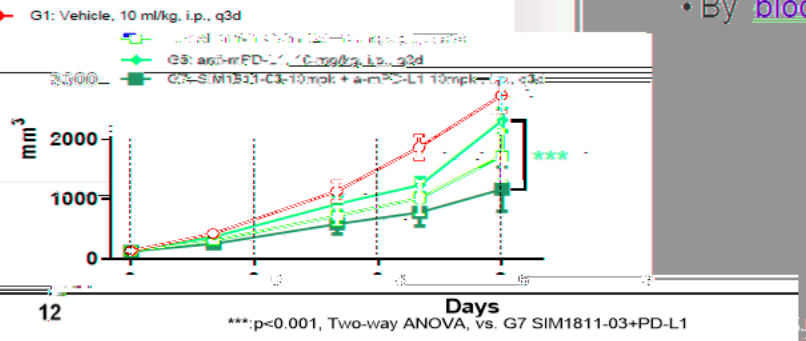
n of TNFR2 by endogenous TNF, it
mediated immunosuppression and tumor cell

dent cell-mediated cytotoxicity (ADCC)-mediated
has a direct killing effect on immunosuppressive
umor cells expressing TNFR2, regulatory T cells
e marrow-derived suppressor cells (MDSCs).

TNFR2 Humanized Animal Model: Single Drug Efficacy



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



It can specifically recognize

- By blocking the activatio
  affects TNFR2-
  proliferation.
- Antibody-depen
  by Fc terminal h
  cells, including t
  (Tregs) and bon

1.Williams GS et al., Oncotarget. 2016;2.Vanamee E et al., Trends in Molecular Medicine.

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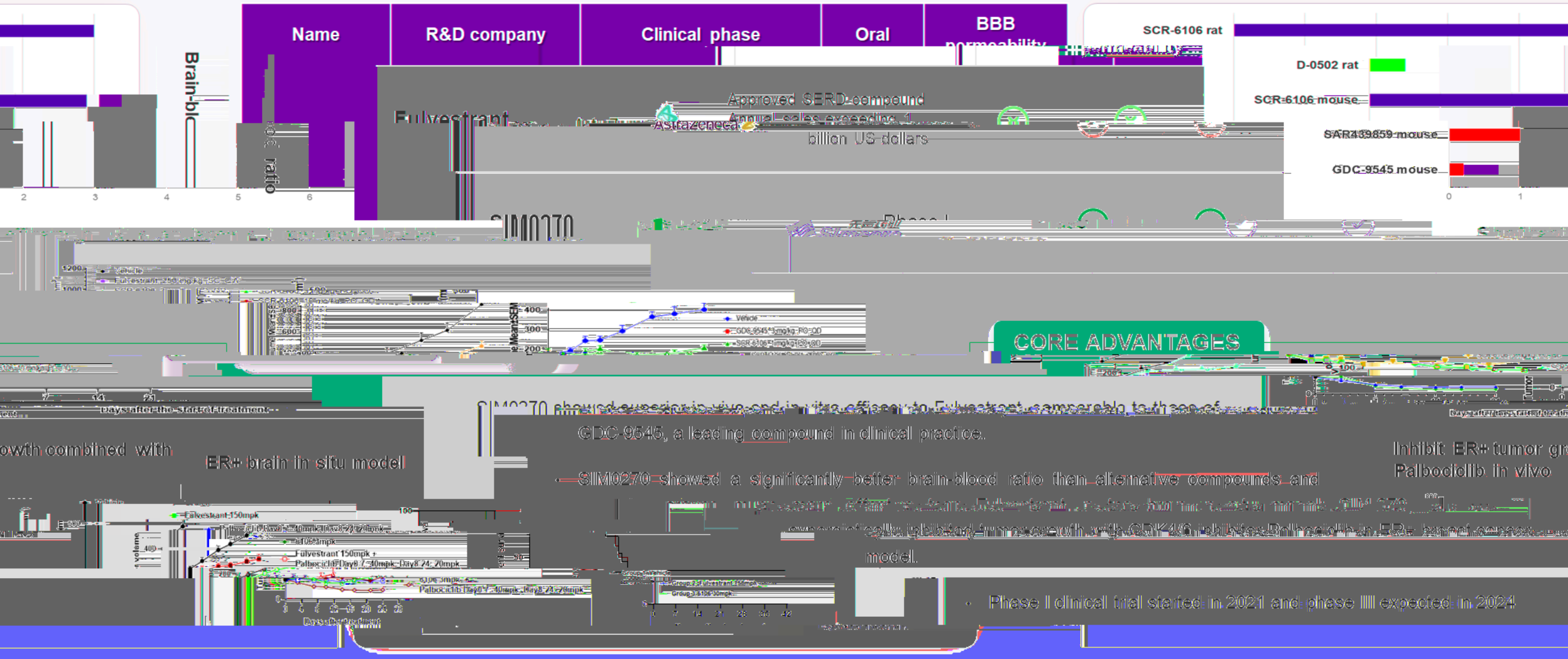
SIM0270: BBB permeable, tumor tissue-enriched,



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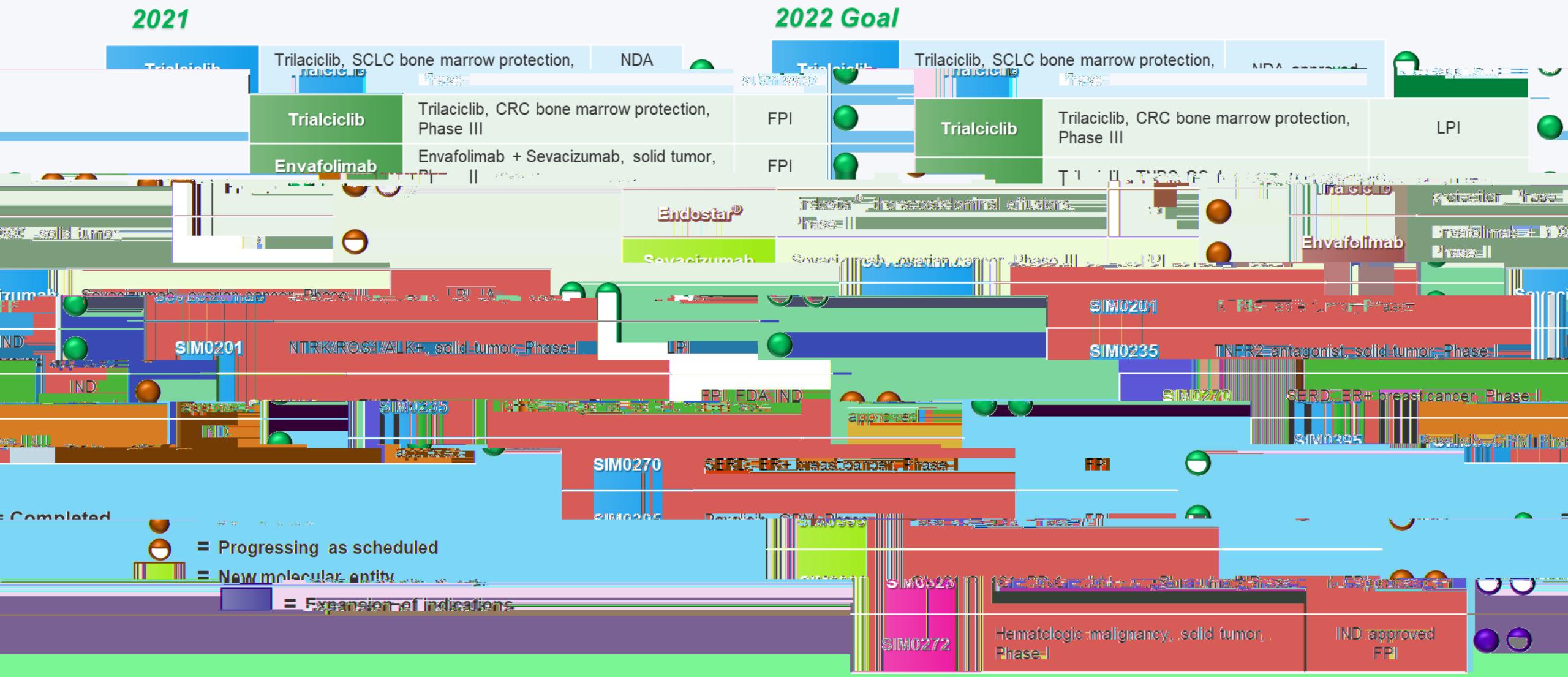
Milestones 2021-2022



