Investor Relations
2020. 09

SAMCHUNDANG PHARM.CO.,LTD

For the health and happiness of human beings

CONTENTS

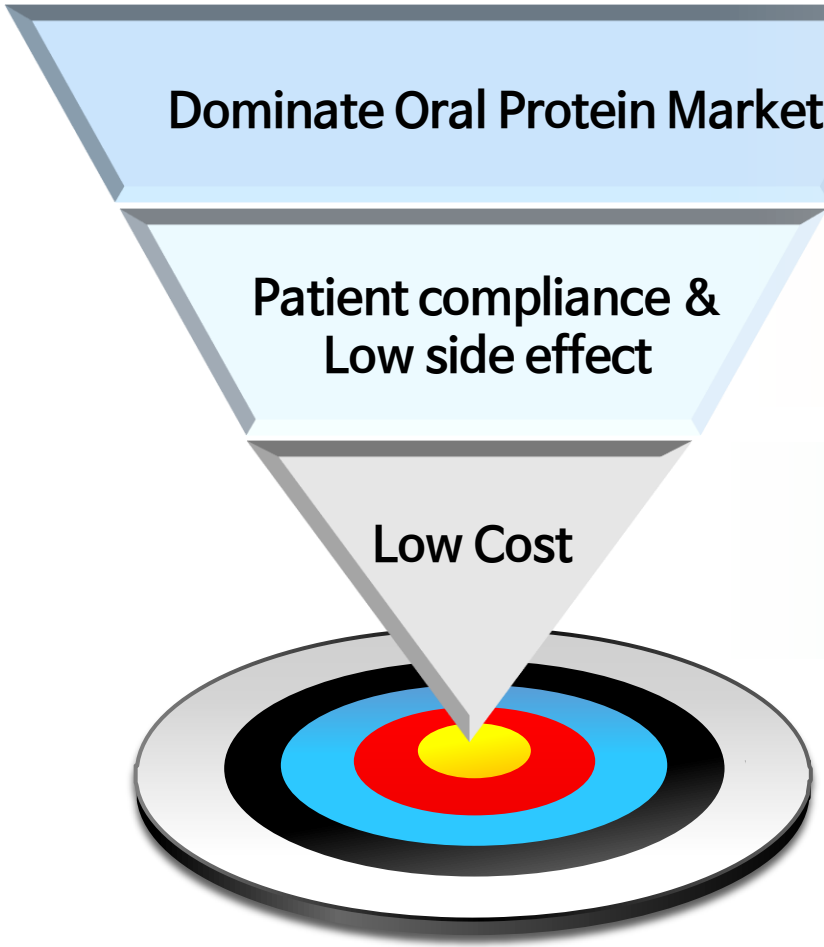
Chapter 1

Platform Tech Background

A company cares for human health and the future

Go together with SCD

Our Goal: IV/SC injection → Oral



Well-executed development strategy
- Take over lucrative market shares

Better treatment for Chronic patient
- Easy and quick administration
- Minimize side effects

Simple production and cheaper API
- Reduce production cost

Delivery of Oral Proteins / Peptides / Antibody

02 Global Oral Tech Status

- **Status**
  - POD™ (protein oral delivery) technology
    - OraMed Pharmaceuticals (oral insulin in Phase 2b)
  - Eligen® (SNAC) technology
    - Emisphere Technologies (oral semaglutide marketed by Novo Nordisk in 2019)
  - Phloral® and Soteria®
    - Intract Pharma (Oral infliximab in Phase 1b for IBD)

- **Limitations**
  - Delayed Onset time ➡ No fast action
  - Low biopotency and high cost ➡Big consumption of API
  - Potential side effect ➡ High amount permeation enhancer
  - Molecular size limitation ➡ Only small protein is feasible

03 SCD Strategy(Key Success Factors)

Succeeding with an oral formulation of a protein requires multiple factors to be in place

KSF	Our Solution
1 Carrier technology	*Nano-encapsulation or complexation*
2 High Protein absorption	*Better protection from enzyme degradation*
3 Low side effect	*Novel formulation using effective excipient*
4 Low API consumption	*High bioavailability and using commercially available APIs*

03 S-Pass Competitive Advantages

S-Pass

- **Quick onset time & Prolong release**
  - ✓ Comparable to IV/SC injection
- **By far the best absorption** rate & lowest cost
  - ✓ 10~100 times more effective than other technologies
- **FDA approved** polymeric excipients
  - ✓ High safety & advantage on registration
- **No oil & No antacid** contained
  - ✓ Minimize side effect
- **Solidified dosage form** to improve stability of API
  - ✓ Tablet/capsule/powder form
- **No surfactant** is used in S-Pass BC tech for safer chronic disease treatment

Chapter 2

S-Pass Technology

A company cares for human health and the future

Future together SCD

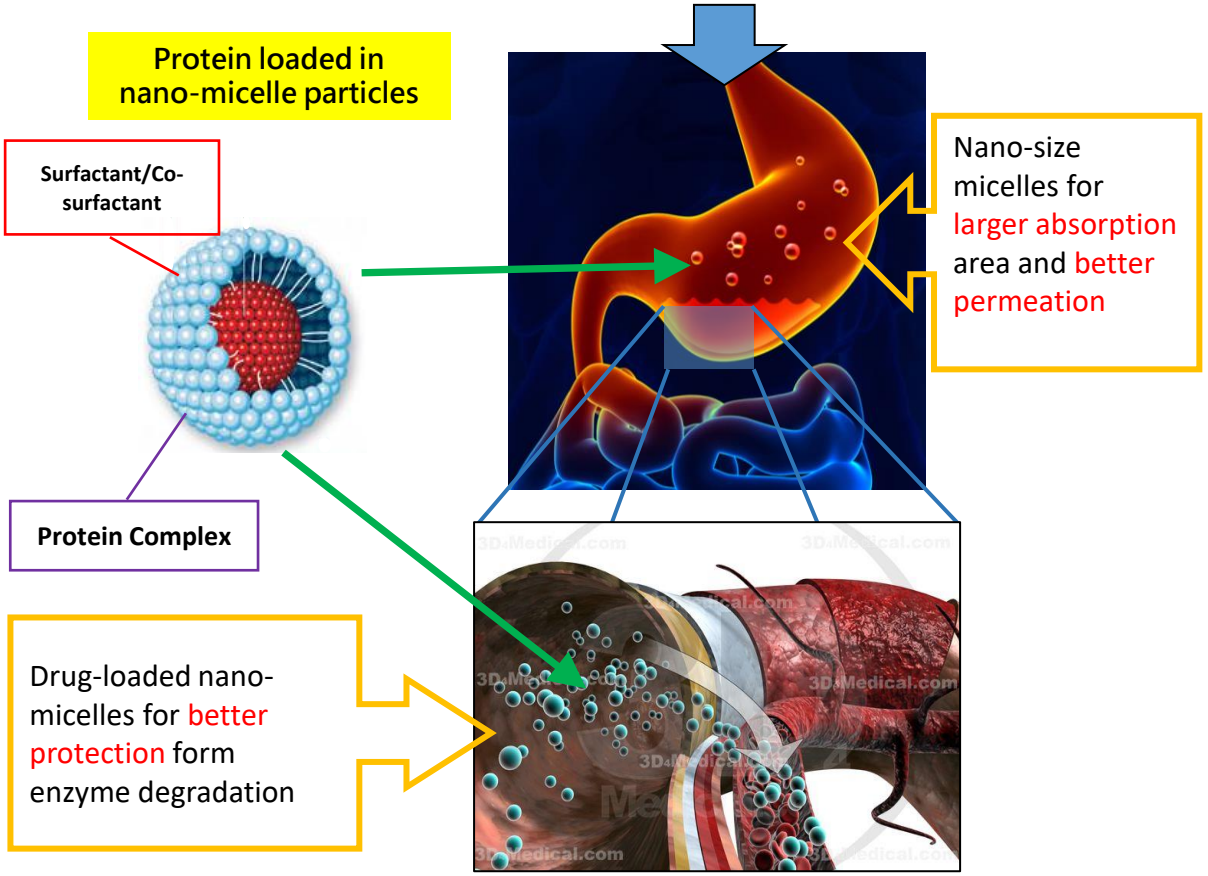
S-Pass MC tech(Novel Micelle-Complex Formulation)

Micelle-Complex Oral Formulation

Filled in capsule

With different polar excipients, protein molecules are encapsulated in polymeric excipients to **form liquid-crystal** liked micelle

The stability and absorption of encapsulated-drugs can be enhanced with their nano-size



