

InnoStar nonclinical Safety Evaluation Platform



Shanghai InnoStar Bio-tech Co., Ltd. (InnoStar) was established in 2010. As a leading contract research organization, we strive for excellence through our services with high quality, win customers by recognized reputation, add values by technical innovation, and maintain efficiency by streamlined management. Our business scope covers screening and discovery services, nonclinical pharmacodynamics, nonclinical pharmacokinetics, nonclinical safety evaluation, clinical sample bioanalysis, biomarkers and translational research. InnoStar was listed on the STAR Market of Shanghai Stock Exchange on September 3, 2024 (Stock code: 688710).

Nantong InnoStar (320,000+ Sqft 500+Staff) Screening and Discovery Services Nonclinical Pharmacokinetics Nonclinical Safety Evaluation Nonclinical Pharmacodynamic • Radioisotope Platform InnoStar (HQ) Ophthalmology Integrated (190,000+ Sqft 570+Staff) **Evaluation Platform** Nonclinical Safety Evaluation Clinical Bioanalysis Biomarkers and Translational Medicine **Shenzhen InnoStar** InnoAllianceU.S. (110,000+ Sqft 80+Staff) Screening and Discovery Services Clinical Bioanalysis **Huangshan InnoStar** Nonclinical Pharmacokinetics (717,600+ Sqft) Nonclinical Safety Evaluation • Primate Laboratory, Animal Breeding, and Research Lab

OECD GLP

AUT

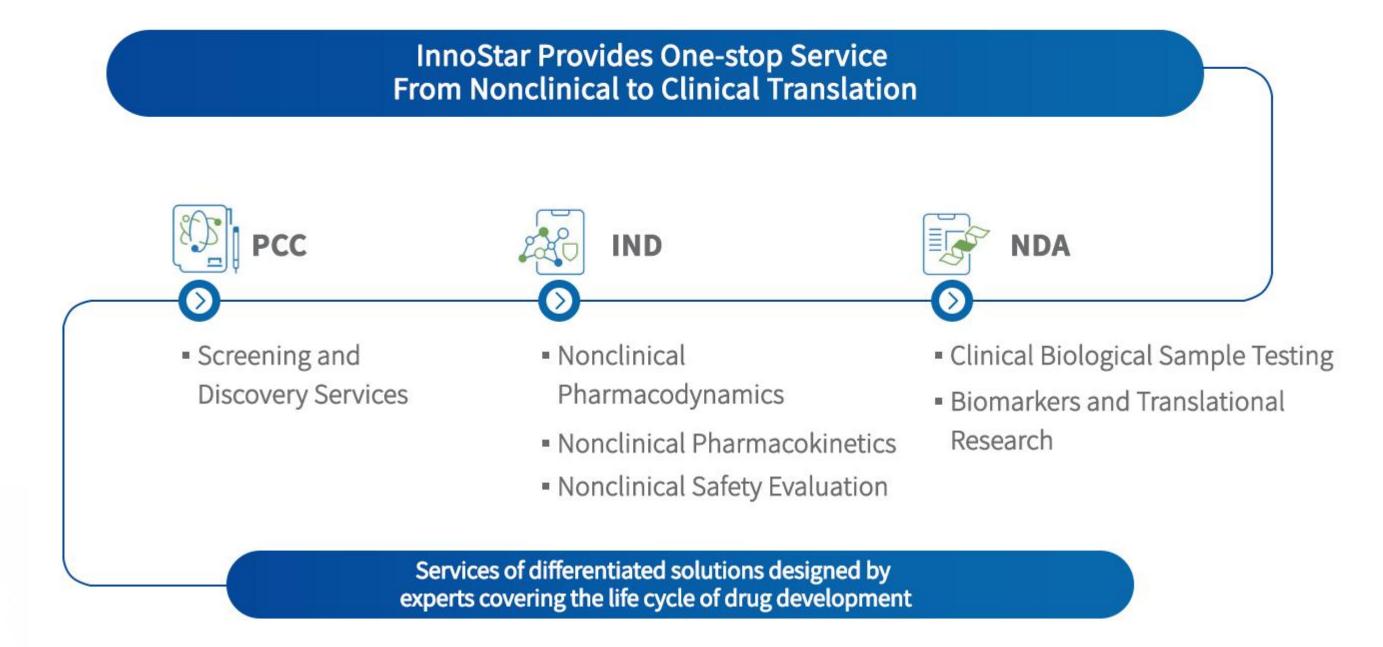
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SCOPE OF BUSINESS