Note: SCLC: small-cell lung cancer, CRC: colorectal cancer, TNBC: triple negative breast cancer, OS: overall survival, ER: estrogen receptor

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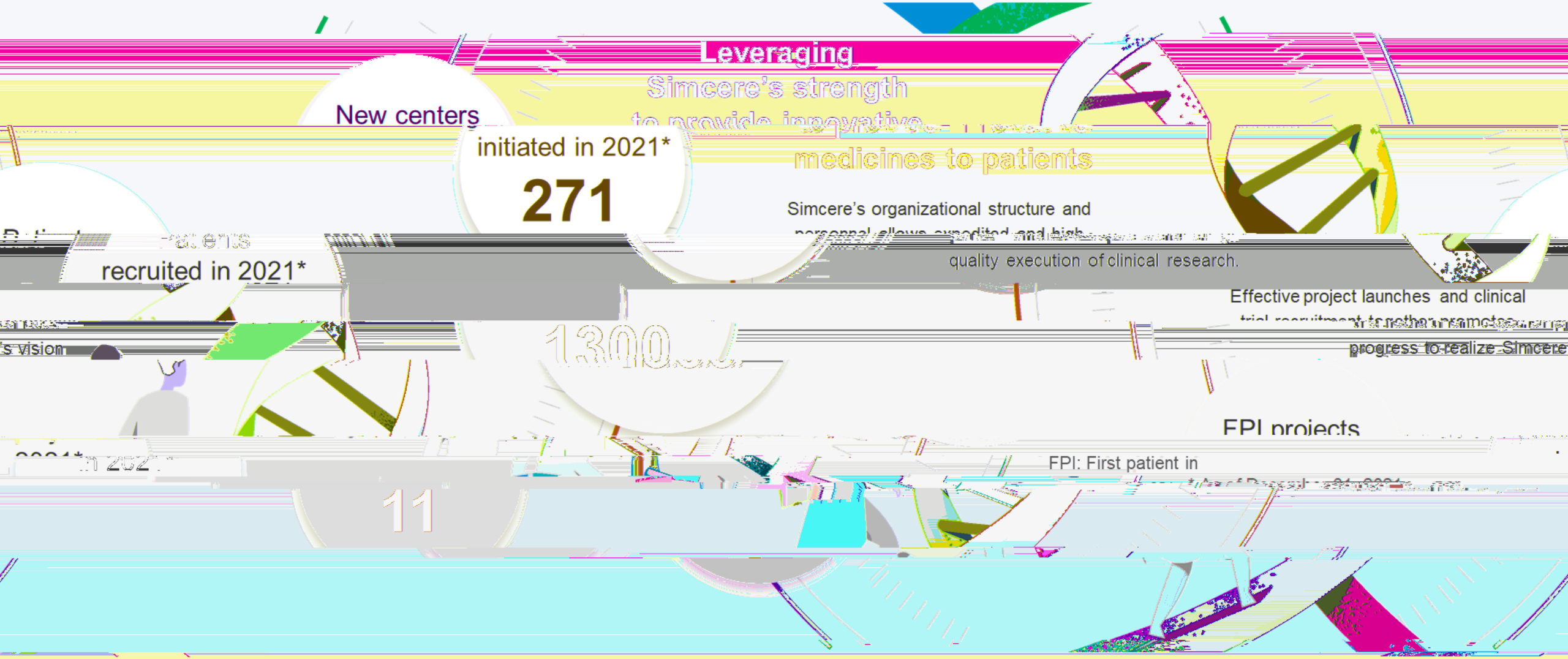
Operational Excellence Driving Simcere's Purpose and R&D Vision



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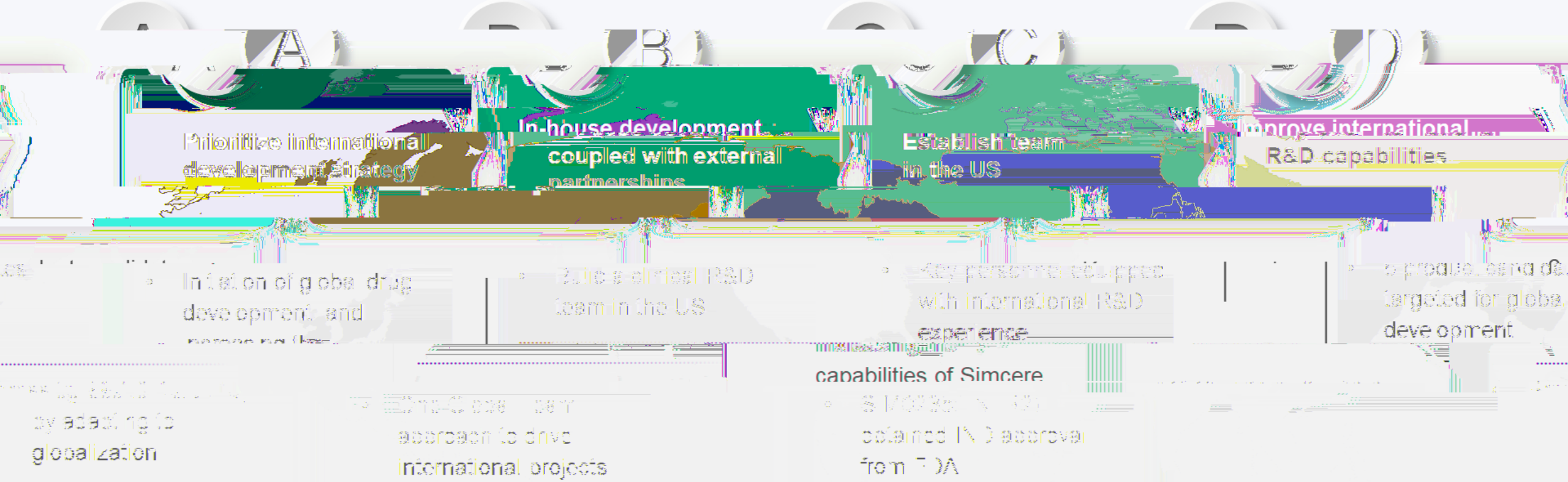
Operational Excellence— New Asset Development

Globalization to Further Extend Asset Value



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Providing Today's Patients with Medicines of the Future

Clinical value-oriented

Innovative pipelines

Operational Excellence

Global R&D Strategy

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Late-stage Non-oncology Pipeline

Danny Chen , PhD
SVP

Overall Strategy

Focus on targets and disease of high unmet needs

Central Nervous System (CNS)

- Sanbexin®/Sanbexin sublingual indication expansions in China and globally
- Develop novel FIC compounds alone and in combination to further improve treatment outcome in AIS and haemorrhagic stroke