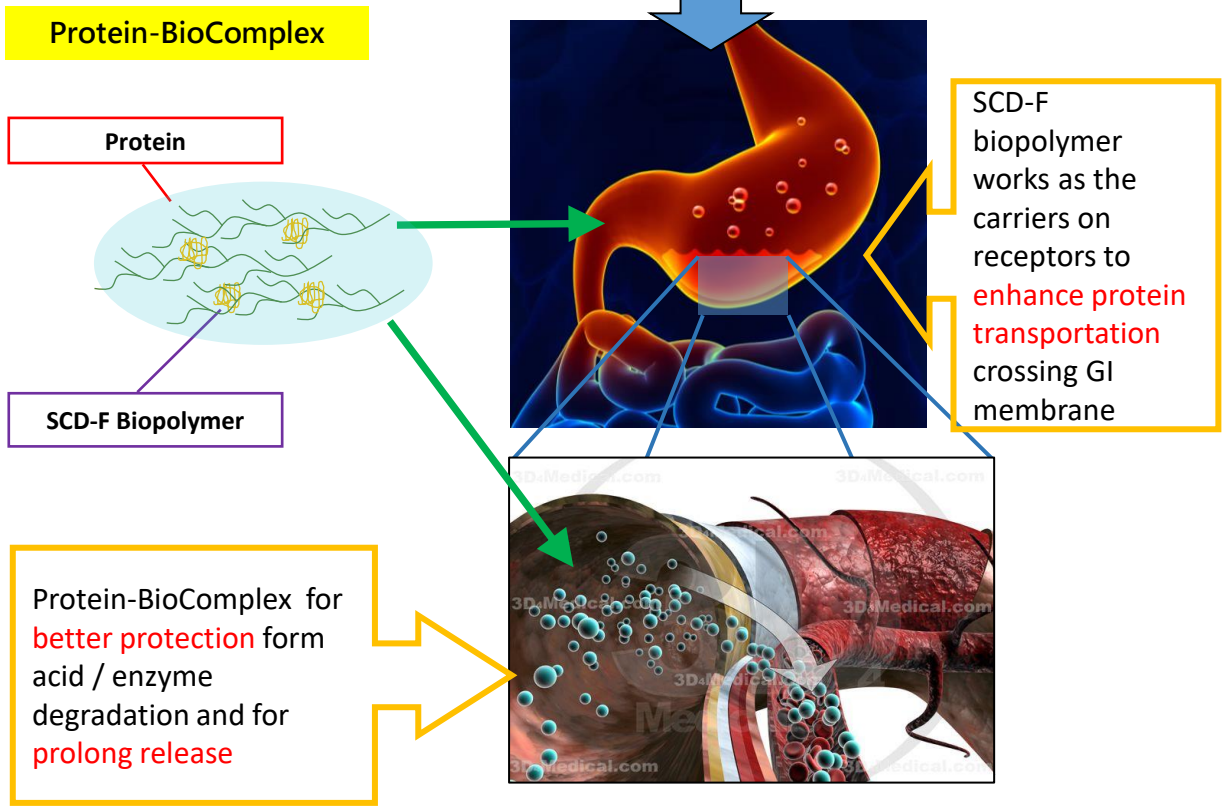
S-Pass BC tech(Protein-BioComplex Formulation)

Protein-BioComplex Oral Formulation

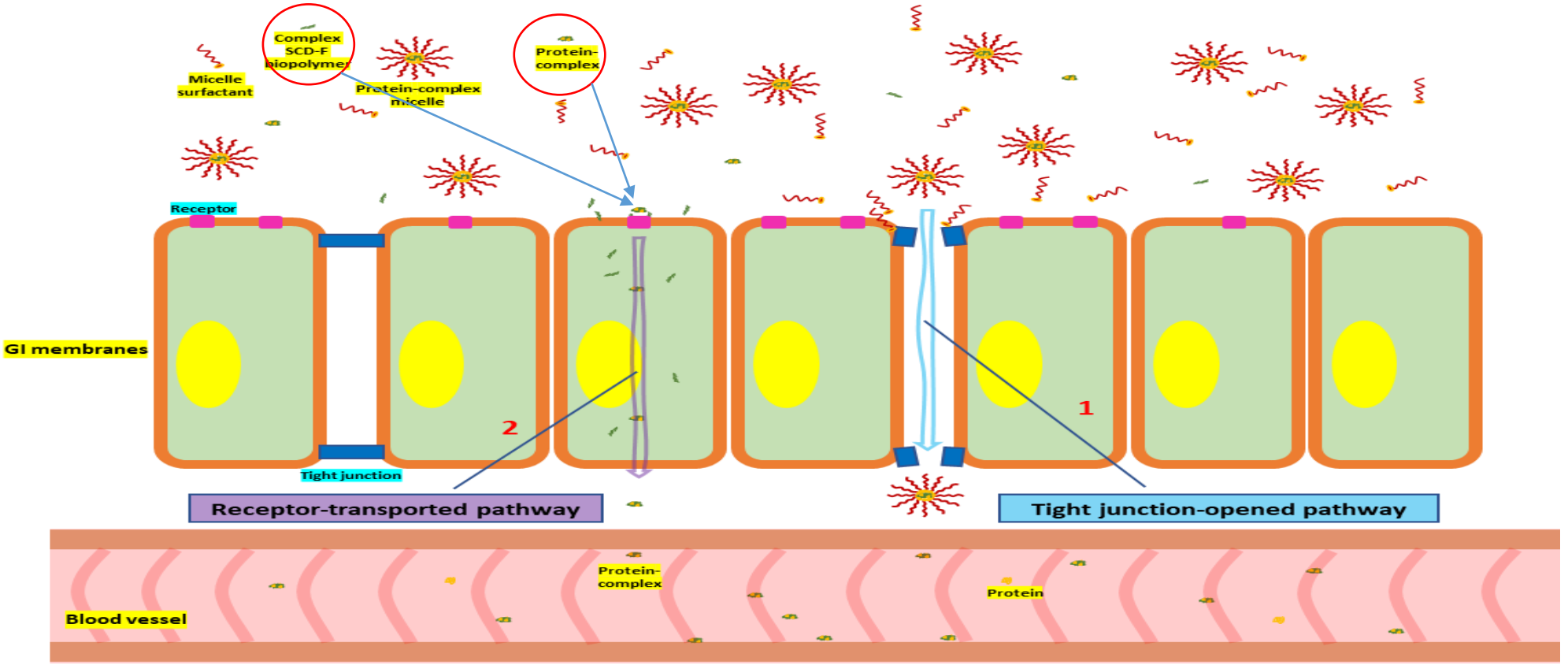
Filled in capsule

With optimized SCD-F biopolymers, protein molecules are complexed with polymeric excipients to Protein-BioComplex

Without any surfactant used, the stability and absorption of protein-biocomplex is improved by applying SCD-F biopolymer



Absorption of Novel Micelle and BioComplex Formulation



Absorption of SCD novel micelle-complex formulation is accomplished by dual-pathways:

1. Tight junction-opened pathway: mediated by micelle-formed surfactant to open tight junction
   - Main pathway of **S-Pass MC tech**
2. Receptor-transported pathway: mediated by complex-formed **SCD-F biopolymer** to trigger receptor-binding
   - Main pathway of **S-Pass BC tech**