PROJECT EXPERIENCE

920+ Already served New drug development clients	100+ Annual average IND package completed amount	30+ Annual NDA/BLA package completed amount
200+ We have served on both international	140 Overseas IND	3
and domestic "first-of-its-kind" innovative drug research and development projects.	Application Successful	FDA NDA/BLAs

注: 数据统计区间: 2015-2024.12.31



NMPA GLP

AUT

U.S.FDA GLP

INSP



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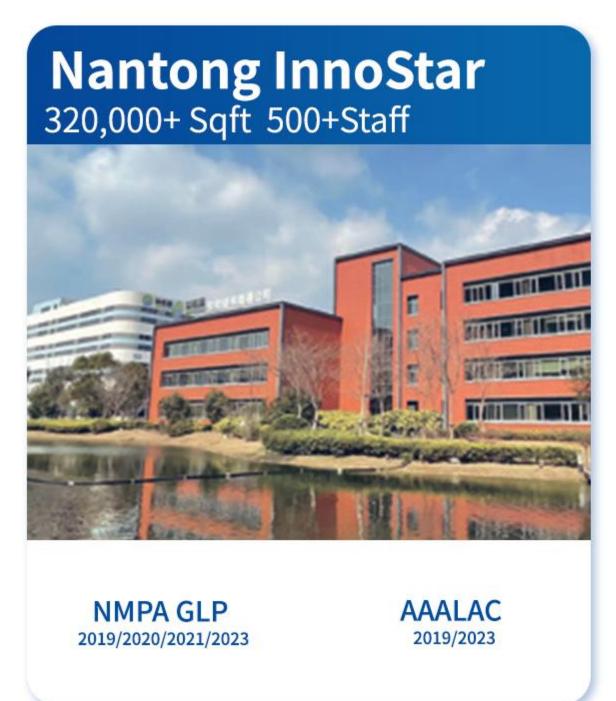
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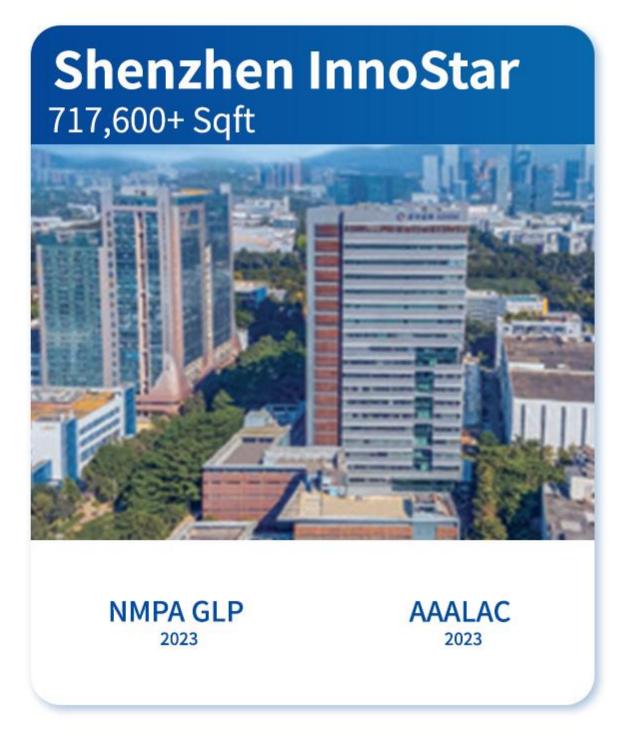
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Service Quality Recognition · · - · - - - 20

One-stop Service from Nonclinical to Clinical Translation









Service content

Platform Introduction

Introduction to the Platform

The non-clinical safety evaluation platform offers internationally recognized safety solutions to support drug development with advanced experimental animal technologies, diverse species resources, and regulatory expertise. It specializes in evaluating toxicity biomarkers, genotoxicity, addiction potential, ophthalmic safety, and cardiotoxicity, playing a crucial role in assessing the safety of cutting-edge drugs, including novel small molecules, biologics, bispecific/multispecific antibodies, ADCs, nanobodies, peptides, nucleic acid therapies, and cell/genetherapies (immune/stem cells, oncolytic viruses, AAV vectors). InnoStar's platform provides precision and compliance in safety assessments, accelerating the development of complex therapeutics through integrated in vitro/in vivo models and tailored safety strategies. The focus is on aligning technical excellence with global regulatory standards, ensuring rapid and safe translation from preclinical studies to clinical trials, and establishing trust among biopharma innovators worldwide.