Autoimmune

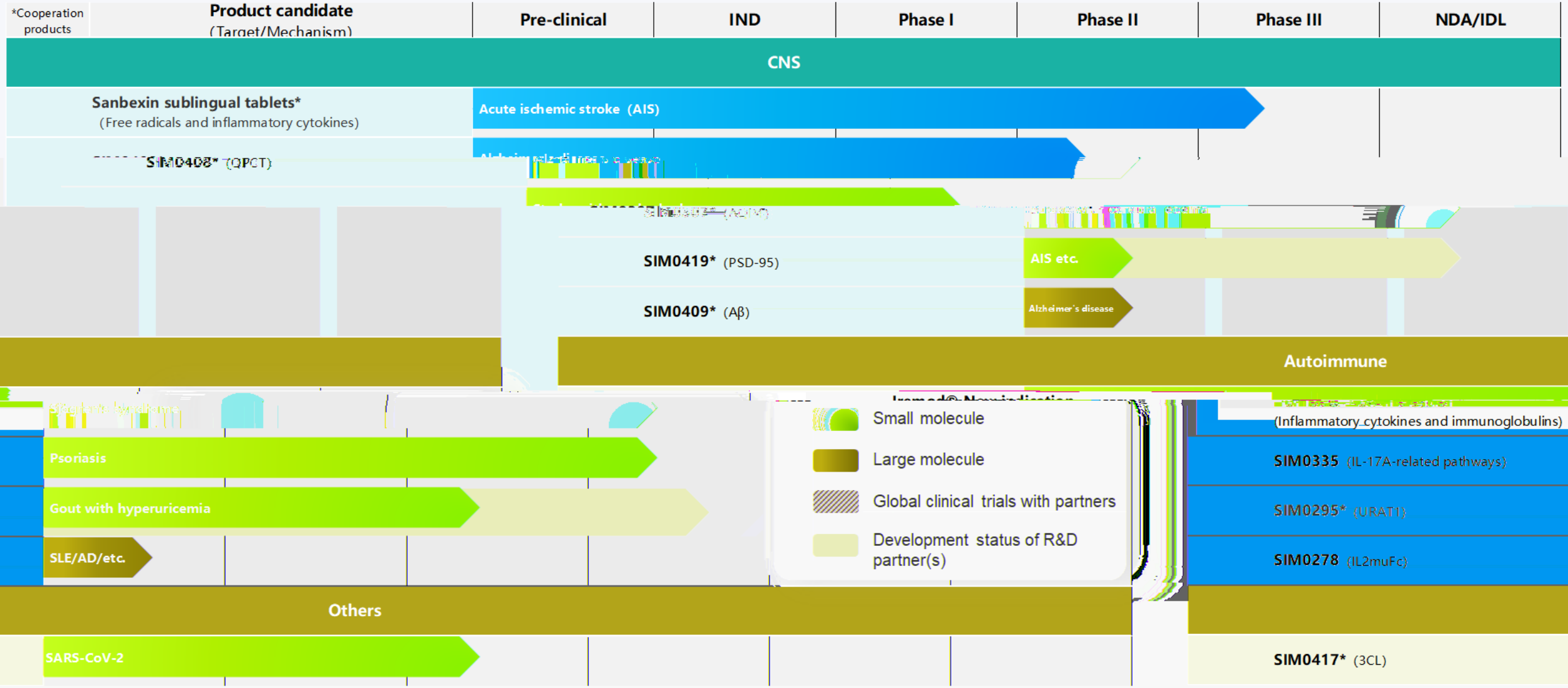
- Breakthrough therapy to address the limitations of current treatment
- Focus on rheumatology and dermatology
- Innovative MoA and products

Summary

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

Non-oncology Pipeline

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



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Key Project Introduction

CNS

CNS Clinical Focus

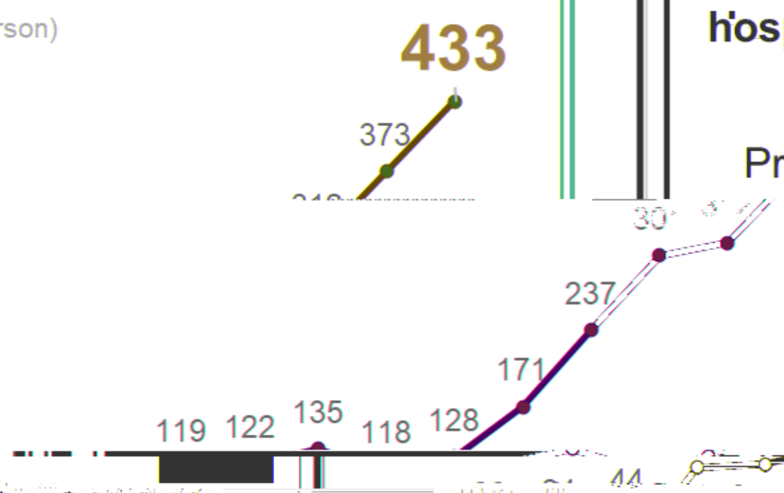
Subsegments of nervous system disease

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

China’s Stroke Treatments Still Have Huge Challenges

Large Number Patients And Low Thrombolytic Rate

Number of Discharged Patients with Ischemic and Hemorrhagic Stroke in China 2005-2019[1]



thrombolysis treatment window due to hospitalization later than 6h from onset.

Proportion of patients receiving rt-PA within 3 hours of onset[2]	China	US
	18.3%	83.6%

Average thrombolytic rate of AIS in China in 2017

Ischemic Stroke Patients 5-year Recurrence Rate[3-4] **41%**

1. China Health Statistics Yearbook 2020
2. DOI: 10.3760/cma.j.cn112137-20210416-00914.
3. The lancet global health 10.1016/S2214-109X(20)30069-3
4. China cardiovascular health and disease report 2020

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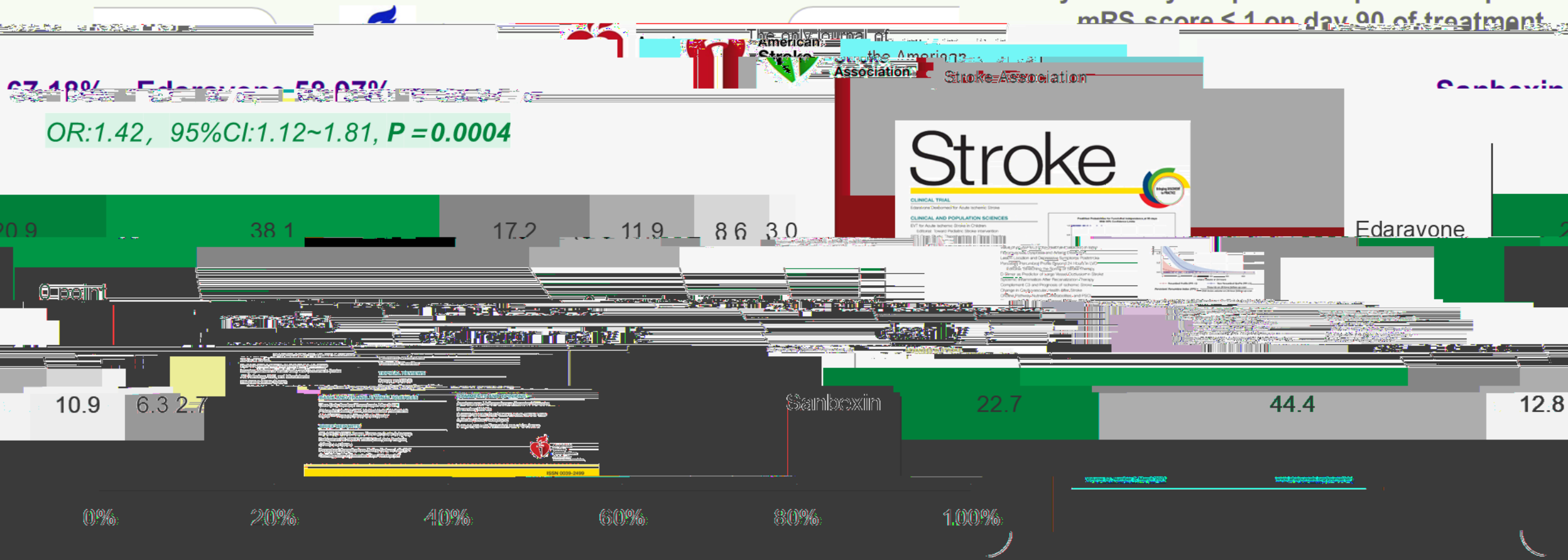
48 clinical centers across the country participated in the trial, including ~1200 subjects, and the data were

ts with

Primary efficacy endpoint: Proportion of patient

mRS score ≤ 1 on day 90 of treatment

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



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Sanbexin®: TASTE II Ischemic Stroke Reperfusion Study