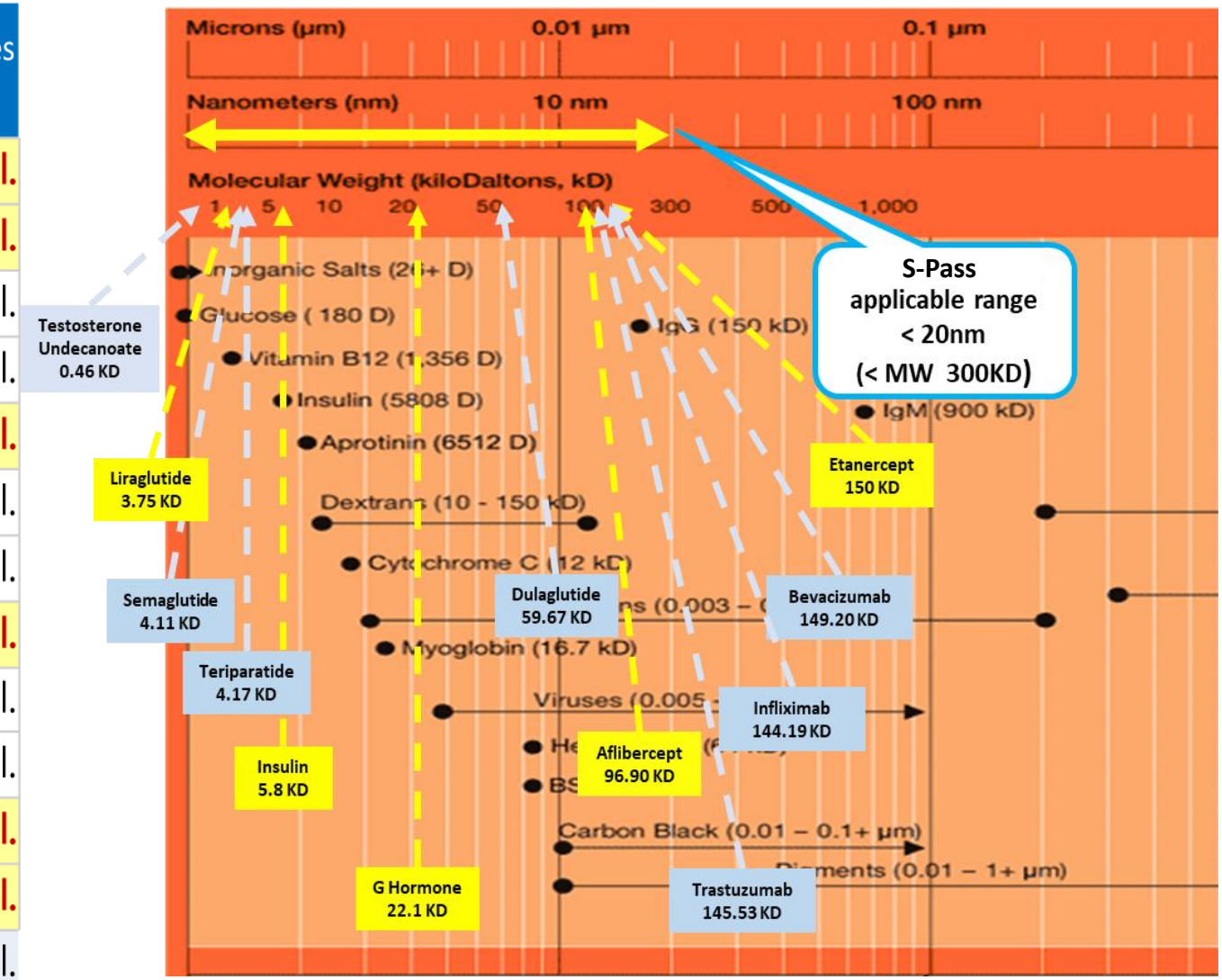
02 S-Pass pipeline

SCD pipeline

Item	Annual sales (2019)
Insulin	U$35.0Bil.
Etanercept(Enbrel)	U$10.6Bil.
Infliximab	U$9.1Bil.
Dulaglutide(Trulicity)	U$7.3Bil.
Liraglutide(Victoza/Saxenda)	U$6.7Bil.
Bevacizumab(Avastine)	U$6.6Bil.
Trastuzumab(Herceptin)	U$6.4Bil.
Somatropin (Genotropin)	U$4.5Bil.
Semaglutide(Ozempic/Rybelsus)	U$2.5Bil.
Teriparatide(Forsteo)	U$1.7Bil.
Aflibercept(Zaltrap)	U$1.4Bil.
Testosterone(Testopel)	U$1.2Bil.
Total	U$93.0Bil.

On going

Nano-size Consideration



Chapter 3

Current Projects

A company cares for human health and the future

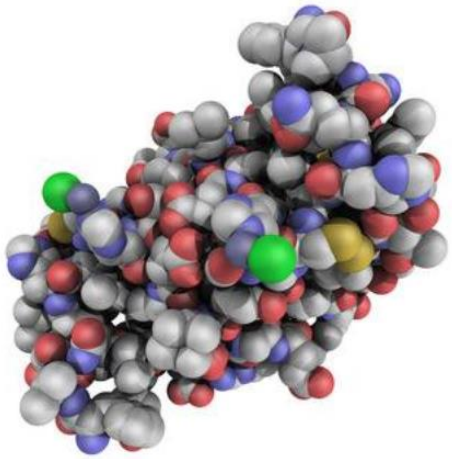
Go together with SCD

01 SCD0503(Oral Insulin)

02 SCD0506(Oral Liraglutide)

01 SCD0503(Oral Insulin)

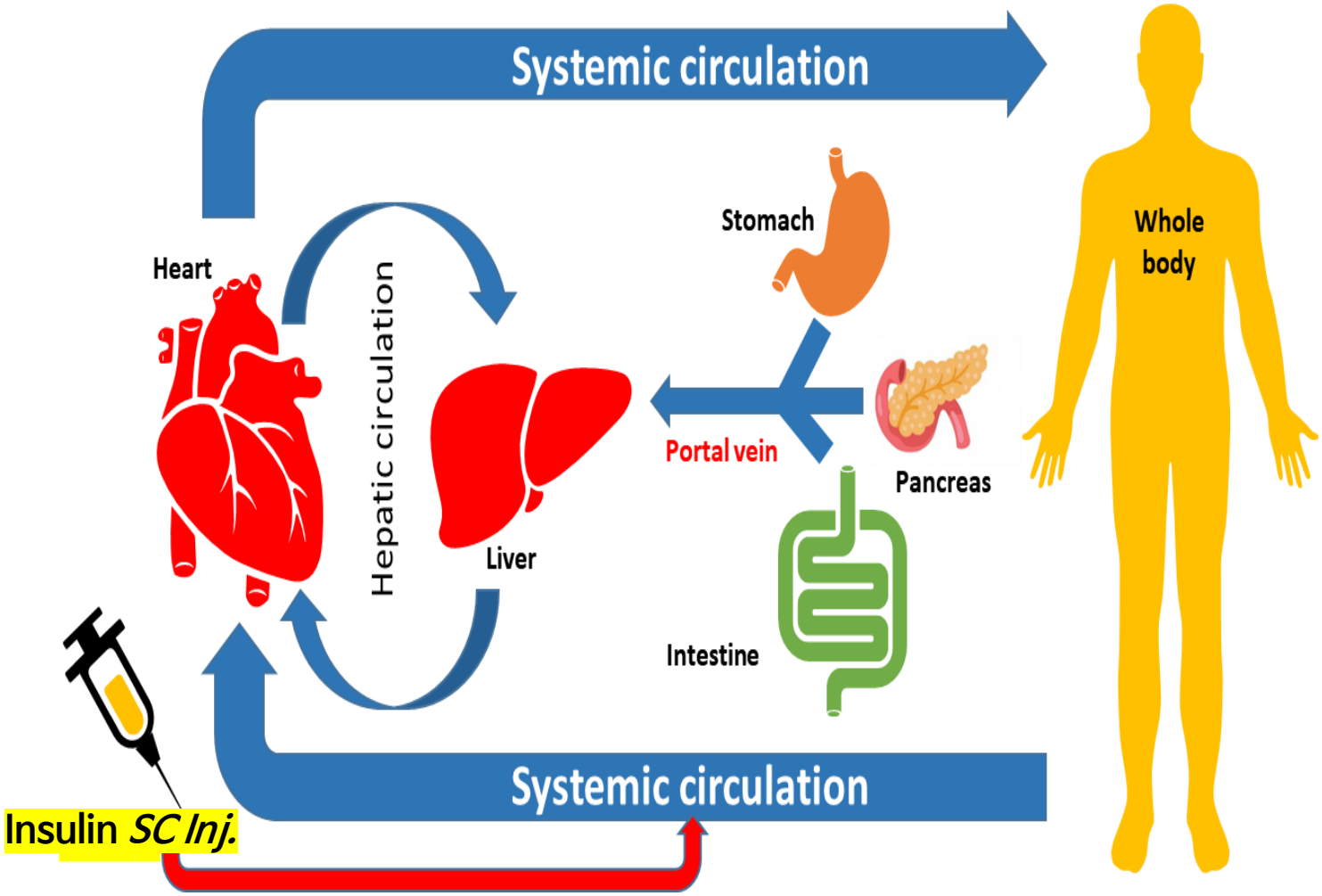
- Target Indications:
  - Type 1 DM
  - Type 2 DM
- API: Human insulin
- Dosage Form: **Hardgel capsule**
- Potential competitor: ORMD-0801 (OraMed)
  - Enteric coating with delay onset
  - Not idea to control postprandial blood glucose



SCD0503(Oral Insulin)

- Exogenous insulin
  - *SC* injection
- Target organ
  - Directly to **whole body** by systemic circulation
  - Less portal/peripheral insulin gradient
- Risk
  - **Weight gain** due to high insulin conc. in systemic circulation
  - **Hypoglycemia** due to overdose of insulin (original for enlarge portal/peripheral insulin gradient)

