

## YIFAN Biological Product Catalogues

Novel Biologics Approved				
Product	Indication	Dosage/Strength	Target	Regulatory Approvals
<b>Efbemalenograstim alfa injection</b> <b>Brand Name:</b> <b>Ryzneuta®</b>	Chemotherapy-induced neutropenia (CIN)	Subcutaneous injection in PFS 1ml:20mg	G-CSF	NMPA: May. 2023 FDA: Nov. 2023 EMA: Mar. 2024 ANVISA: Dec. 2024

Novel Biologics Under Development					
Product	Indications	Stage	Target	Advantages	
<b>F-652 Recombinant Human Interleukin22-Fc Fusion Protein Injection</b>	Alcoholic Hepatitis (AH), Acute-on-chronic Liver Failure (ACLF), Acute Graft versus Host Disease (aGVHD)	Highest global status: clinical phase II	IL-22	<p>*Developed based on Yifan's DiKine™ platform validated on the approved product (Ryzneuta)</p> <p>*Obtains GMP-certified manufacturing sites by NMPA, FDA, and EMA, capable of both pilot and commercial scale production</p>	<p>*Good safety profiles and trend for improved efficacy in phase IIa for monotherapy and combined therapy with steroids from 200+ subjects in US, China, and Australia</p> <p>*FDA granted aGVHD orphan drug, with possibility of conditional approval for ACLF treatment</p>
<b>F-899 Recombinant Human Growth Hormone-Fc Fusion Protein Injection</b>	Growth hormone deficiency	Clinical phase Ia completed	GH		*Longer elimination half-life, supporting longer administration intervals

Core Biosimilars Under Development						
Product	Indications	RLD	Stage	EP/USP	CP	US DMF
<b>Human Growth Hormone (Somatropin)</b>	Growth hormone deficiency	Norditropin® Novo Nordisk	<p>*Pre-IND submitted</p> <p><b>*Drug substance marketable</b></p> <p>*BDP marketable by Q3 2025</p>	Y	Y	Filed
<b>Insulin Glargine</b>	Diabetes	Lantus® Sanofi	<p>*Pre-IND in preparation</p> <p><b>*Drug substance marketable</b></p>	Y	Y	Ready to File

<b>Insulin Degludec</b>		Tresiba® Novo Nordisk		Y	Y	/
<b>Insulin Aspart</b>		NovoRapid® Novo Nordisk		Y	Y	/
<b>Teriparatide</b>	Osteoporosis	Forteo® Eli Lilly	*Pre-clinical studies completed *Drug substance marketable	Y	Y	Ready to File
<b>Liraglutide</b>	Weight management, Type II diabetes	Victoza® Novo Nordisk	Research & Development	Y	Y	/
<b>Semaglutide</b>	Weight management, Type II diabetes	Ozempic® Novo Nordisk	Research & Development	Y	Y	/

\*RLD: Reference listed drug

Tool Enzymes				
Project	Expression System	Cleavage/Digestion	Usage	Potency
<b>Recombinant Trypsin</b>	E.coli.	Specific cleavage on the C-terminal of lysine (K) and arginine (R)	*Alternative therapy for indigestion *Food Industry: Protein depressant *Biotech/Pharmaceutical Industries: Enzymatic digestion and gene splicing	Specific Activity ≥ 5000 U/mg
<b>Recombinant Carboxypeptidase-B (CPB)</b>		Specific hydrolysis of the C-terminus of protein peptides containing basic amino acids (lysine, arginine, and histidine) on the N-terminal	*Biotech/Pharmaceutical Industries: Enzymatic digestion and enzyme-induced synthesis	Specific Activity ≥ 80 U/mg
<b>Lys-C</b>		Specifically target on enzymatic digestion for lysyl peptide bonds, including aspartate-lysine (DK) and proline-lysine (PK) peptides		Specific Activity ≥ 20 U/mg
<b>Recombinant Bovine Enterokinase (Light Chain)</b>	Yeast	Cleavage of the C-terminus of lysyl peptides containing 4 consecutive aspartates (DDDDK)	*Hemorrhage prevention and treatment *Biotech/Pharmaceutical Industries: Enzymatic digestion	Specific Activity 5.0 U/μL*
<b>Kex-2 Protease</b>		Specific recognition and cleavage on the C-terminal of basic peptides such as arginine-arginine (RR), lysine-arginine (KR)	*Biotech/Pharmaceutical Industries: Enzymatic digestion	Specific Activity ≥ 8 U/mg

\*In aqueous form

***If you are interested, welcome to get in touch  
with us***

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