













Yifan Group & Companies

Global

**Partners** 

**Product Portfolio**  **Pipeline** 





## YIFAN at a glance





## has evolved into a global pharmaceutical company with strong commercial presence across many regions

Poland (EU).

Biotechnology

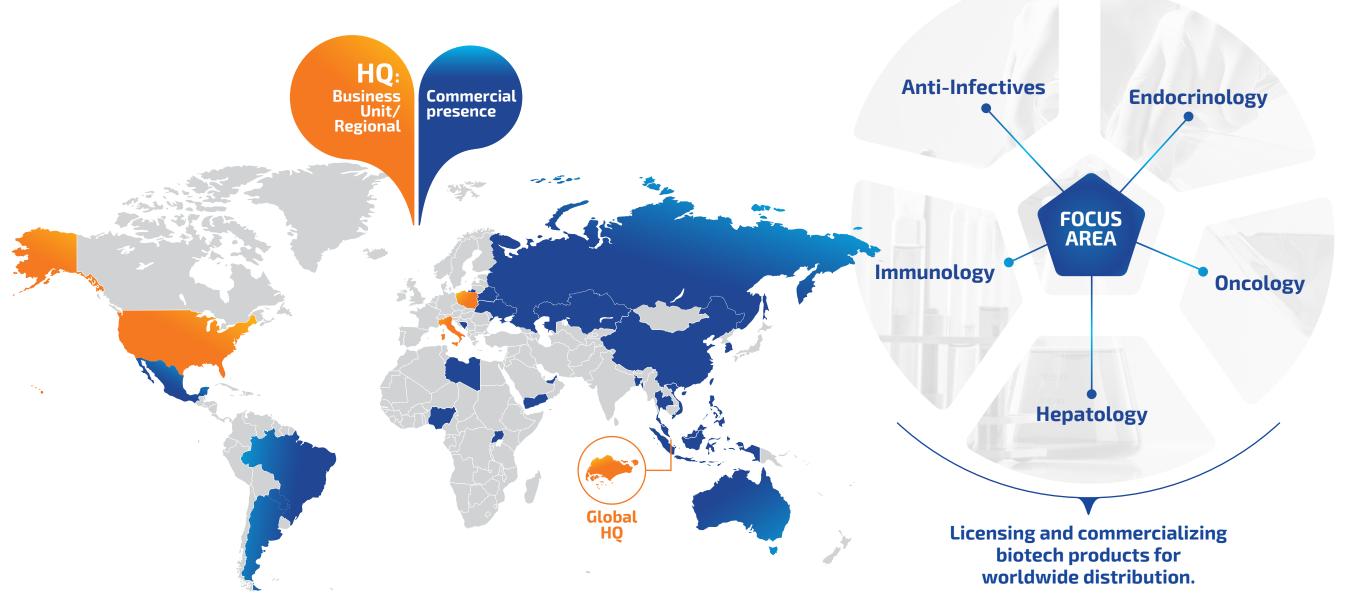
arm with

**US** assets





## Commercial arm dedicated to deliver high quality healthcare solutions worldwide





## Develops and manufactures human insulin and insulin analogs



- Facility is **GMP-compliant** and approved in European Union
- **Positive audits** from Big Pharma, and Health Regulatory Agencies (e.g. ANVISA)
- Quality Control and Quality Assurance designed to meet **EMA requirements**.
- **R&D team** with bioengineering, analytical labs and lab scale manufacturing plants
- Full cycle of insulin production from biosynthesis to packaging (cartridges and vials)



## Develops and manufactures injectable pharmaceutical products

Development and production of injectables

A fully owned subsidiary of Yifan Pharmaceuticals.



Development and production of injectable pharmaceutical products, with the authorization to manufacture

sterile drugs, precursors, corticosteroids and narcotics.

3 manufacturing lines (filling), 2 visual inspection machines US FDA/EU approved.