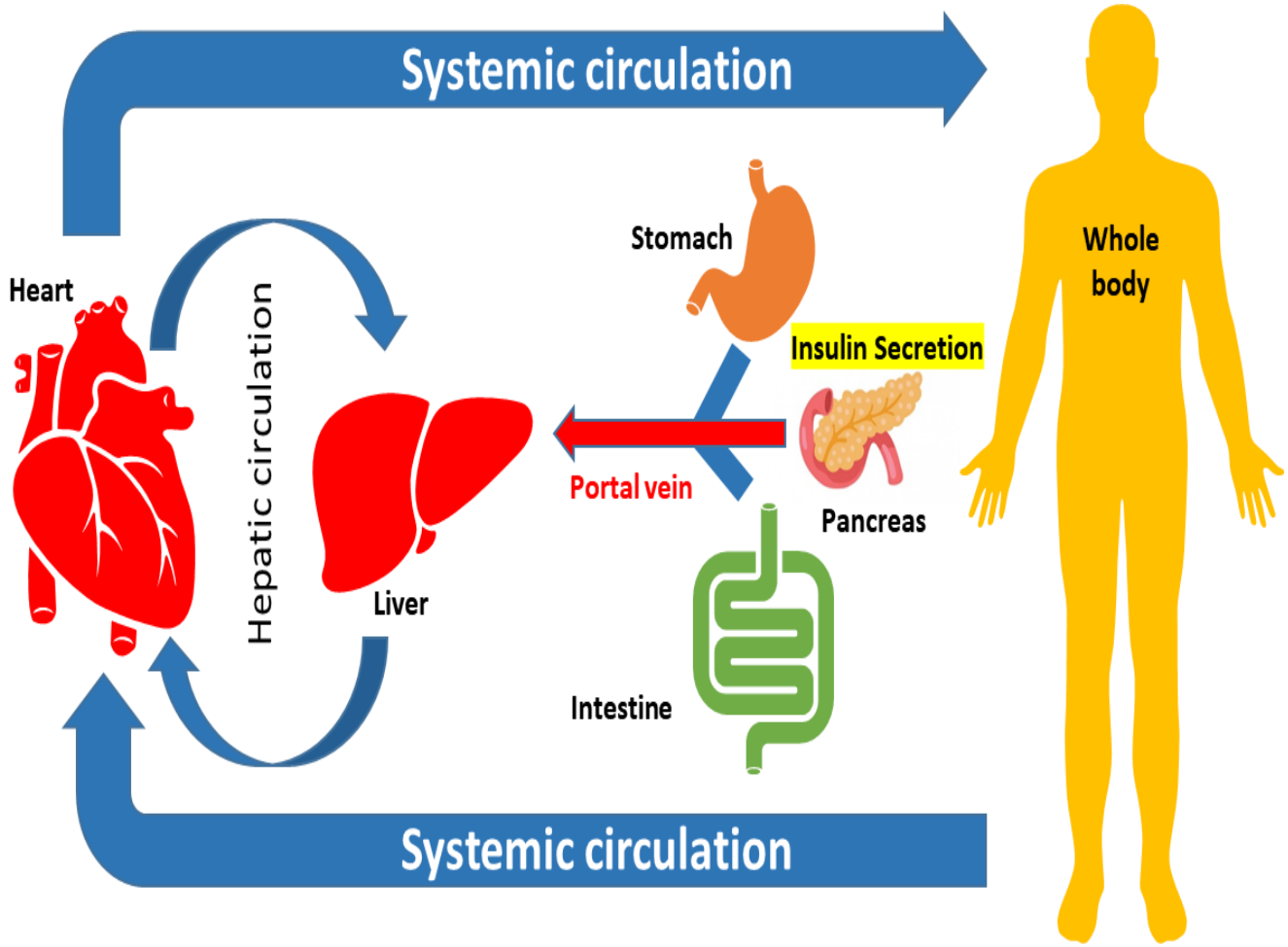
Insulin Flow (with SC injection)



SCD0503(Oral Insulin)

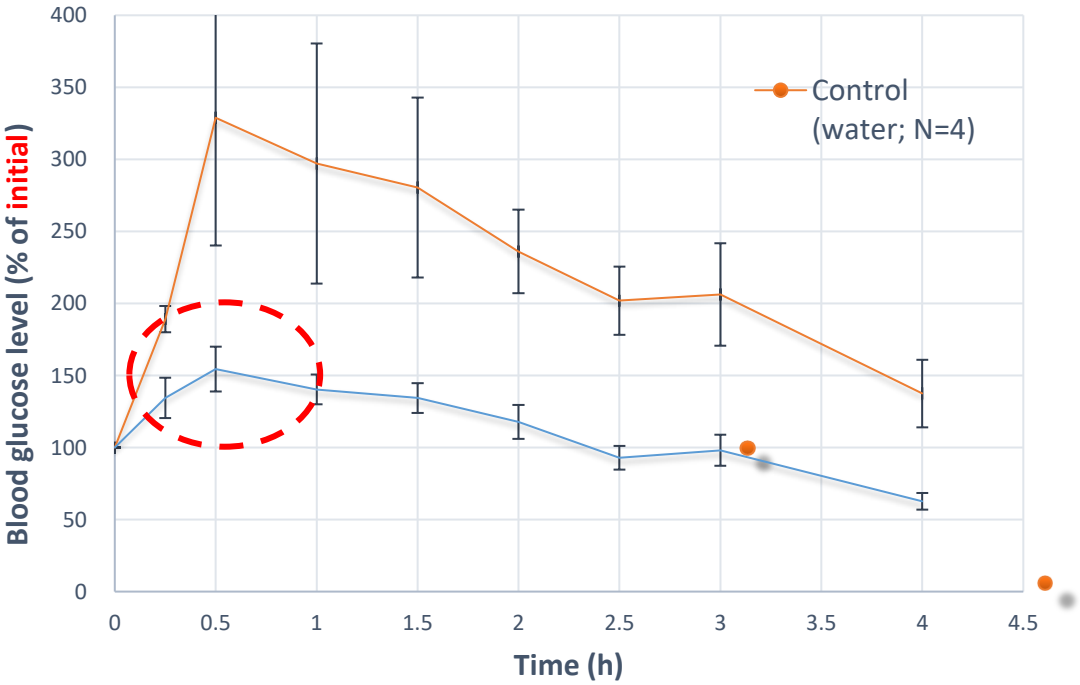
- Endogenous insulin
  - From pancreas
- Target organ
  - Liver by portal vein
  - Portal/peripheral insulin gradient by 80% first-pass effect
  - Hepatic insulinization
  - Less than 20% of insulin going to systemic circulation`

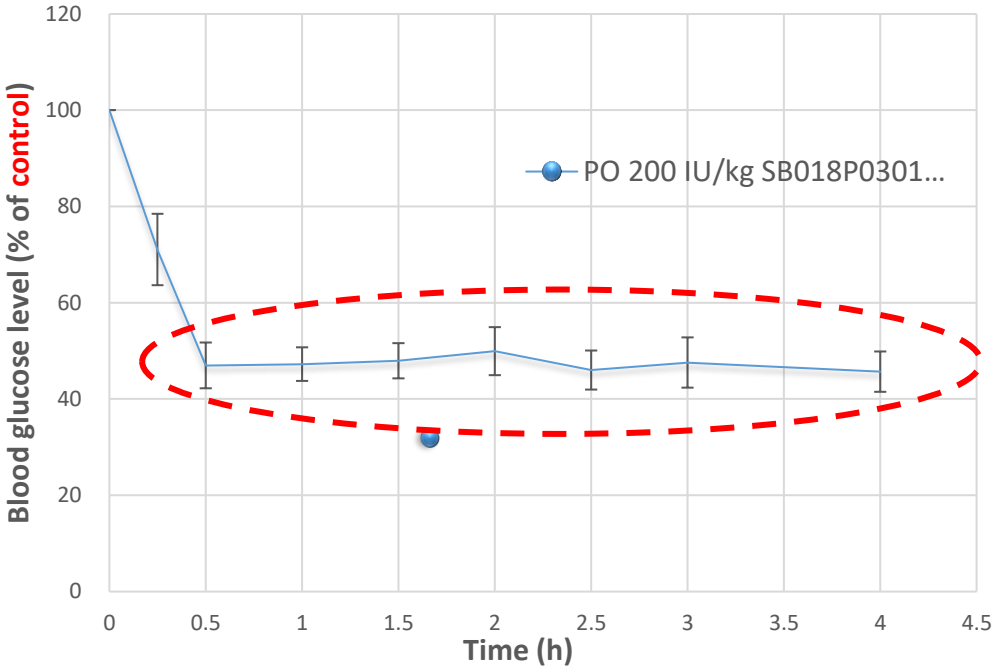
Insulin Flow (Natural & SCD oral Insulin)



SCD0503(Oral Insulin)