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Safety pharmacology studies

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cardiovascular system

-Calm dogs/pigs/monkeys: DSI and EMEA implantable/EMKA vest -In vitro electrophysiology: potassium channels (hERG), sodium and calcium channels

respiratory system

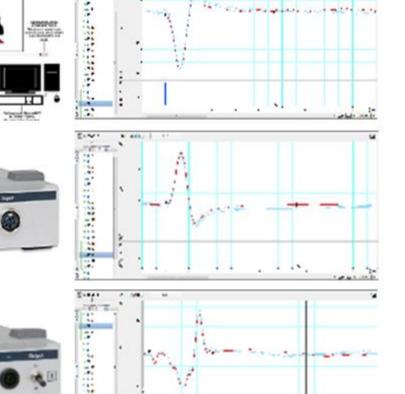
- -Rats/mice: EMKA whole body volume mapping system
- -Respiratory rate/tidal volume/minute ventilation

- C. N. S

- -Rats/mice/sprague-dawes rats/monkeys:
- -Functional observation combination experiment (FOB)
- -Improved Irwin method
- -Behavior, learning and memory, etc

complementary testing

- Gastrointestinal system
- Urinary / renal system



Species of animal

Rats/mice

squirrels

dogs

pigs

monkeys

route of medication

- Oral (gavage, capsule, tablet) and nasogastric administration
- Intravenous (injection/drip), subcutaneous, intradermal, intra-abdominal, intramuscular injection
- Transdermal application, transmucosal (oral) administration, eye drops, nasal drops, and infiltration administration
- Subretinal injection / vitreous injection
- Inhalation administration/intratracheal administration
- Intratumoral injection

- Administration by vaginal/rectal/bladder instillation
- Intracerebral/intraventricular/subarachnoid injection/ intracranial implantation pump injection
- Intra-articular injection (knee/hip)
- Intramyocardial injection
- Administration was via the spleen

General toxicology tests

Type of test

- MTD, dose range determination
- Single-dose toxicity test
- Repetitive dosing toxicity tests
- sensitivity test
- Hemolytic test
- Local irritation test
- In vivo photo toxicity test
- T cell-dependent antibody response test
- In vivo and in vitro tumor formation tests
- Tumor in the body

route of medication

- Oral (gavage, capsule, tablet) and nasogastric administration
- Intravenous (injection/drip), subcutan eous, intradermal, intra-abdominal and intramuscular
- Transdermal application, transmucosal (oral) administration, eye drops, nasal drops, and infiltration
- Subretinal injection/gas injection
- Inhalation administration/gastric administration
- Intratumoral injection
- Administration by vaginal/rectal/bladder instillation
- Intracranial injection/intraventricular injection/subarachnoid injection/intracranial implantation pump
- intraarticular injection
- Intramyocardial injection
- Administration was via the spleen

Species of animal

- Mice, rats, guinea pigs
- Rabbit, dog
- Non-human primates (including marmosets)
- miniature pig
- Golden hamster
- Immunodeficient mice
- Humanized animal model

Specimen collection

- cerebrospinal fluid blood
- urine
- Liver

aqueous humor

- semen milk
 - (biopsy)

Genetic toxicology tests

Core combination test

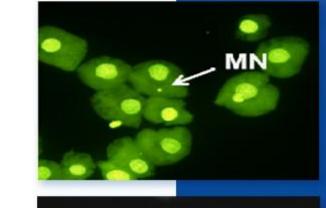
- Bacteria(Ames)
- In vitro and in vivo chromosomal aberration tests
- Genetic mutation tests (MLA, HPRT or XPRT)
- In vitro and in vivo micronucleus
- Comet test of multiple organs in vivo

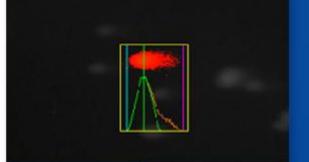
clone

- Chinese hamster fibroblasts (CHL cells)
- Chinese hamster ovary cells (CHO cells)
- Mice lymphoma cells (L5178Y cells)
- Human lymphoblast (TK6 cells)

route of medication

Oral gavage, intravenous (injection/ drip), subcutaneous, intraperitoneal and intramuscular administration