Planning to enroll over 1300 subjects, across nearly 80 clinical centers in China

- March 18, 2022：FPI
- Complete 80% enrollment expected in 2022

After vascular recanalization, Sanbexin can directly enter the ischemic site to promote the recovery of ischemic

Protect the brain

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

The NA-1 ESCAPE Phase III trial (subgroup analy

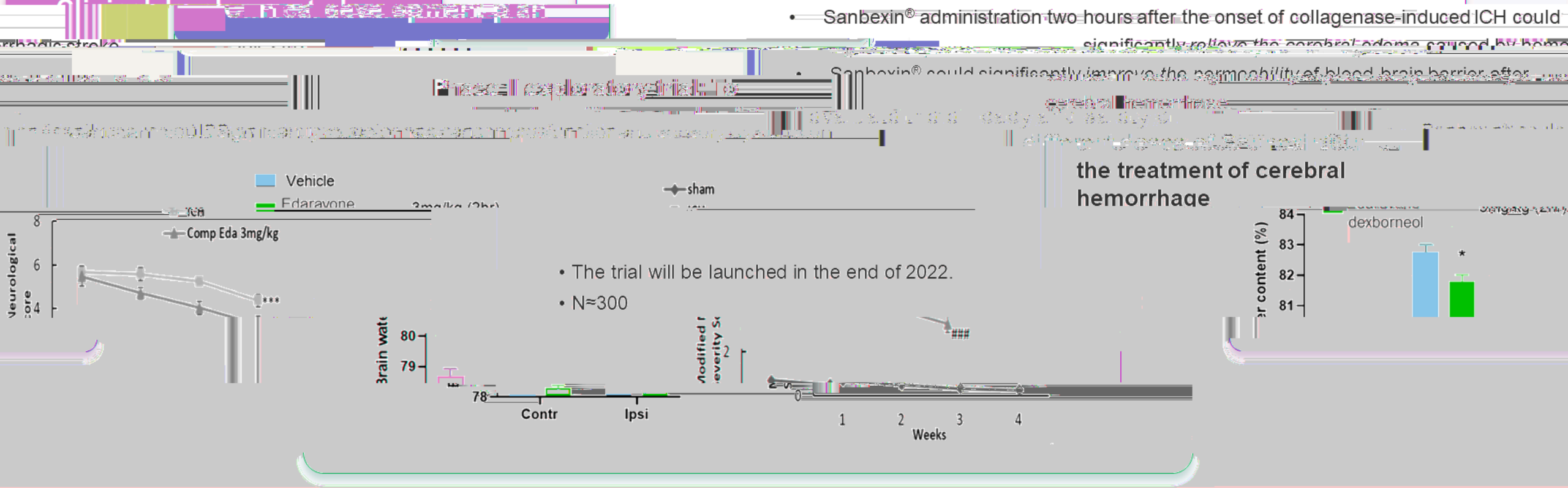
Sinocare

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
- Sanbexin® could



the treatment of cerebral hemorrhage

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

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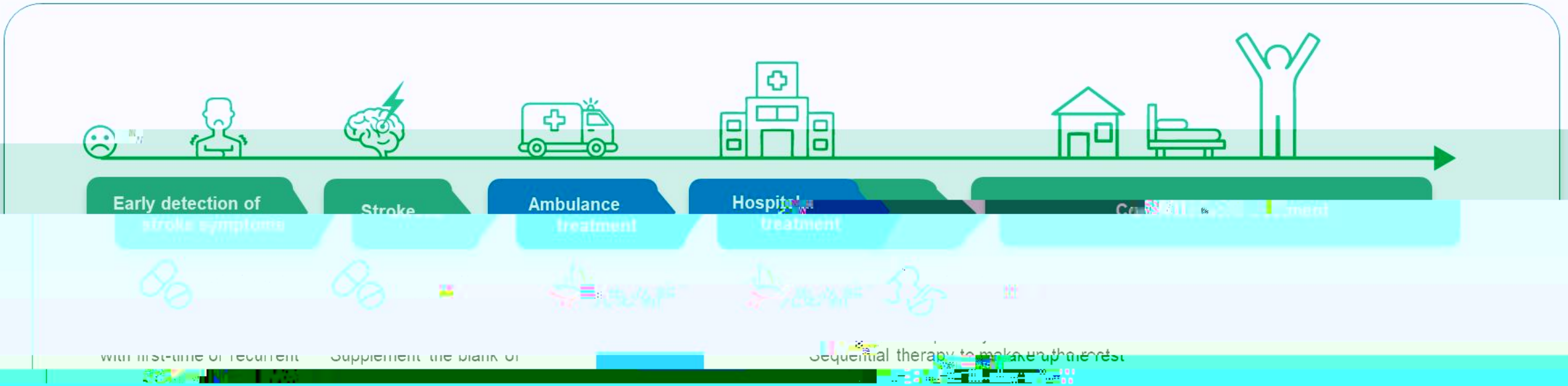
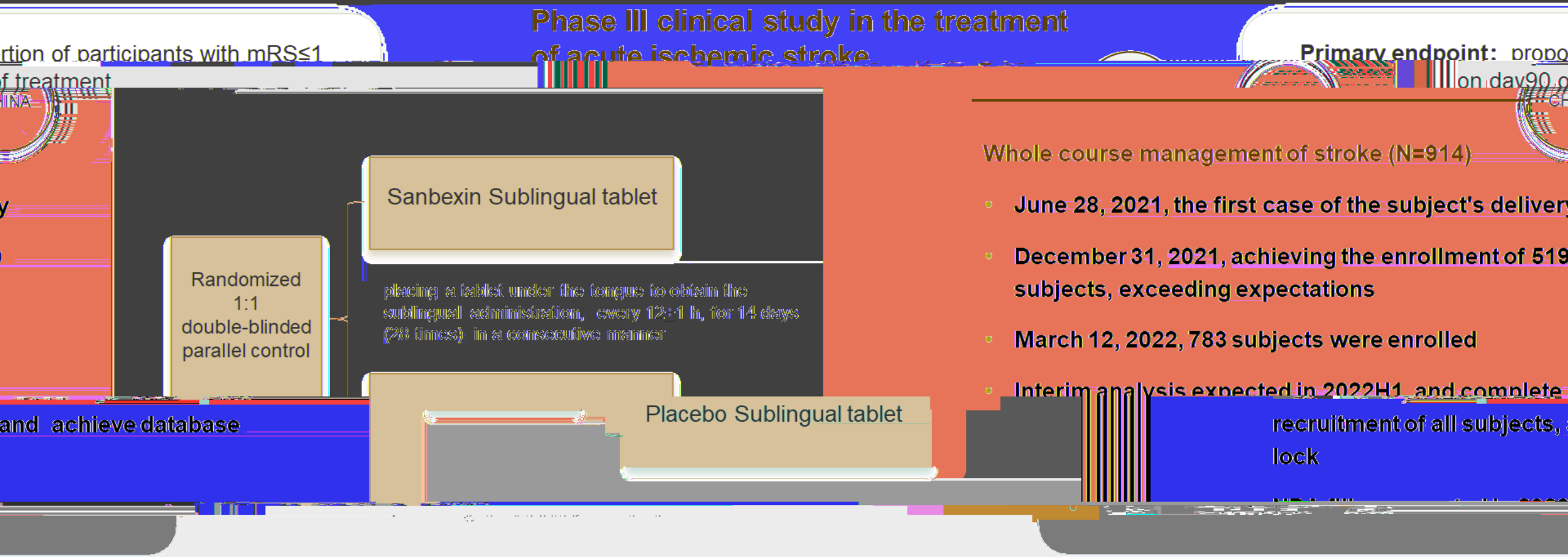
Sanbexin Sublingual Tablet