Nonclinical PD Study in Type 2 DM animal model

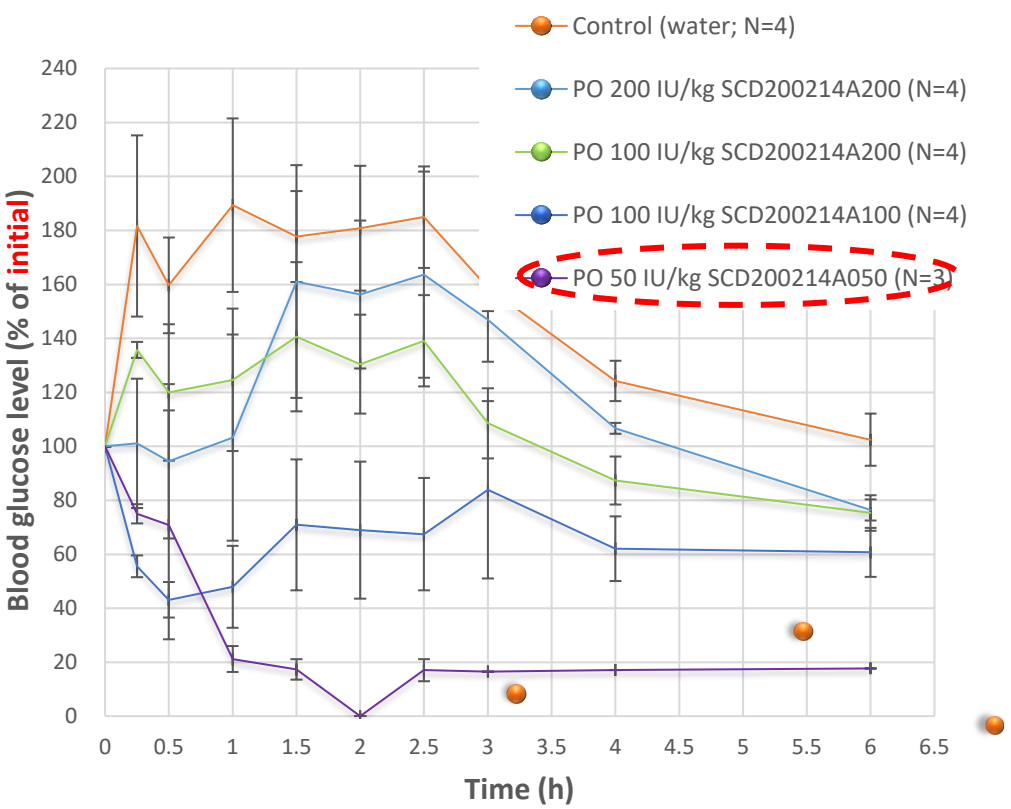


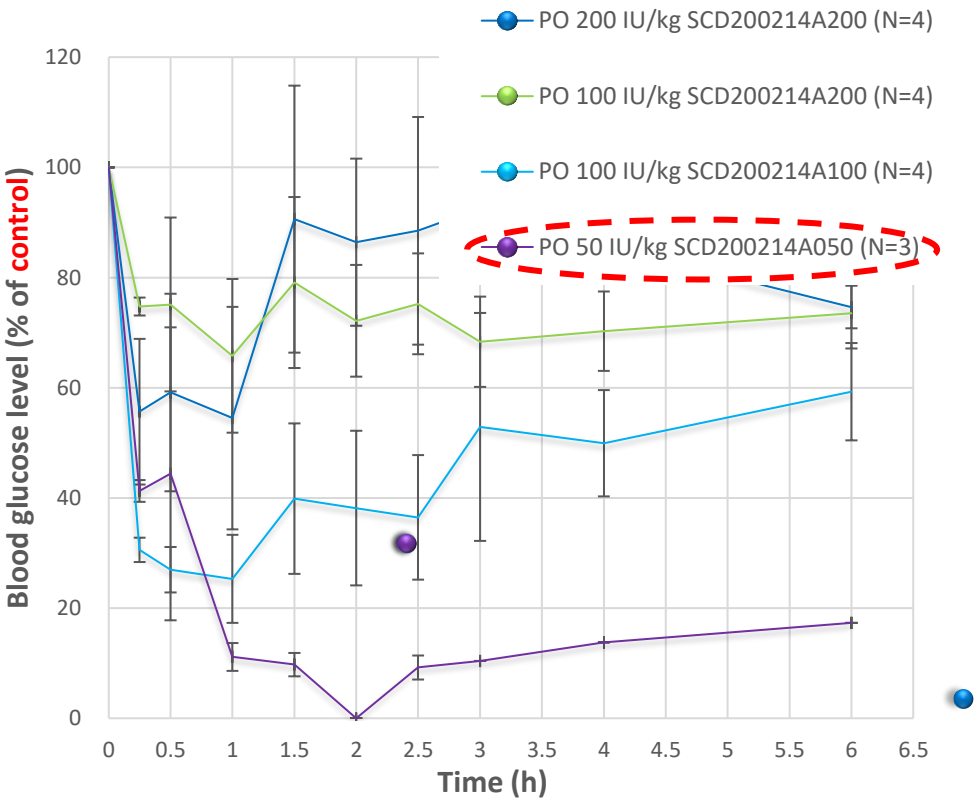


- Oral Insulin is effective to maintain blood glucose in low level *via* single oral dose administration for more than 4 hours
- Oral Insulin formulations present the efficacy of both quick onset around 30 min and 〉40% reduction of blood glucose comparing to the control group

SCD0503(Oral Insulin)

Nonclinical PD Study in Type 1 DM animal model

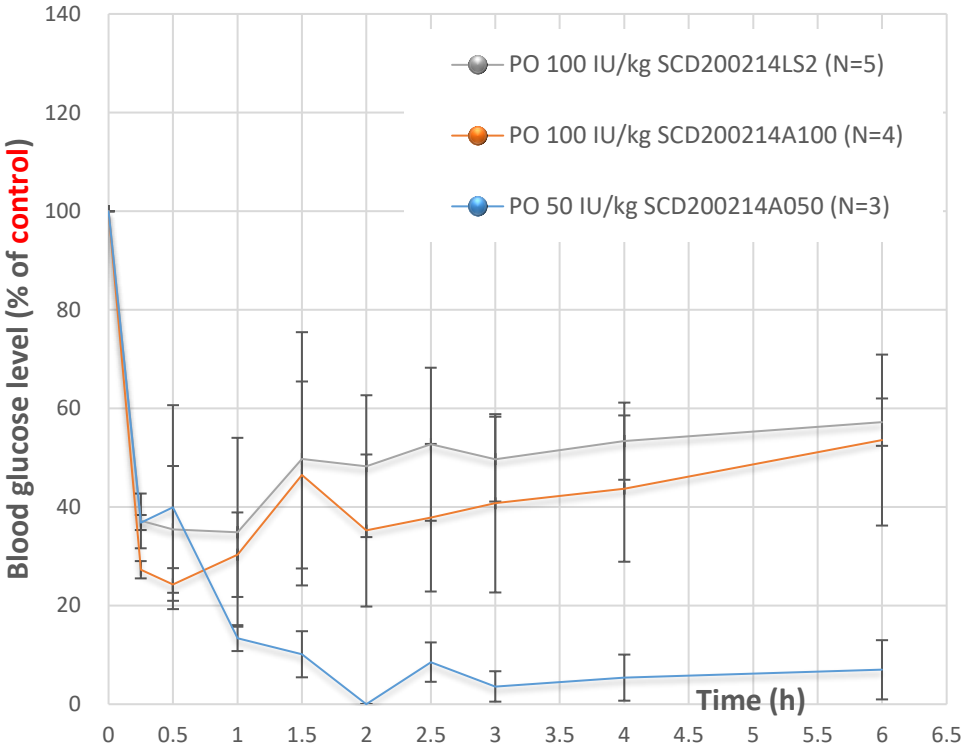


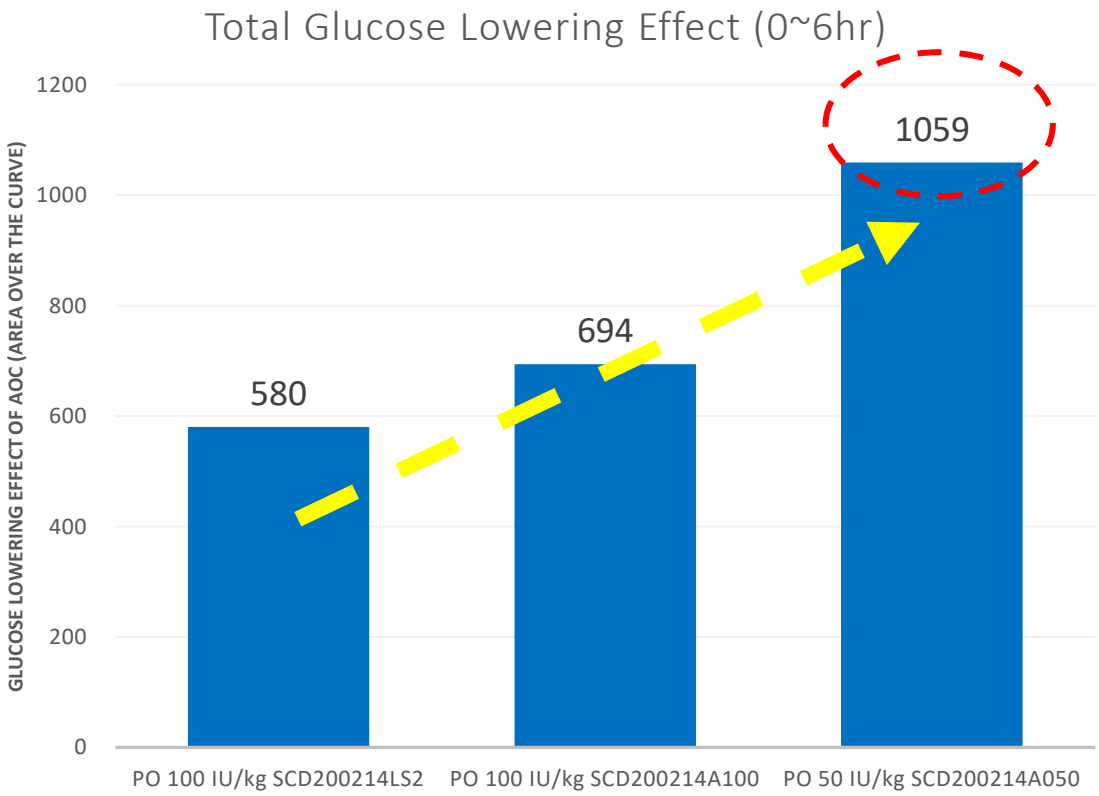


- Oral Insulin is effective to lower blood glucose immediately (〈 15 min.) and to control glucose level more than 6 hours and present the efficacy to have 〉 40% reduction of blood glucose *via* single oral dose administration vs control
- A series formulations applied by S-Pass BC tech platform is **more effective** even with **lower dose (50 IU/kg)** 〉 and show promising biopotency around 20% comparing to SC injection