Additional tests/ mechanism studies

- In vitro and in vivo Pig-a gene mutation tests
- In vitro genetic toxicity test of multi-ple biomarkers
- In vivo liver micronucleus test

Extracellular metabolic activation system:

Rat S9 and human S9

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Teratology and reproductive toxicity

Core projects

- Fertility and early embryonic toxicity tests (Seg I)
- Embryo-fetal developmental toxicity test (Seg II)
- Perinatal developmental toxicity test (Seg III)
- Combined test of reproductive toxicity I/II/III
- Perinatal developmental toxicity test enhanced by crab monkeys (ePPND)
- Non-human primate embryo-fetal development toxicity test (NHP, EFD)
- Multi-generational breeding trials

Professional evaluation projects

- Evaluation of blood-hemolysis barrier and placental
- Evaluation of rodent behavior
- Evaluation of growth and development and reflex
- Bone development evaluation
- Non-human primate neurosis is a combination of academic assessment
- Human-like primate grip strength and mother-child

Species of animal

Mice, rats

hare

- Non-human primates
- Humanized animal model

route of medication

- Oral (gavage, capsule, tablet) and nasogastric administration
- Intravenous (injection/drip), subcutaneous, intradermal, intramuscular
- Transdermal application and nasal administration
- Given via the vagina

Specimen collection

- Blood (mother, fetus)
- embryonic tissue
 - milk
- maza



semen





Immuno-toxicity and immunogenicity tests

Service content

- Immunotoxicity is routinely accompanied by general toxicology.
- immunogenicity

route of medication

- Intravenous (push/drip), subcutaneous, intradermal, intramuscular injection
- Inhalation/intratracheal administration

Specimen selection

- Blood (PBMC)
- spleen

Unstimulated



Stimulated

Animal species and genera

- Mice, rats
- Non-human primates (including marmosets)
- Rabbit
- Humanized animal model

Service Advantages

Our institution has established detection platforms for humoral immunity (antibody titer detection) and cellular immunity (ELISPORT, ICS).

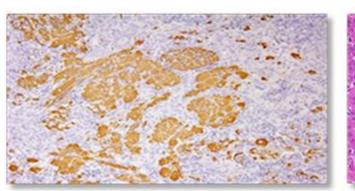
We have completed the immunogenicity screening of multiple projects, including traditional and novel preventive vaccines as well as therapeutic vaccines.

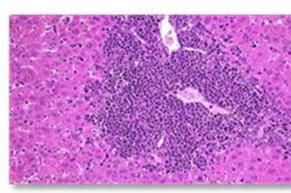
Carcinogenic test

cardinogenic test

- Carcinogenicity test in rats for 2 years
- Carcinogenicity test in 18-24 month old mice
- Carcinogenicity test in rasH2 transgenic mice for 6 months
- Carcinogenesis test in 6-month-old P53 gene knockout mice
- Tumor/carcinogenesis test in immunodeficient mice (cell therapy products)
- In vivo tumorigenicity test/in vivo tumorigenicity test (cellular therapy products)

Types of tumor marker auxiliary diagnosis





- Cytokeratin
- S-100、GFAP、Nurofilament
- Actin smooth muscle
- Chromogranin A
- Vimentin

Safety evaluation of inhalation preparations

service content

- Acute toxicity evaluation
- Repeated drug toxicity evaluation
- Stimulating research
- Allergic studies
- Pulmonary function evaluation (such as ventilation function evaluation, gas exchange function evaluation,
- Aerodynamic particle size distribution (ASAP) -Cascade impactor meth-
- Aerosol concentration analysis
- Bronchoalveolar lavage fluid (BALF) analysis and detection techniques

Animals can be evaluated

- rat/mouse
- cavy
- dog

Formulations can be evaluated

- Aerosols (MDIs)
- Spray (Nebulizer)
- Powder aerosols (DPIs)
- liquid preparation

monkey

Method of administration

- Nebulization throu Nasal drops gh the trachea
 - The drug is
- Oral and nasal exposure
- the brain by Nasal administration smell
- delivered to



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Pharmaceutical safety and photo toxicity test

Photo toxidity test

• In vitro phototoxicity test:

3T3 neutral red uptake phototoxicity test



In vivo photo toxicity test:

single dose/repeated dose photo toxicity test



Type of test

hemolysis test

- Aggressive testing
 - Phototoxicity test of neutral red uptake in 3T3 cells in vitro
- In vivo photo toxicity test hypersensitive test