To further expand the effectiveness of Sanbexin in stroke treatment and recovery



Sanbexin Sublingual Tablet



SIM0237: The First Innovative Drug Targeting Aquaporin 4 (AQP4)

- A drug developed based on the scientific achievements of the 2003 Nobel Prize in Chemistry (Aquaporin Physiology)
- China's first and the world's only AQP4 inhibitor that has been approved for clinical trials and development

Phase I clinical trial in China

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

Chinese population

Simcere Aeromics

Int. J. Mol. Sci. 2017, 18(1), 55; https://doi.org/10.3390/ijms18010055

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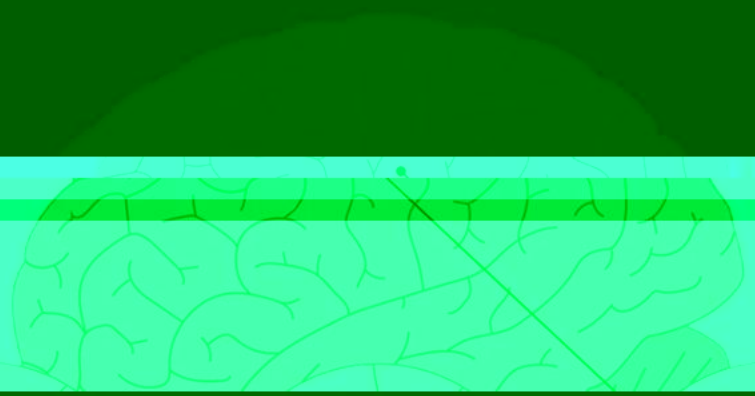
Stroke Pipeline Layout

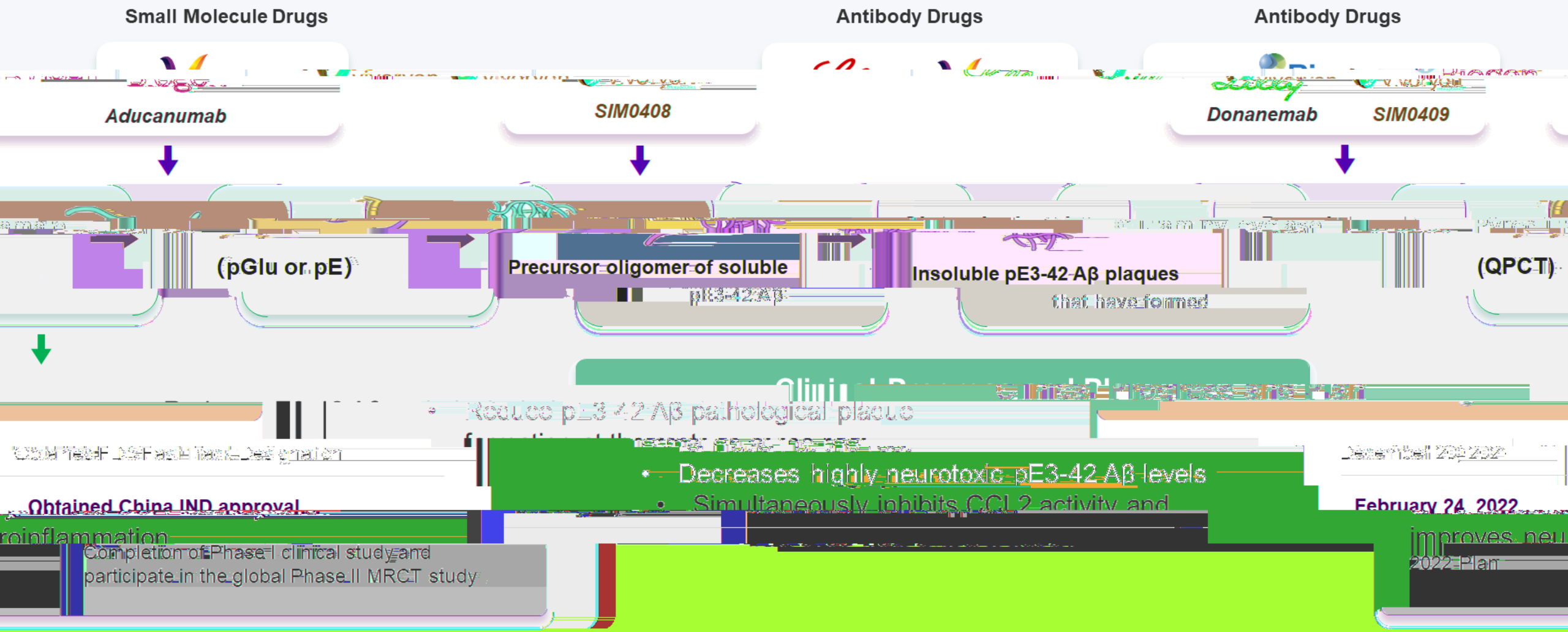


combination of multiple mechanisms

01 Reduce neuroinflammation

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

QPCT oral small molecule inhibitor



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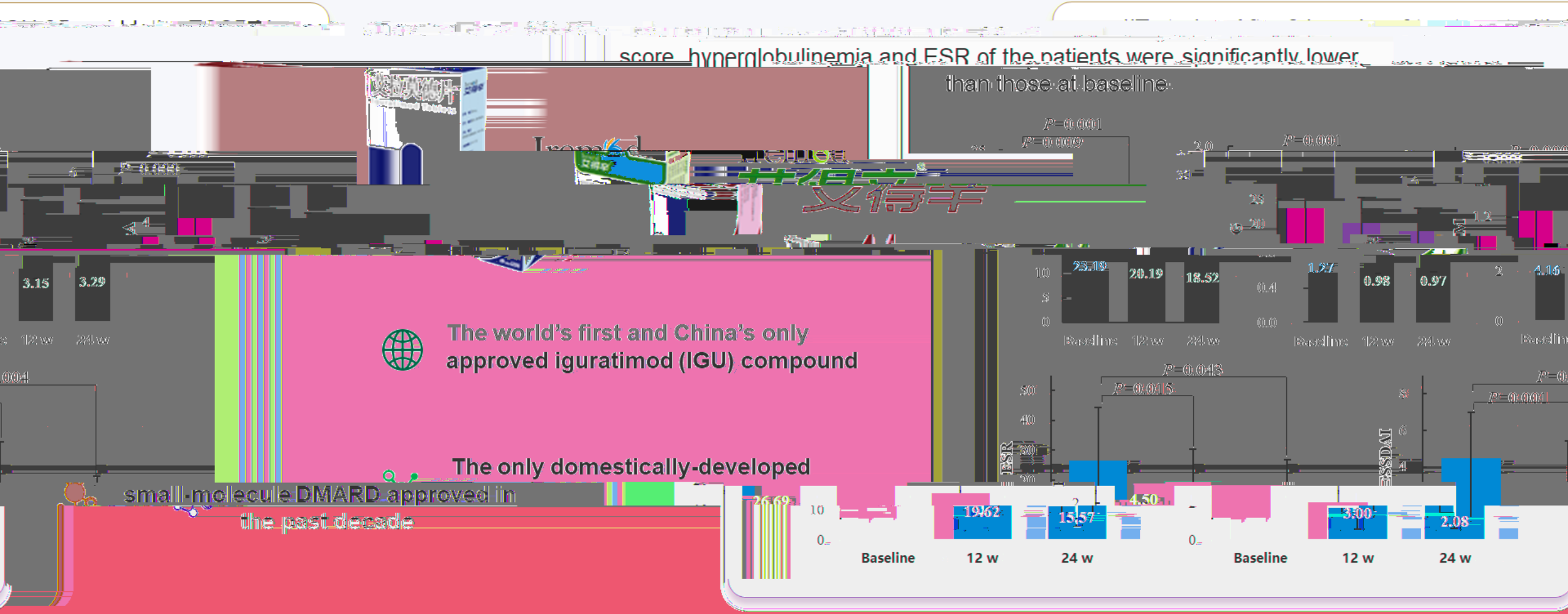
Key Project Introduction