## Biotechnology arm of Yifan with US Assets and an experienced leadership team



#### **Leadership formerly**

from Amgen, Sanofi, Novartis, FDA, Eli Lilly, Daiichi Sankyo, Imclone



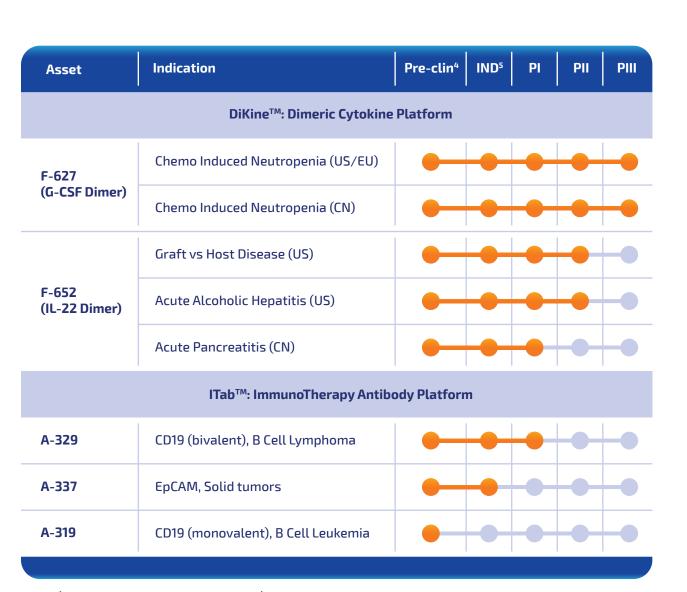
#### Innovative pipeline

First-in-class and best-in-class drug development programs from discovery through global Phase III



#### Global reach

R&D center in Shanghai, drug substance cGMP facility in Beijing, Regulatory in the US with CR01s and DP2 CMO supporting globally



Notes: 1) Granulocyte-Colony Simulating Factor; 2) Chemotherapy Induced Neutropenia; 3) Graft vs Host Disease; 4) Pre-clinical; 5) Investigational New drug

Our Global Partners

### Our Global Partners

















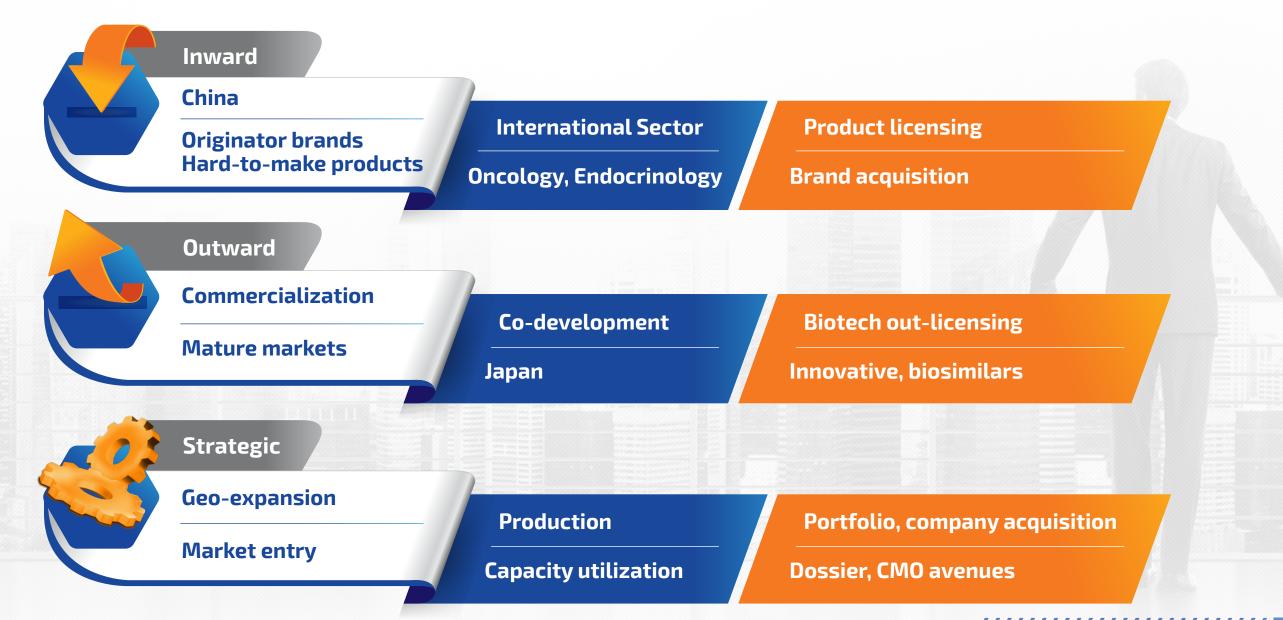




TEIKOKU SEIYAKU



## Partnering initiatives focus on inward and outward transactions, for small and large molecules, covering mature and developing markets



Product portfolio: Endocrinology

# GENSULIN® SciLin<sup>TM</sup>

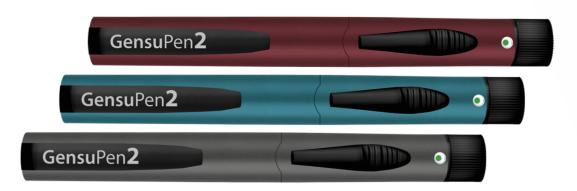
High quality European human insulin with 20 years of experience confirms the products' effectiveness, safety and stability