Species

- Rat, rat
- rabbit
- non-human primate

route of medication

- Excitatory tests:
- intravenous injection, subcutaneous injection, intradermal injection, intramuscular injection, intraperitoneal injection, topical administration, vaginal administration, mucosal administration, inhalation administration, etc
- Hemolysis test:

human blood, rabbit blood, monkey blood or in vivo hemolysis (intravenous injection)

Allergy tests:

intravenous injection, subcutaneous injection, intradermal injection, intramuscular injection, intraperitoneal injection, topical administration, inhalation administration, etc

In vivo photo toxicity test:

oral gavage, intravenous injection, subcutaneous injection, intradermal injection, intramuscular injection, intraperitoneal injection, topical administration;

Service advantages

- 1. It can carry out a variety of drug administration stimulation tests, allergy tests and hemolysis tests.
- 2. In vitro tests can be carried out on a variety of systems (such as human blood, rabbit blood and monkey blood), and in vivo hemolysis tests can be further confirmed if necessary.
- 3. The in vitro 3T3 cell neutral red uptake photo toxicity test has been successfully verified by PMDA of Japan.

Pathology

General anatomy

- whole organ dissection and sampling of rats, mice, dogs, monkeys, rabbits and pigs
- **Conventional H E section staining**
- rat, mouse, dog, monkey, rabbit, pig whole organ H E section staining Histopathology diagnosis
- Toxicology team led by DJSTP&JCVP experts

Non-clinical trial pathology consultation and histopathology peer review Pathological section scanning (digital remote pathology diagnosis) Database of experimental animal background of self-lesion Immunohistochemical staining of various markers

- IgG, C3 immune complex
 α-smooth muscle actin
- CD3, CD20, CD68

Cell keratin (CK)

- $(\alpha-SMA)$ Myoglobin (Myoglobin)
- Wave protein
- (Vimentin)
- Keratin (Desmin)
- CD34

■ S-100

- Ion calcium binding
- linker molecule 1 (Iba 1) insulin

Various special staining

- PAS staining (perinacetaldehyde Schiff staining)
- Masson Three-color dyeing
- Toluidine blue staining
- Von Kossa Chroming
- prussian blue staining
- Modified Gomori Ammonia silver staining
- Victoria Blue dye
- PTAH staining (phosphotungstic acid hematoxylin staining)
- Congo red staining
- Victoria Blue dye
- Ali Xins indigo dyeing
- Oil red staining
- LB staining (fast blue staining)

clinical pathology

- Conventional histopathological sections
- Aperio system for pathological section (digital remote pathology diagnosis)
- Pathology peer review (Peer Review)
- Various immunohistochemical tissue markers
- -Lymphocyte classification marker staining
- -Tumor source identification staining
- -Circular immune complex staining
- A variety of special staining
- -Melanin staining classification (including hemosiderin, Prussian blue staining)
- -staining (glycogen staining)
- -Masson Trichromatic staining (collagen fiber staining)
- -Congo red staining -Tetraethylammonium blue staining (amyloid staining) (histiocyte staining)

Organize Cross TCR

Gliadin fibrillar acid protein

Ki-67, proliferating cell nuclear

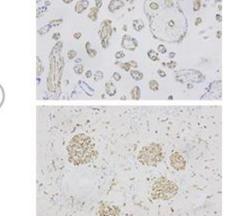
(G FAP)

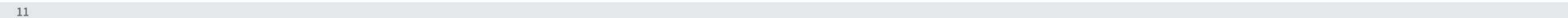
glucagon

antigen (PCNA)

Calcitonin (Calcitonin)

- TCR试验类型
 - -人源化单抗
 - -多特异性抗体
- -抗体-药物偶联(ADC、PDC)
- -纳米抗体
- -细胞因子融合蛋白
- TCR试验平台优势
- -遵循GLP法规的TCR平台
- -全种属试验动物和正常人体组织样本库
- -石蜡组织和冰冻组织TCR能力
- -配备生物安全等级二级实验室(P2实验室)
- -TCR试验同行评议服务



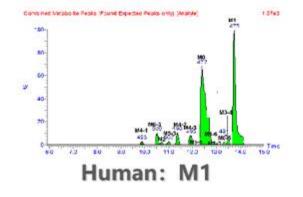


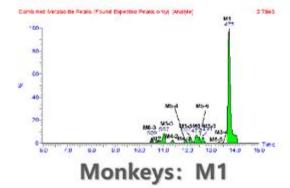
Representative cases

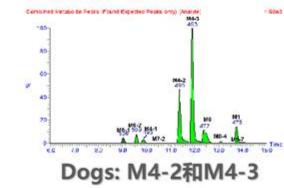
Representative case study [Small molecule drug]