Autoimmune

Iremod® New Indication: Sjogren's Syndrome

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



The world's first and China's only approved iguratimod (IGU) compound

The only domestically-developed small-molecule DMARD approved in the past decade

Lizhanguo team. EULAR. Ann Rheum Dis, 2019, 78 (suppl 2): A1696 (No.AB0465).
https://doi.org/10.3389/fphar.2021.621208

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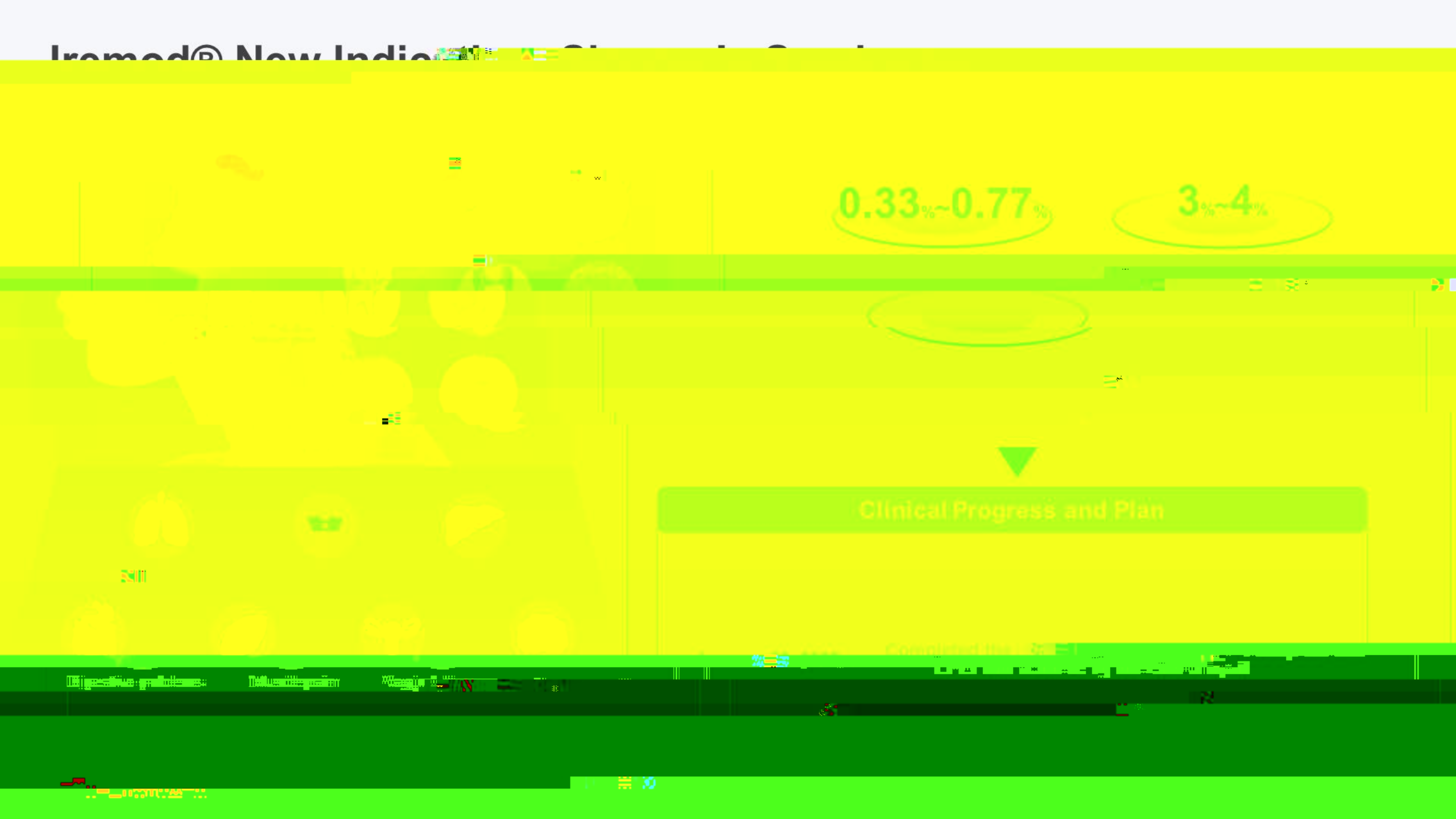
0.33%~0.77%
3%~4%
Clinical Progress and Plan

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.

bility

2 or higher during the trial;

TEAE;

to discontinuation;

e: postprandial

on the metabolism and elimination of LNK01001;

change significantly with fasting or eating

acodynamic relationship (pSTAT Inhibition assay)

Phase 1 PK and PD summary:

- **SAD:** PK parameters increase proportionally in the range of 6 mg to 84 mg along with the increase of 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
- No dose-related incidence of adverse events
- **FE:** AUC shows no significant change with fasting or eating state

Phase I studies in healthy subjects demonstrats good safety and tolera

- No TEAE above >
- No SAE;
- No death-causing
- No TEAE leading

administration has no significant effect
elimination of half-life period(T1/2) Not

- **PD:** good Pharmacokinetic and Pharma

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Milestones Expected in 2022

Iremod® (Sjogren's syndrome)

Result summary of phase II; Regulatory communication before phase III

SIM0417(3CL)

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

Sanbexin®(Cerebral hemorrhage)

Hemorrhagic stroke as a newly added indication of

SIM0408(QPCT)

(international multicenter)
FPI

®(Reperfusion)