SCD0503(Oral Insulin)

Nonclinical PD Effect Comparison in SCD0503 to Target T1DM





- Pharmacodynamic effect of SCD0503 is further improved from formulation LS2 to A050
  - ✓ Dose is further reduced into half from 100 IU/kg to 50 IU/kg
  - ✓ Efficacy is improved almost double from 580 to 1059
- A series formulations applied by S-Pass BC tech promising Biopotency around 20% comparing to sc injection

SCD0503(Oral Insulin)

Technology Comparison of ORMD-0801 *vs* SCD0503

ORMD-0801

Technology
- POD (protein oral delivery)
- permeation enhancer / protease inhibitor
- enteric coating: absorption starting from intestine (onset time 1.5 hours)
- concerns in long term side effect

Proposed Clinical Dose
- 32 mg /day
- API consumption
  oral : injection ≈ 16 : 1

Estimated API Cost
- COG = U$ 1.06 /day

* Treatment cost of Injection 2mg/day : U$10 / day

SCD0503

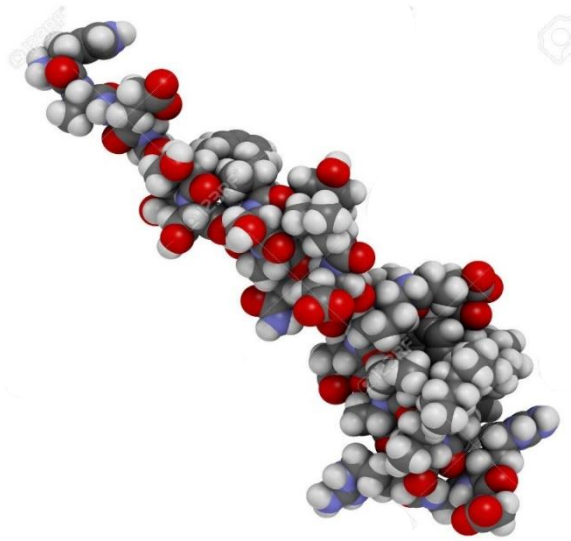
Technology
- S-Pass
- permeation enhancer / SCD-F biopolymer
- nano-tech: absorption starting from upper GI (onset time 0.5 hour)
- no risk in long term side effect with safe excipients

Proposed Clinical Dose
- 10 mg /day
- API consumption
  oral : injection ≈ 5 : 1

Estimated API Cost
- COG = U$ 0.33 /day

*Treatment cost of Injection 2mg/day: U$10 / day

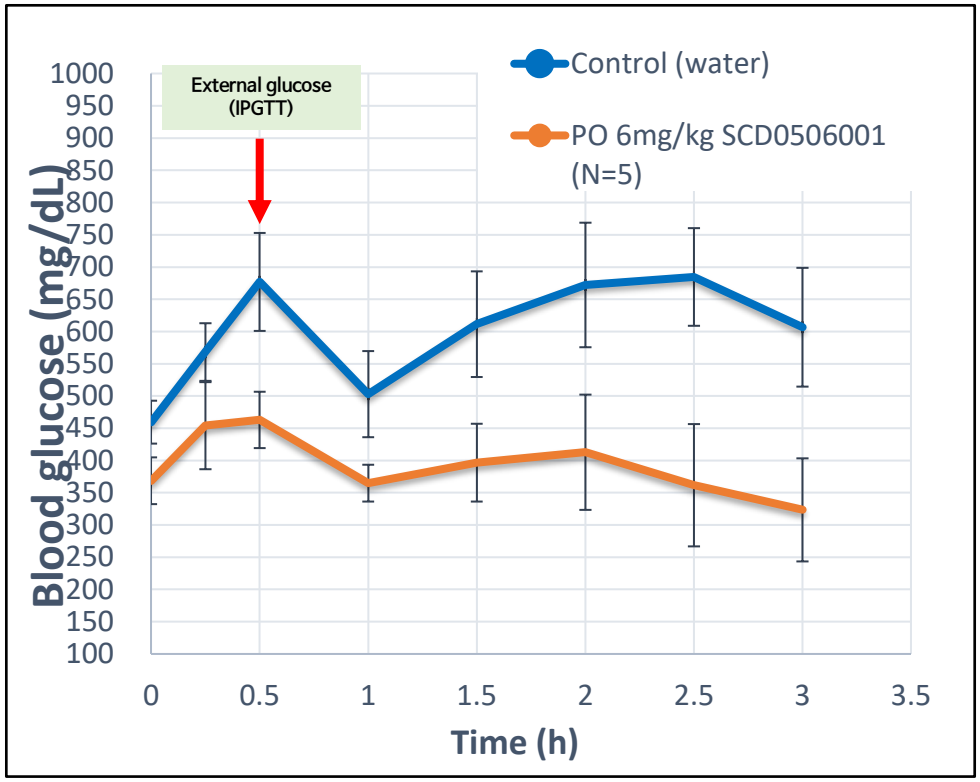
SCD0506/0507(Oral Liraglutide)

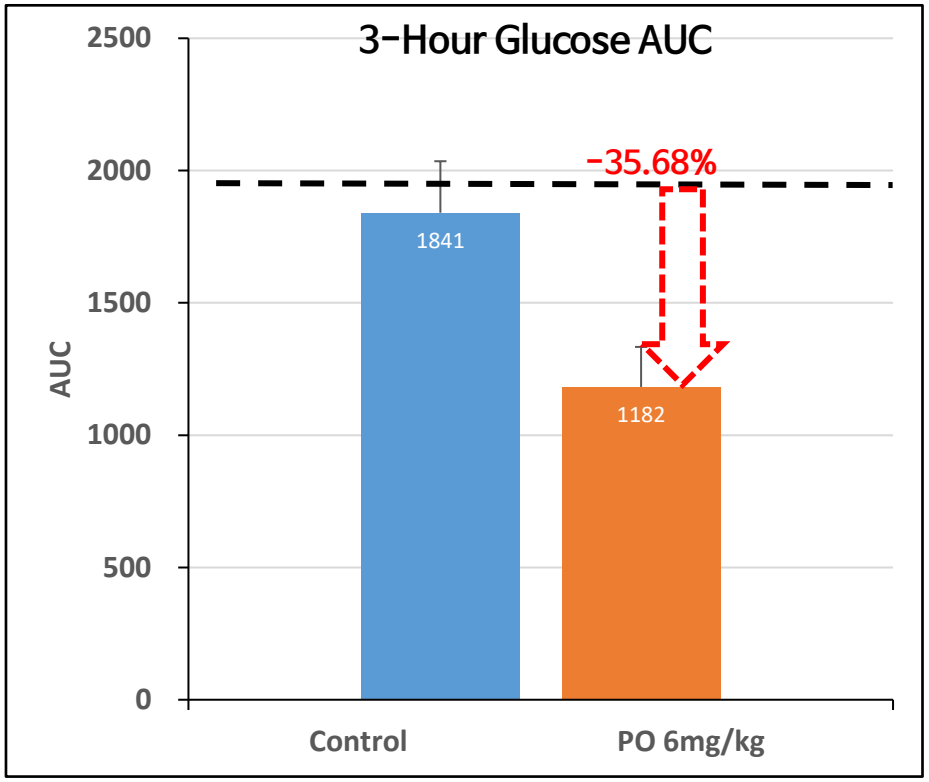


- Target Indications:
  1. Type 2 DM (SCD0506)
  2. Obesity (SCD0507)
- API: liraglutide
- Dosage Form: **Once daily hardgel capsule**
- Potential competitor: Oral Semaglutide (Novo Nordisk)
  - Once-daily tablet (RYBELSUS®) approved by FDA in Sep. 20th, 2019
  - Question to new excipient used (SNAC)

SCD0506(Oral Liraglutide)