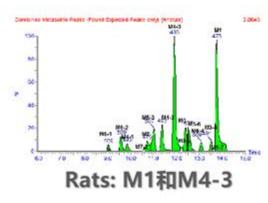
A small molecule drug

The main metabolites of hepatic microsomes in different species









Species selection

- The main metabolic pathway of the test substance in human, monkey and mouse liver microsomes is original oxidation and dehydrogenation, while the main metabolic pathway in dog and rat liver microsomes is single oxidation and oxidation dehydrogenation. According to the study of liver microsomal metabolism, it is believed that the metabolic characteristics of monkey, mouse and human are similar.
- M4-2 is a highly toxic metabolite. The high dose of crab-eating monkey is 25mg/kg (about 5 times the effective dose), and the animals tolerate the drug well after 28 days of administration

Representative case presentation [Specific antibodies]

A multi-specific antibody

- Efficacy in animal model: 0.01 mpk
- Preliminary experiment: IV, 1 time/day, 28 days

	f-4-1:	Dose	C _{max} (ng/mL)	
sex	fatalism	group	Mean		
		L	842	±	234
	D1	М	3721	\pm	432
		Н	22558	±	2760
		L	410	±	NA
Male	D14	M	1102	±	NA
		Н	4230	±	248
		L	14	±	NA
		М	6	±	NA
		Н	287	±	NA

- D14 There was a blood concentration at the Cmax point only after the end of drug administration
- ADA detection found that D10 began to produce ADA and had neutralizing activity
- Animal body weight and toxicity changes gradually recovered in the later stage

GLP trial

design

- acoign
- Dosage: 1x,3x,10x
- IV, 1 time/day, 28D+28D
- Standard endpoints: weight, clinical observation, temperature, ECG, ophthalmology, clinical pathology, pathology
- Special endpoints: cytokines, toxicity, ADA, neutralizing activity, absolute lymphocyte count, activated lymphocytes, RO, etc
- Add midline anatomy

bear fruit

The toxicity was greater in the middle period, and most of the patients had begun to recover by the end of the drug administration

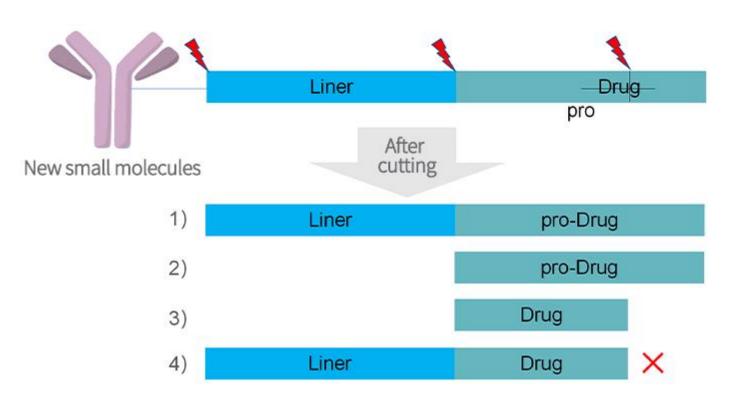
focus

•

- Immunogenicity has an effect on TK
- Immunogenicity affects toxicity
- Pay attention to the results of the preliminary experiment, adjust the experimental design in time if necessary, and increase the mid-term dissection

Representative case presentation [ADC drug] Evaluation of ADC design of prodrug

Characteristics of ADC structure in prodrug design



Representative case presentation [ADC drug]
 Activity and toxicity characteristics of each component

Drug>>>>Pro-drug ≈ Linker-pro-drug

Test Article	Dose group	Dose Level	Main study (Mortality)
Drug	Low Dose	15	4/10
Drug	High Dose	45	10/10
Pro-drug	Low Dose	600	0/10
Pro-drug	High Dose	1800	10/10
Linker-pro-drug	Low Dose	600	2/10
Linker-pro-drug	High Dose	1800	10/10

The toxicity characteristics of ADC, pro-drug and linker-pro-drug were consistent with those of Drug

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Correlation between toxicity and exposure of each component