## Insulin Delivery Devices injectable pharmaceutical products

THOUSANDS OF SATISFIED PATIENTS WITH GENSUPEN® AROUND THE WORLD



- GENSUPEN 2®
  A new generation of Insulin pen devices
- Modern, automatic pen injectors with a dial-back mechanism
- Maximum dose 60IU, minimum increment 1IU



Automatic, low-force delivery system Constant speed of the drug injection

A visible signal indicating end of the dose injection Convenient emplacement of the trigger button

Automatic delivery of insulin, reducing the pain and risk of tissue traumatization, significantly improving convenience, providing patients with better metabolic control and satisfaction in their treatment.



### **Analog Pipeline**

Development process ongoing for insulin technologies including: Advancing diabetes portfolio with new analog pipeline

#### Lispro

(rapid-acting insulin analog)

### Glargine

(long-acting insulin analog)

### **Aspart**

(rapid-acting insulin analog)

- Commercial launch:
  From 2023 through 2025 starting with
  Lispro, followed by Glargine and Aspart
- Global scope: Process and clinical development programs along with regulatory filings for US, EU and RoW (ex. Japan)
- Regulatory approach: BLA filing in US and MAA filing in EU will be submitted at around the same time

### SciTropin A<sup>™</sup>

### (Somatropin)

#### Biosynthetic human Growth Hormone manufactured in Europe



SciTropin A<sup>™</sup> is synthesized in E.coli cells that are identical to naturally occurring Human Growth Hormone suitable for:

#### Children

Growth disturbance due to insufficient secretion of growth hormone (growth hormone deficiency, GHD)



# Adults Replacement therapy in adults with pronounced growth hormone deficiency



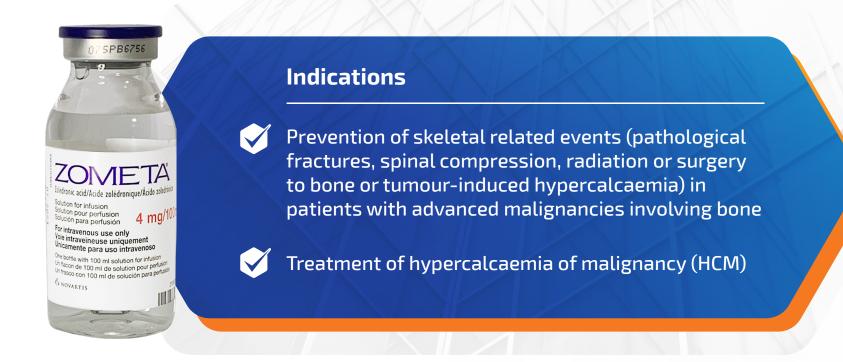
Product portfolio:
Oncology and
Hepatology



### Legacy of proven efficacy and safety for bone metastasis and hypercalcemia of malignancy

**Zometa**<sup>®</sup> has a legacy of proven efficacy and safety profile

**Zometa® 4mg/100ml** is a ready-to-use infusion, which is more convenient and accurate for HCPs



Currently marketed in APAC: Australia, Brunei, Hong Kong, Indonesia, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

## Advancing a portfolio of innovative assets addressing unmet medical needs

Asset	Overview	Recent Accomplishments	Upcoming Milestones
F-627	<ul> <li>Dimeric rhG-CSF fusion protein</li> <li>Novel formulation to compete with Neulasta and biosimilars in the \$6bn global CIN market</li> </ul>	<ul> <li>Global pivotal trial positive read out May 2020</li> <li>Dec 2019, China pivotal trial successfully completed</li> </ul>	<ul><li>US BLA filing in Oct 2020</li><li>China BLA filing in Oct 2020</li></ul>
lTab	<ul> <li>Bi specific antibody platform for immune oncology</li> <li>Multiple assets in pre-IND and Phase I for China and global development in liquid and solid tumor types</li> </ul>	China Phase I trial for CD19/CD3     antibody to treat B cell     malignancies FPFV Sep 2019	China Phase I trial for CD19/CD3 antibody to treat B cell malignancies completion in 2021
F-652	<ul> <li>Dimeric rhIL-22 fusion protein to treat multiple inflammatory disorders</li> <li>Active development programs in AH, aGvHD, COVID-19, and AP</li> <li>Potential FIC, orphan drug and Breakthrough status</li> </ul>	<ul> <li>ODD for aGvHD granted in Oct 2019.         aGVHD resultpresented at TCT         Feb. 2020 and EBMT Mar. 2020</li> <li>AH Phase II Study published         in Hepatology in Nov 2019</li> <li>COVID-19 pre-IND approved May 2020</li> </ul>	<ul> <li>aGvHD EMA OD submission May 22, PRIME June 4. Phase 2b-3 in plan</li> <li>AH IND submission May 2020. FDA BTD submission in preparation. Phase 2b in plan</li> <li>COVID-19 IND submission</li> </ul>