Nonclinical PD Study in Type 2 DM animal model





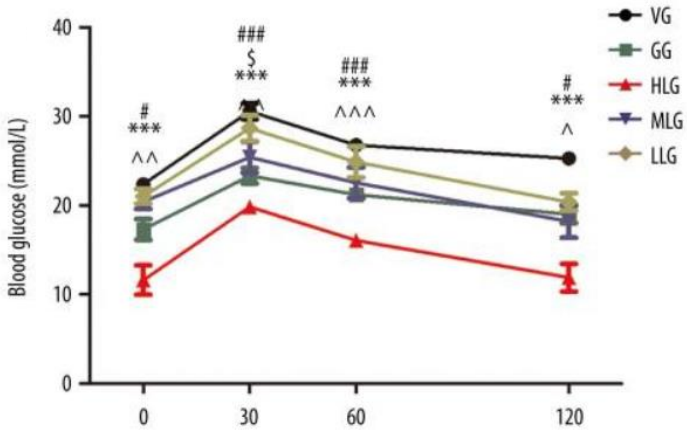
- IPGTT: intraperitoneal glucose tolerance test
  (right after oral dosing of liraglutide, 2g/kg of glucose is given to mice by IP immediately)
- 6mg/kg of SCD Oral Liraglutide by S-Pass MC tech is effective in T2D
  - ✓ Quick efficacy to lower blood glucose starting from 30 min after oral administration
  - ✓ Effectively control glucose level after external glucose administration by IPGTT through 3 hours

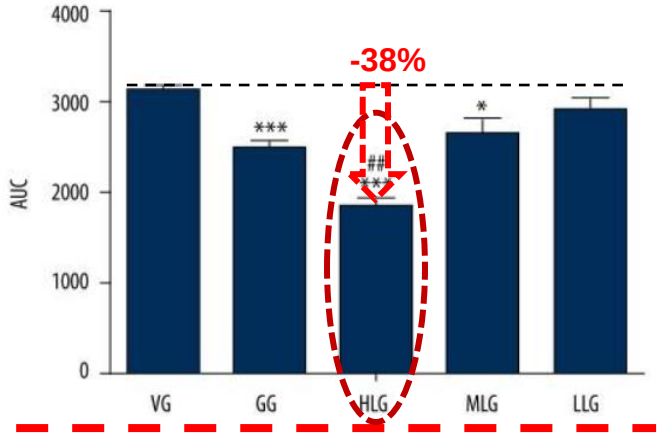
SCD0506(Oral Liraglutide)

Nonclinical PD Comparison between *SC(Victoza)* & SCD0506

SC study

- VG: control; GG: 450 μg/kg insulin glargine; HLG: high-dose liraglutide 300 μg/kg; MLG: mid-dose liraglutide 150 μg/kg; LLG: low- dose liraglutide 75 μg/kg
- The efficacy in AUC reduction with HLG treatment (300 μg/kg) is around **38%**



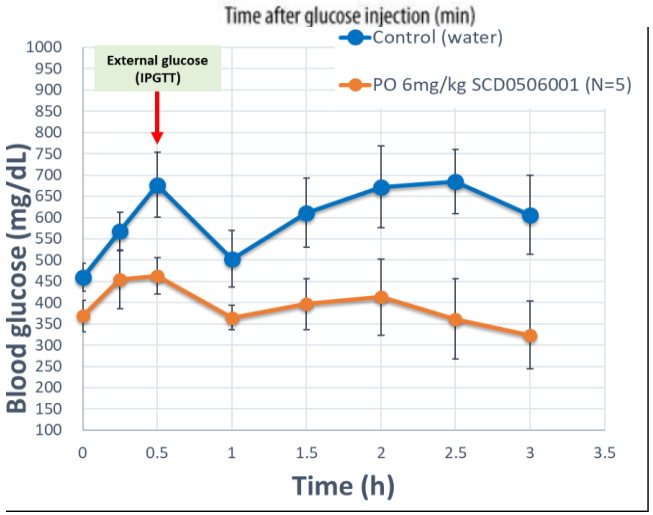


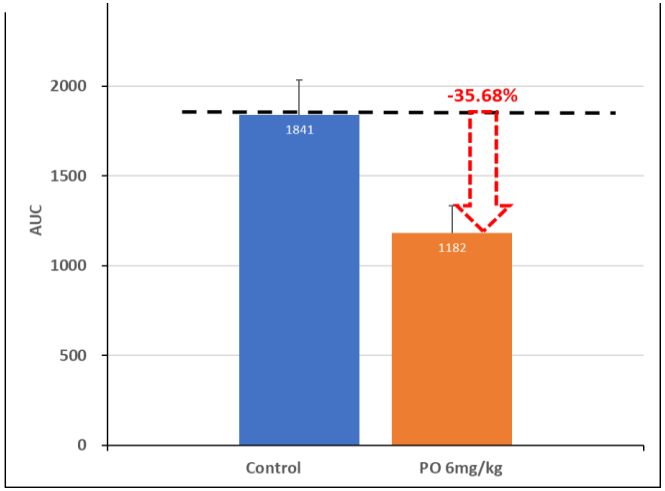
Oral study

- The efficacy in AUC reduction with SCD0506 treatment (6 mg/kg) is around **35.68%**

Dose Comparison (with similar efficacy)

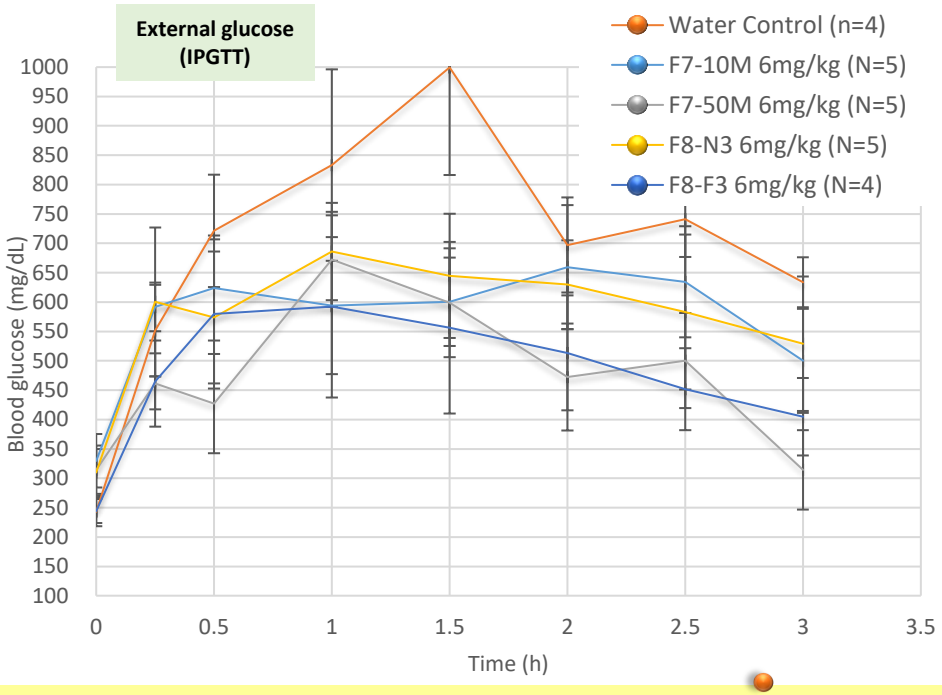
- Oral : SC = **21 : 1**
- The dose is around 20 which is showing its promising comparing to other oral protein pipelines in development
- Relative biopotency: **~ 5%**

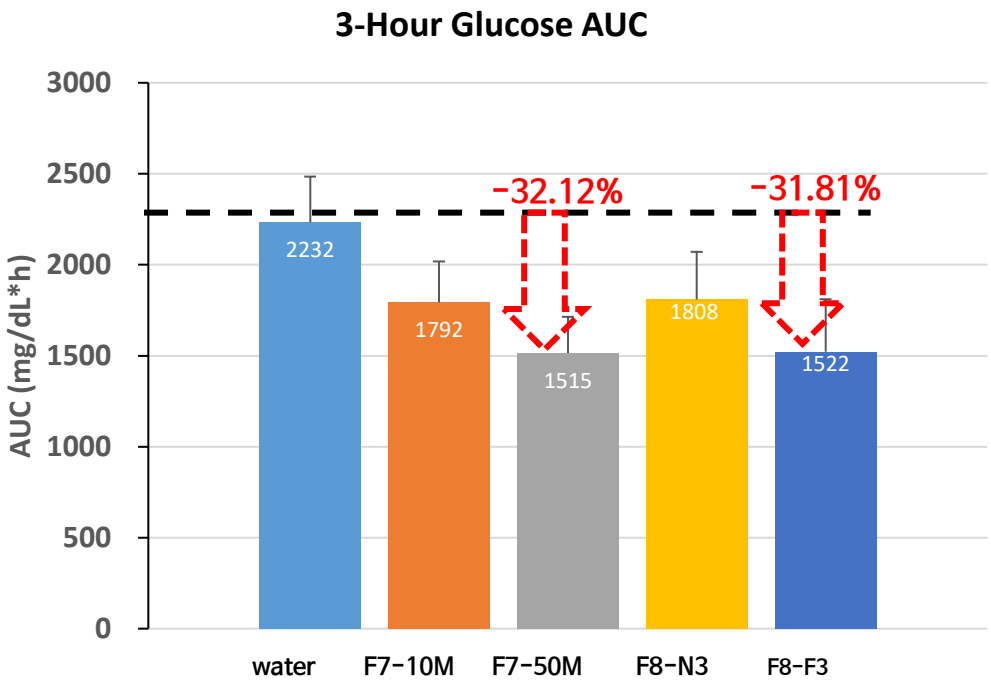




SCD0506(Oral Liraglutide)