Exposure co	mparison						
Tank Autinia	Dose	Dose	Main study	A	NUC	(-max
Test Article	group	Level	(Mortality)	Drug	Pro-Drug	Drug	Pro-Drug
Drug	Low Dose	15	4/10	16	NA	43	NA
Drug	High Dose	45	10/10	120	NA	130	NA
Pro-drug	Low Dose	600	0/10	2.5	900	1.9	2100
Pro-drug	High Dose	1800	10/10	55	4900	38	9100
Linker-pro-drug	Low Dose	600	2/10	NA	NA	NA	NA
Linker-pro-drug	High Dose	1800	10/10	NA	NA	NA	NA

Drug or prodrug was not detected in the plasma of animals in the ADC group, and the plasma shedding rate of animals in vitro was <0.3%

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Representative case

Representative case presentation [ADC drug] GLP experiment design

Summary of preliminary experimental results

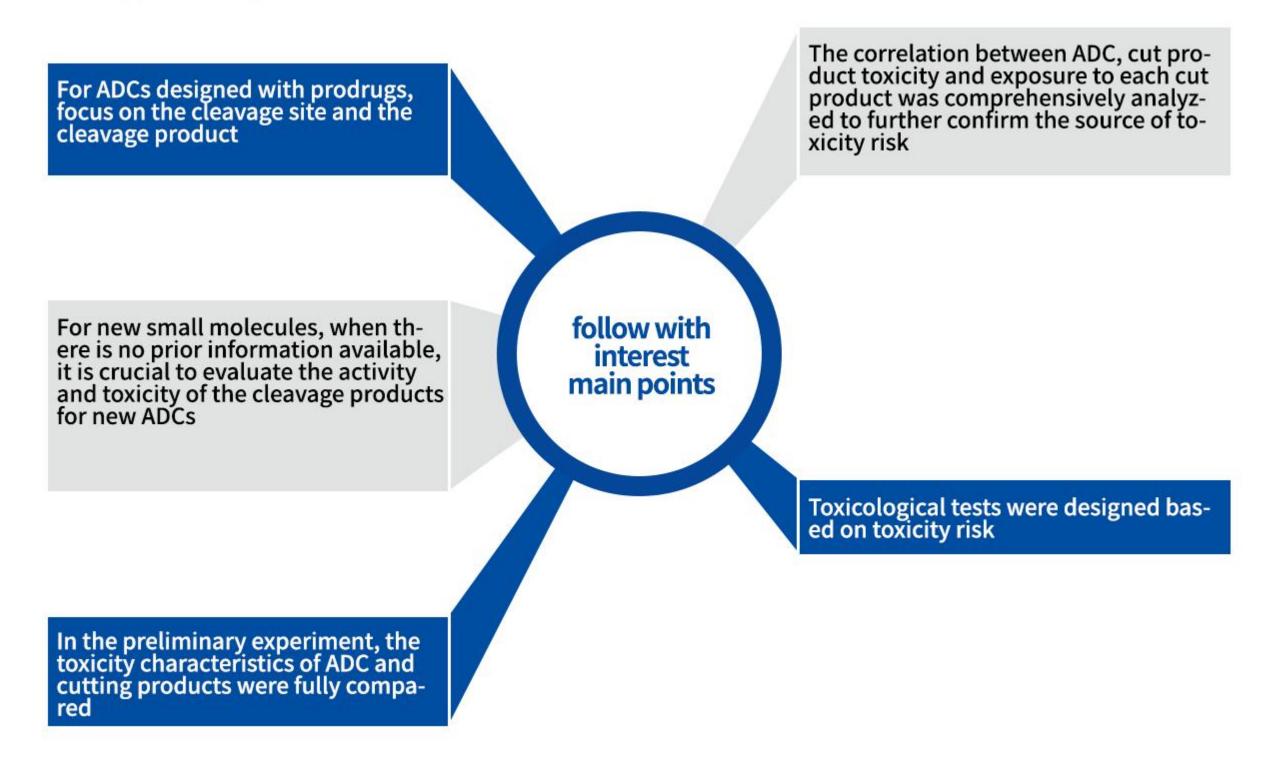
- The activity of Drug was much higher than that of other components, and the toxicity was related to the activity
- The toxicity expression of ADC, Pro-drug and linker-pro-drug was consistent with that of Drug, suggesting that Drug was the main source of toxicity
- The Pro-drug and Drug of ADC group were below the detection limit, indicating less shedding in peripheral circulation

Test article	Group
Vehicle	Control
ADC	Low dose
ADC	Mid dose
ADC	High dose
Drug	Equal molar of drug in ADC high dose