## ITab<sup>™,1</sup> platform generates unique CD3-activating multi-specific antibodies to address unmet needs in the Immuno-Oncology space

Tumor affinity

Mono/bivalent binding in bi- and tri-specific formats

- Strong and targeted tumor affinity
- Accumulation of activated T cells within tumors

Safety

2<sup>nd</sup> generation CD3 engaged with selective T cell activation

- Low risk of cytokine release syndrome
- Manageable safety window

Stability

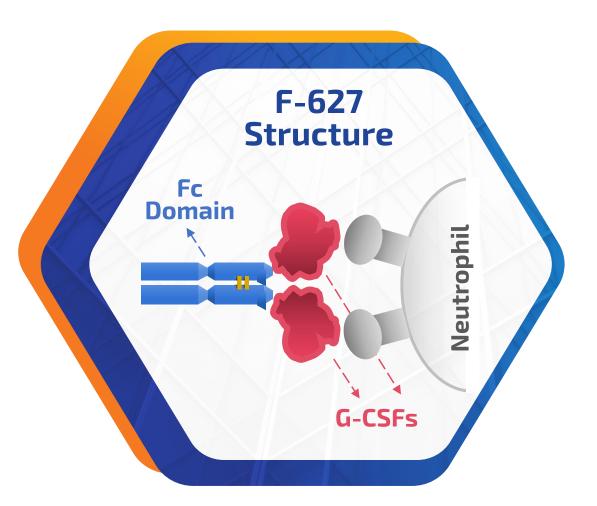
CHO2 expression manufacturing

- Commercial scale manufacturing in 30L bioreactors
- High stability with low aggregation

Asset	A-337	A-319	A-329	
Target	Target EpCam CD1 (Bivalent) (Monova		CD19 (Bivalent)	
Indication	Solid Tumors  B cell malignancies		Non-Hodgkin's Lymphoma	
Status	Ph I (Australia)	Ph I (China) FPFV3 Sep 2019	IND ready	

Notes: 1) ImmunoTherapy Antibodies; 2) Chinese hamster ovary; 3) First Patient First Visit

## F-627 is a novel long-acting G-CSF<sup>1</sup> with completed China and global Phase III trials for CIN<sup>2</sup> with US, EU and China filings in 2020



- Novel dimeric Fc fusion protein structure
- Avoids PEGylation used in other long-acting G-CSFs

### Advantageous combination of efficacy and improved safety

- F-627 combines the strength of Neupogen with convenience of Neulasta
  - The only novel long-acting G-CSF with data against both pegfilgrastim and filgrastim
- F-627's non-pegylated formulation reduces the possibility of severe allergic reactions caused by the pegylation<sup>1</sup>
- Robust clinical development program incl. placebo, Neupogen and Neulasta-controlled Phase III trials.
- Global commercial partnering process for US, Europe and Japan.

## F-652 is a dimeric recombinant human IL-22 fusion protein with unique potential to treat multiple inflammatory disorders

Endogenous IL-22 plays a pivotal role in tissue protection and repair during injuries or infections

F-652 programs ongoing for treatment of Alcoholic Hepatitis, GvHD1 and Acute Pancreatitis

**IL-22** 

#### **Epidermal keratinocytes**

- Increased anti-bacterial defense
  - Retarded differentiation and cornification

### Intestinal epithelial cells

- Increased anti-bacterial defense
- Elevated mucus production

### Respiratory epithelial cells

- Better anti-bacterial defense
- Enhanced proliferation

#### **Hepatocytes**

- Increased acute-phase protein production
- Elevated liver progenitor cell proliferation

#### **Synovial fibroblasts**

- Elevated RANKL expression
  - Increased production of monocyte-attracting chemokines





#### Pancreatic cells

- · Inhibition of autophagy
- Enhanced islet cell proliferation

### First-in-class approach to treat inflammatory disorders

- Traditional therapies mediate immune system
- IL-22 addresses impacted tissues by eliciting host defense against infection, and tissue repair to maintain tissue homeostasis

#### **Strong scientific position**

- Published discoveries in Nature Med. Science (2008), Immunity (2012) and Nature (2015)
- Ph IIa for Alcoholic Hepatitis completed and filing for breakthrough status underway
- Ph IIa for Acute GvHD1 ongoing and received orphan drug designation in Oct 2019
- Strong scientific position