reperfusion for AIS
treatment, phase IV
the enrollment goal

Sanbexin

Sanbexin® combined with

Achieve

Sanbexin Sublingual Tablet

Y-2 for AIS treatment, phase III

SIM0307（AQP4）

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

SIM0335

CKBA for treatment of mild to moderate psoriasis, phase II

FPI, LPI

SIM0278

IL-2 for treatment of systemic lupus Erythematosus
FDA IND

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

Kevin Oliver , PhD
SVP, Global Head of BD&L

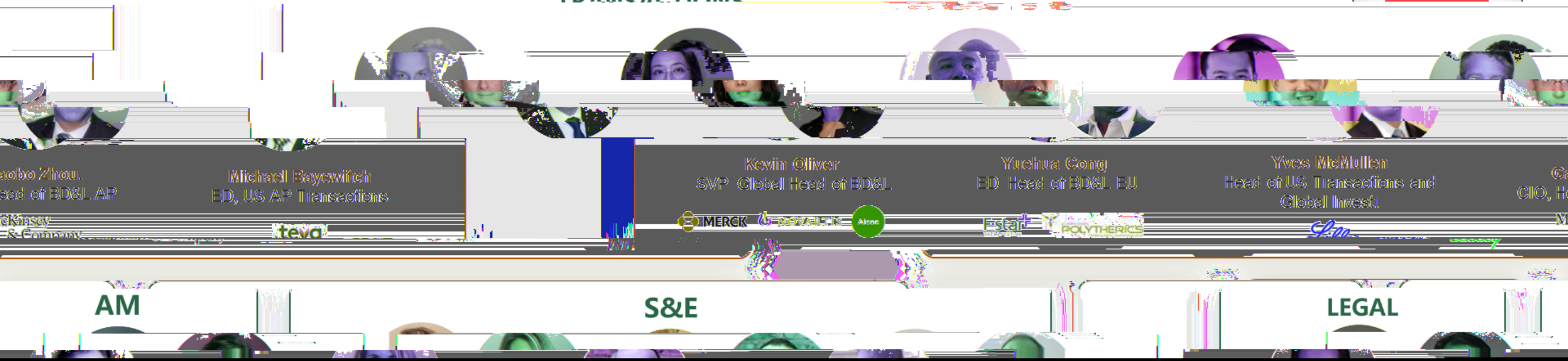
Simcere's BD/M&A Team has high credibility, is diverse and has a deep reputation in the industry

250+
acquisitions integrated collective experience

2018、2019、2020
Professional (ASAP) Excellence Awards

30

TRANSACTIONS



aobo Zhou,
ead of BD&L AP
cKinsey
& Company

Michael Baycwitch
ED, US AP Transactions
teva

Kevin Oliver
SVP Global Head of BD&L
MERCK NOVARTIS Alcon

Yuchua Cong
ED Head of BD&L EU
Estar POLYTHERICS

Yves McMullen
Head of US Transactions and
Global Invest.

Ca
CIO, H

AM

S&E

LEGAL

BD is geographically established to become ‘Partner of Choice’

(S&E)

Management

Management

Manage

Manage

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Global c[illegible]centered in Boston, will focus on six key, global operational strategies

Platforms as innovation driver

Global clinical center of excellence

High return of investment

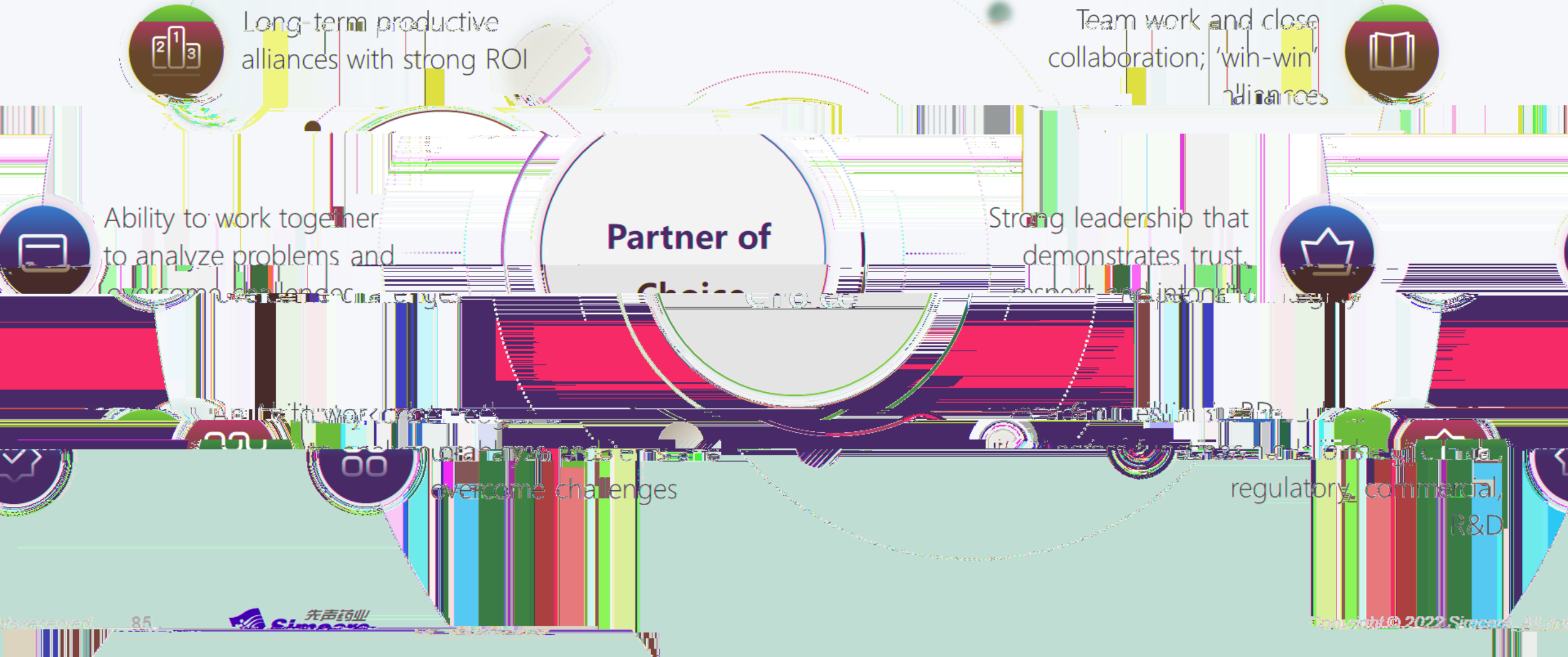
perational xcellence

Open business development: Clinical/Academic/Pharma

Academic partnership to drive innovation

Simcere

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



Simcere values its existing 35+ alliances and IP positions

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Strategically driven BD: In-licensing interests in Oncology

tive modalities

oughput structure-based drug screening
ging Targets)

ovel drug targets with First-in-class and/or Best-in-
(preferred)

Earlier stage assets (> late preclinical) with innovative

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

Small molecule and biologics

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

Focus on assets with clinical PoC in relevant indications

Novel drug classes/modalities (RNA therapeutics, Tetra-

First-in-class

Modality agnostic

Innova

High-thro
(Challeng

No
types

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

tnership models (In-licensing/Co-dev, R&D
ons, JV & Equity Investment, M&A)

Flexible par
collaboratio

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

General

Focus on high unmet medical need in China

Later-stage assets with clinical PoC in relevant indications

Earlier stage assets (≥ late preclinical) with innovative mechanisms need to have potential to deliver highly differentiated patient benefit

Flexible partnership models (In-licensing/Co-dev, R&D collaborations & Equity Investment opportunities)