Nonclinical PD Study in Type 2 DM animal model





- IPGTT: intraperitoneal glucose tolerance test
  (right after oral dosing of liraglutide, 2g/kg of glucose is given to mice by IP immediately)
- 6mg/kg of SCD0506 by S-Pass BC tech is effective in T2D
  - ✓ Quick efficacy to lower blood glucose starting from 30 min after oral administration
  - ✓ Effectively control glucose level after external glucose administration by IPGTT through 3 hours
- Expect to have **long acting effect (better biopotency)** as well as **lower production cost** with S-Pass BC tech application

SCD0506(Oral Liraglutide)

Semaglutide: SC(Ozempic) vs Oral(Rybelsus)

Dosing Route	Pharmacokinetic		Clinical Dose	
	AUC (nmol*h/L)	AUC/μg	mg	mg/day
SC (0.5mg)	3670	7.36	0.5mg per week (1mg maximum)	0.07mg/day
Oral (10mg)	250.3	0.025	7mg per day (14mg maximum)	7mg/day
Oral to SC ratio	-	**0.0034**		**100**

- The relative BA of Oral to SC is less than 1% (only 0.34%)
- The clinical dose ratio (Oral : SC) is around 100
- No significant side effect for high dose administration via oral route

✓ Comparing to oral semaglutide, the dose ratio of SCD0506 (~21) is more favorable in further clinical application with the relative Biopotency ~5%

SCD0506(Oral Liraglutide)

Dose Comparison (vs Oral Semaglutide)

Oral Semaglutide

Technology
- Eligen ®
- absorption enhancer (SNAC)
- new excipient with concern in long term side effects

API and Proposed Clinical Dose
- API: semaglutide
- 14 mg / dose / day
- API consumption
  oral : injection ≈ 100 : 1

Estimated API Cost
- High (U$ 7.70/day)

* Treatment cost(US) of oral Rybelsus : U$ 25.75 / day

SCD0506

Technology
- S-Pass MC / S-Pass BC
- permeation enhancer / SCD-F biopolymer
- no risk in long term side effect with safe excipients

API and Proposed Clinical Dose
- API: liraglutide
- 29.4 mg / dose / day
- API consumption
  oral : injection ≈ 16.3 : 1

Estimated API Cost
- Low (U$ 1.62/day)

* Treatment cost(US) of Victoza Injection : U$ 30.7 / day

Chapter 4

New Project

A company cares for human health and the future

Go together with SCD

01 Oral Monoclonal Anti-body

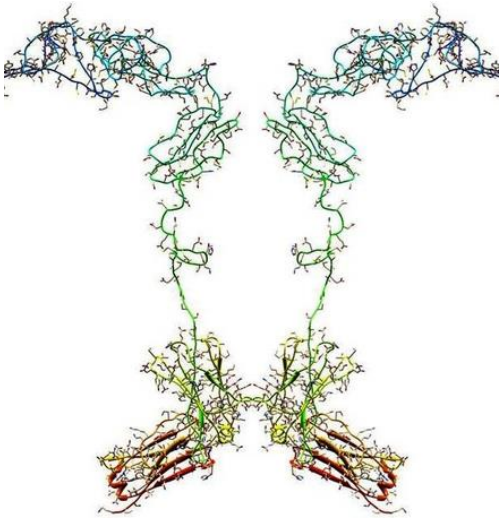
SCD0509(Oral Monoclonal Antibody)

API : Etanercept

- Target Indication:
  1. Rheumatoid Arthritis
  2. Psoriatic Arthritis
  3. Ankylosing Spondylitis
  4. Plaque Psoriasis

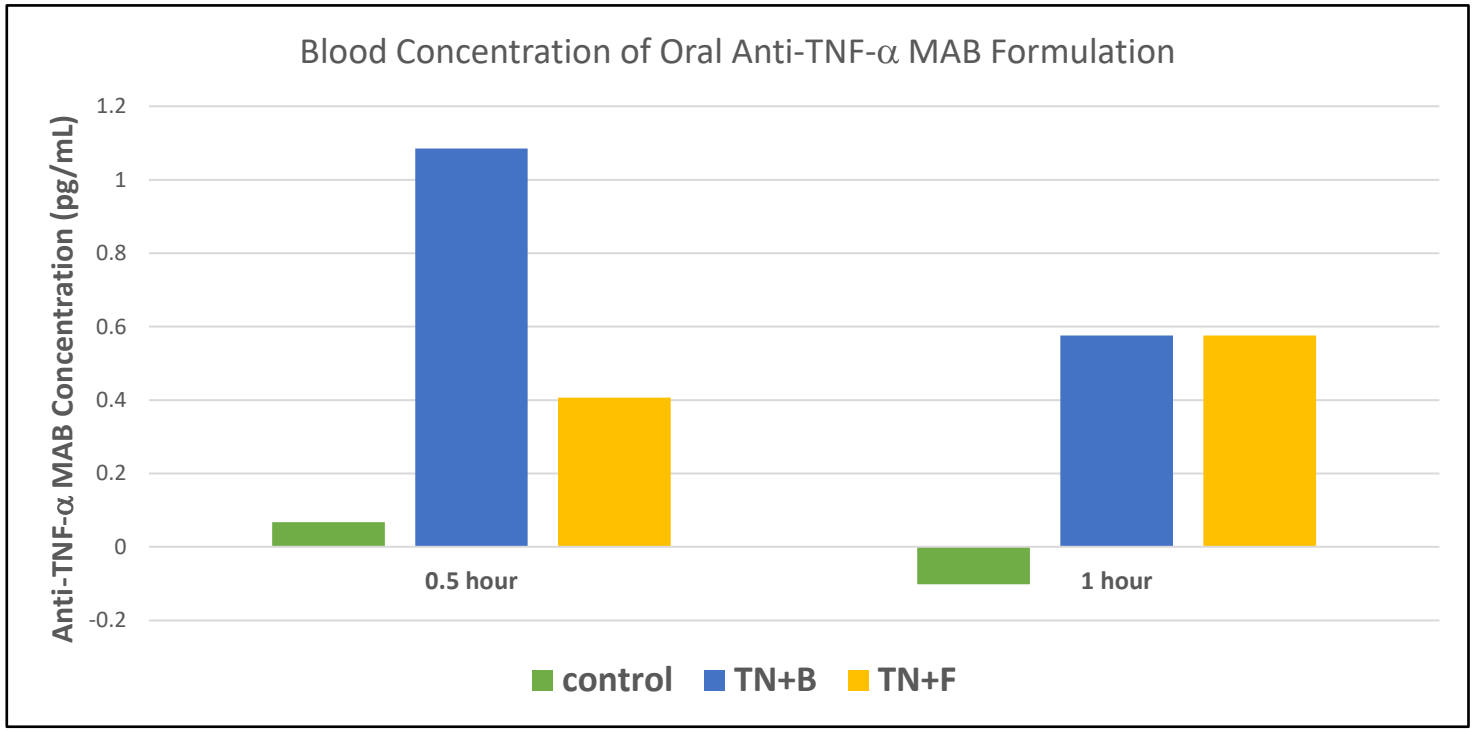
- Dosage form: Hardgel capsule
  - S-Pass BC technology
  - Protect from enzyme degradation
  - Enhance absorption via carrier mediated endocytosis
  - Twice per week

- Potential competitor: N/A



SCD0509(Oral Monoclonal Antibody)

Nonclinical Study to show the Absorption of Etanercept with S-Pass technology in the Mice (World 1st)



- SCD0509(anti-TNF-α MAB) is administered with two oral formulations (TN+B and TN+F) at 11mg/kg to mice. Blood concentrations are measured at 0.5 h and 1 h, respectively by ELISA. Purified water is used as control *via* oral administration.
- MAB can be delivered into the body *via* oral administration route with S-Pass technology.
- Etanercept is one of the largest molecule among MAB.

Technology Comparison of Intract Pharma *vs* SCD

Intract Pharma

Technology

- API: Infliximab; Indication, IBD
- Phloral® and Soteria®
- Target absorption in lower part of intestine (colon)
  - enteric coated (polymer and polysaccharide) to provide release of antibody in the colon (Phloral® tech)
  - excipients to protect MAB from enzymes (Soteria® tech)
  - onset time is delayed due to targeting colon for drug delivery
- Currently only targeting on local treatment by MAB without systemic efficacy

SCD

Technology

- S-Pass
- Target absorption in upper GI
  - no need to deal with complicate microorganism environment (such as in colon) to control protein release
  - permeation enhancer / SCD-F biopolymer
  - quick onset time due to starting absorption in upper GI
- Can be utilized for both local and systemic treatment

Chapter 5

Q & A

A company cares for human health and the future

Go together with SCD

Go together with

SCD

SamChunDang Pharm.Co.,Ltd.