#### Market potential<sup>2</sup>

 Alcoholic Hepatitis 10yr cumulative sales projection > U\$\$4b

Notes: 1) Graft vs Host Disease; 2) Alcoholic Hepatitis for US, EU-5 and JP included. GvHD and Acute Pancreatitis not included

Product portfolio:
Anti-Infectives



### **Registered products**

Active Pharmaceutical Ingredient	Dosage Form	Volume/strength	MA Holder Countr	y of MA
Amikacin	Ampoule	500mg /2ml	6	
Bupivacaine <sup>1</sup>	Ampoule	Multiple		
Cefotaxime	Vial, Ampoule	Multiple		
Chloramphenicol sodium succinate	Vial, Ampoule	1g/10 ml solvent		
Dobutamine <sup>1</sup>	Vial	250mg /20ml		
Erythromycin lactobionate	Vial, Ampoule	Multiple		
Fructose-1,6-Diphosphate Trisodium Salt	Vial	10g/100ml solvent		
Furosemide	Ampoule	20mg/2 ml		
Gentamicin sulphate	Ampoule	Multiple		1
Heparin	Vial, Ampoule	Multiple	fisioph@rma 🎉	
Lidocaine hydrochloride <sup>1</sup>	Ampoule	Multiple		
Megestrol acetate	Tablets	160mg	Ita	aly
Midazolam HCl	Ampoule	Multiple		
Pamidronate	Vial	Multiple		
Piperacillin	Vial, Ampoule	Multiple		
Piperacillin/tazobactam	Vial	Multiple		
Potassium aspartate	Ampoule	Multiple		
Tobramycin	Ampoule	Multiple		
Triamcinolone acetonide <sup>1</sup>	Vial	Multiple		
Vancomycin hydrochloride	Vial	Multiple		

<sup>&</sup>lt;sup>1</sup> Bupivacaine, Dobutamine, Lidocaine hydrochloride and Triamcinolone acetonide are not available in US



## Registered products with Fisiopharma as Contract Manufacturing Organization (CMO)

Active Pharmaceutical Ingredient	Dosage Form	Volume/ strength	MA Holder	Country of MA
Amiodarone	Ampoule	150mg/3ml	Third Party	Canada
Chloramphenicol	Vial	1000mg	<b>Co-owned</b>	Israel Canada Australia Netherlands
Cyanocobalamine	Vial	10ml, 30ml	Third Party	Canada
Dexamethasone	Vial	20mg/5ml	Third Party	Canada
Fructose biphosphate disodium salt	Vial	5g	Third Party	Vietnam



### **Products under development**

Active Pharmaceutical Ingredient	Dosage Form	Volume/ strength	Dossier Owner	Dossier Availability	Excluded Territory
Sugammadex	Vial	2, 5 ml	Fisiopharma	2020	China
Triamcinolone Acetonide (new formulation)	Vial	1, 5, 10 ml	Third Party	2019	US
Propofol (new formulation with aqueous base – low contamination risk and less pain)	Vial	<b>20</b> , 50, 100 ml	Third Party	2020	N/A
lloprost	Ampoule	2 ml	Third Party	2019	China

### Why partner with Scigen?



- We believe in delivering solutions that matter to the people of today and innovating for the people of tomorrow.
- To us, it is more than a business - it is a mission.



- We combine a specialty pharmaceutical business with a leading biologics biotechnology engine.
- We partner to bring the best drugs we can find to the patients who need it most.



- Our R&D efforts aim to deliver better patient outcomes through better science.
- We understand that humility and service matter as it is not about us, it is about making patients' lives better.

## Reach out to our representative for a deeper conversation today



**Ba The Nguyen** 

Country Manager Vietnam bathe.nguyen@scigen.com.sg



Deepak Kadecha

Regional Head - Middle East, Africa & India deepak.kadecha@scigen.com.sg



**Bharath Jayaraman** 

Head of Commercial Markets APMA **bharath.jayaraman@scigen.com.sg** 



**Grzegorz Ornowski** 

Region Head - Europe & CIS grzegorz.ornowski@scigen.com.sg



**Churairat Erstmann** 

Commercial Manager Thailand churairat.erstmann@scigen.com.sg



Rubens Paulella

Region Head - Latin America rubens.paulella@scigen.com.sg

#### SciGen Pte Ltd

150 Beach Road, #32-05/08 Gateway West, Singapore 189720

Tel

+65 6779 6638

Fax

+65 6779 3784