CNS

Neurology: Focus on Stroke

Neurodegeneration: Parkinson's, Alzheimer's

Pain, Sleep

Psychiatry: Depression, Anxiety, Schizophrenia

Autoimmune

Indications with immune-mediated pathology and high unmet need in China

Current focus on rheumatology and dermatology

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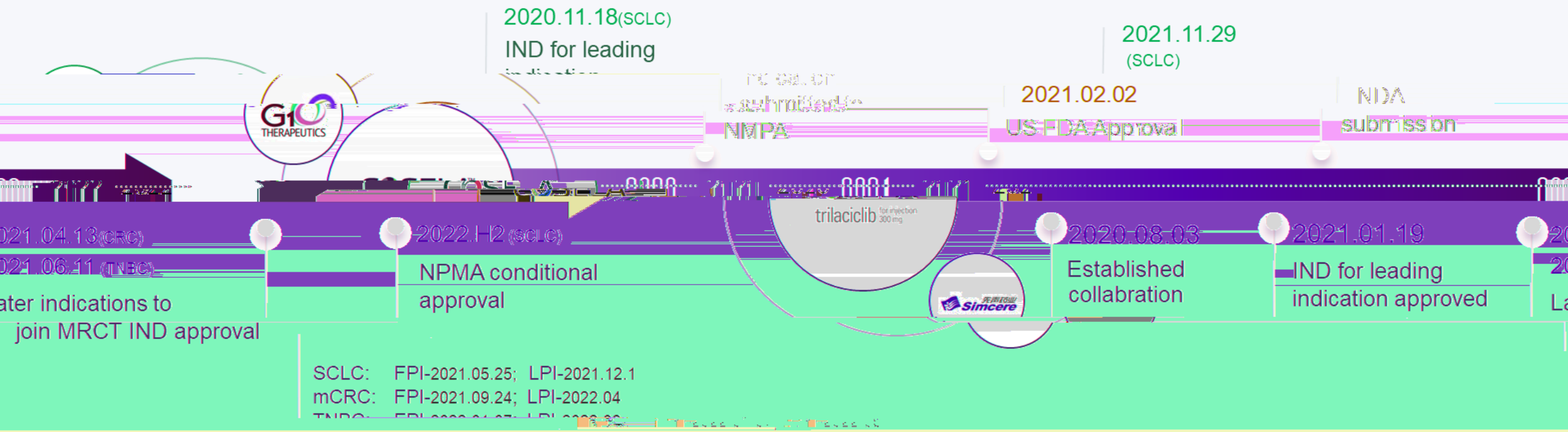

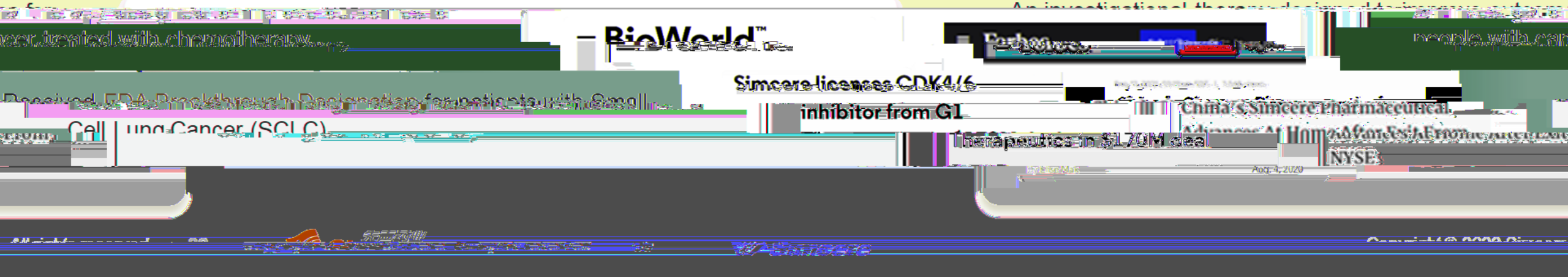

Exclusive License Agreement for small molecule, PQ912, and biologic in Greater China

2020 2021 2022

2022.2.24
IND approval

2022.7
Phase II
(MRCT) - FPI

2021.12.14
IND submission

2022.5

2020.06.29
Established
collabration

Targeting Medicines to Treat

available clinical opportunities

ents

Phase 2 N3pE Amyloid-
Alzheimer's Disease.

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3DMed Alphamab Exclusive License Agreement for Envafolimab in Mainland China

康宁杰瑞 ALPHAMAB ONCOLOGY

2020.12.17

BLA submission to NMPA

2021.12.3

First prescription

2020

2021

2021.11.24

BLA approva

llabration

先声药业 Simcere

2020.03.30

Established

co

d by Chinese in China

the world.

First PD-L1 develope

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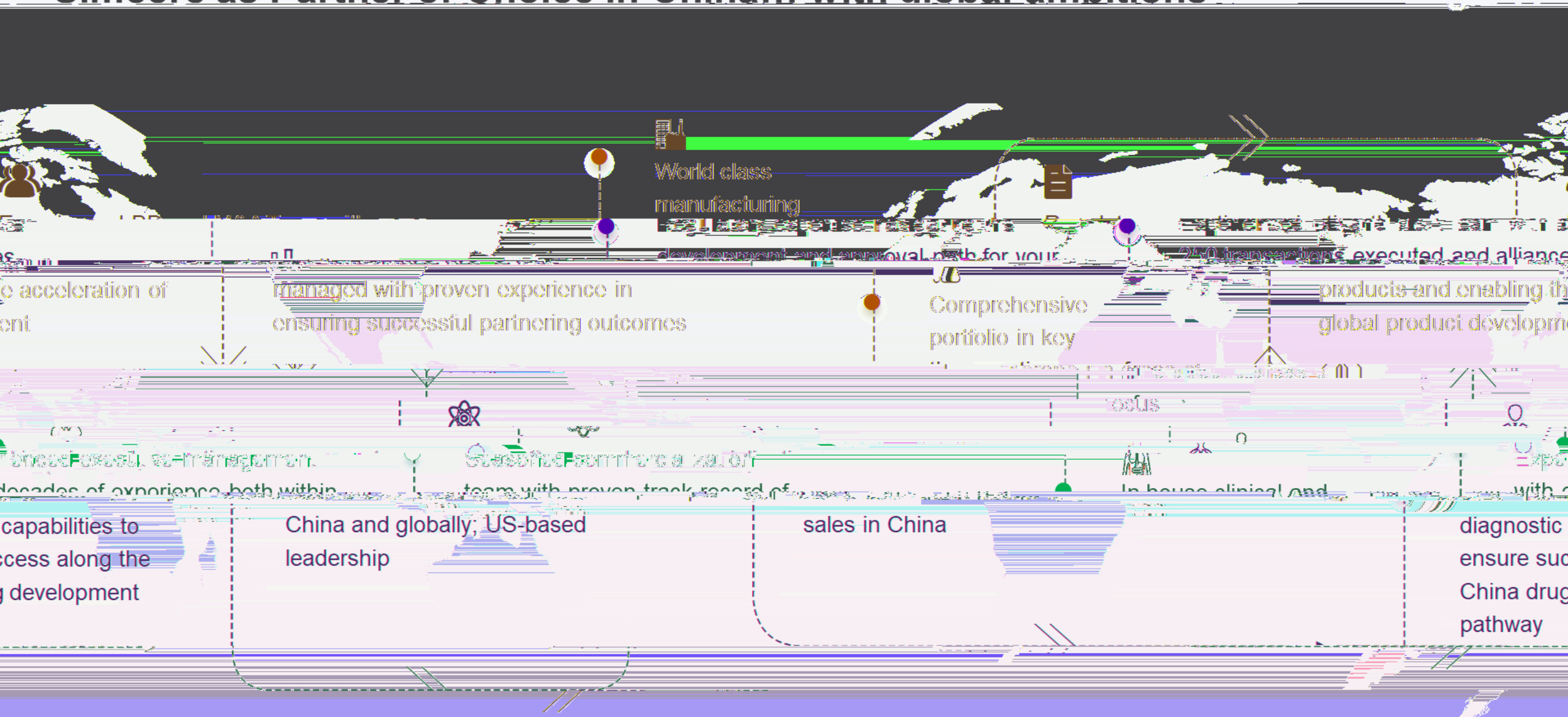
Simcere as Partner of Choice in China… with global ambitions



capabilities to
ccess along the
g development

China and globally; US-based
leadership

sales in China

diagnostic
ensure suc
China drug
pathway

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Q & A

ATTENDEES

HOST : Jason Bao
Secretary of the Board

Dr.Tang

Mr.Zhou

Dr. Mookerjee

Dr. Chen

Dr. Oliver

Andrew Zh
SVP

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Simcere

SIMCERE PHARMACEUTICAL GROUP LIMITED

2022 R&D DAY

STOCK CODE: 2096.HK

IR CONTACTS