TK test substance

- ADC group: ADC, Tab, Drug, Pro-drug
- Drug group: Drug



Representative case study [siRNA] Drug: siRNA | Indications: Hypercholesterolemia | Stage: IND

Distribution: rodent (rat) tissue distribution test; mouse, rat, monkey or human plasma protein binding test; Metabolism and excretion: rat excretion and metabolism test, in vivo metabolitication (rat+monkey plasma and I homogenate); study on the metabolites; Drug interactions: study of reversible and time-dependent inhibition of CVP enzymes and induction of CVP enzymes in human and identification metabolites; Drug interactions: study of reversible and time-dependent inhibition of CVP enzymes and induction of CVP enzymes in human and identification metabolites; Drug interactions: study of reversible and time-dependent inhibition of CVP enzymes and induction of CVP enzymes in human and identification for 4 weeks followed by 8 weeks of toxicity test; NOAEL: high dose Reproductive and developmental toxicity tests Reproductive and developmental toxicity tests Bo rats: repeated administration for 4 weeks followed by 8 weeks of toxicity test; NOAEL: high dose Not carried out Ames, in vitro chromosomal aberration test and mouse bone marrow micronucleus test—negative Carcinogenicity test Drug formulation safety Drug formulation safety Drug formulation (at least one releving and additional test (with long toxicity), hemolysis test, active allergy test Pay attention to the characteristics the delivery system and add toxicity assessment of the delivery system and add toxicity assessment of the delivery system on necessary Analysis of mRNA sequence homology	test item	experiment design				
macokinetics study in SD rats; Distribution: rodent (rat) tissue distribution test; mouse, rat, monkey or human plasma protein binding test; Metabolism and excretion: rat excretion and metabolism test, in vivo metabolite identification (rat + monkey plasma and I homogenate); study on the metabolic stability of plasma and liver S9 in mice, rats, monkeys and human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification metabolics; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes and induct						
Reproductive and developmental toxicity tests Ames, in vitro chromosomal aberration test and mouse bone marrow micronucleus test—negative Carcinogenicity test Orug formulation safety Local irritation test (with long toxicity), hemolysis test, active allergy test Pay attention to the characteristics the delivery system and add toxicity assessment of the delivery system and add toxicity assessment and add toxicity asse		Metabolism and excretion: rat excretion and metabolism test; in vivo metabolite identification (rat + monkey plasma and live homogenate); study on the metabolic stability of plasma and liver S9 in mice, rats, monkeys and human and identification of metabolites; Drug interactions: study of reversible and time-dependent inhibition of CYP enzymes and induction of CYP enzymes in human and identification.				
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follow with

interest

main points

Consider the expected biological effects and mechanism of action, pay attention to the setting of PD indicators, etc

No related animal species: humanized mouse models can be considered, and animal-derived homologous small nucleotide analogs should be used with caution for alternative studies--the toxicity of single-stranded small nucleotides is often unrelated to pharmacological effects

stics of nucleotides (short plasma halflife, tissue accumulation, etc.) were fully considered

Immune toxicity and immunogenicity were concerned in the experiment

Project Experiences

920+ 100+ 30+

Clients Globally

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Overview of Project Experiences

pharmaceu- tical chemicals	•••••	Molecular glue drugs	PROTAC medicinal	Peptide drugs	prepa Liposomes, es, micrones	rations microspher- edles, fluid cr- celles, etc	Small molecule chemical drugs All kinds of innovation targets	•
biologicals	Carrier delivery of drugs	recombination protein	fusion protein	Microecolo cal product probiotics	Monoclor dies, bispect esPolyant le antibody antibody	oody ugs nal antibo- ific antibodi- ibody (trip- quadruple TCENano- bodies	ADC (single target, double antibody, double payload), PDC, RDC, AOC	•
Cell/ gene therapy medicinal	•••••	Oncolytic drugs Oncolytic bacteria, oncolytic viruses	Gene therapy products Viral vectors, non-viral vectors gene editing	therapy	ne cell products CR-T, DC cells, , CAR-M	p	cell therapy products C, MSC, HSC, etc	•
Vaccines and drugs	*****	Therapeutic vaccines Therapeutic cancer vaccines (PCV-TAA, TSA)	Inactiv attenuated prote	actic vaccine ated/virus d, recombinant in vaccine, vaccine, etc				•
Nucleic acid drugs	*****	miRNA	Aptamer	ASO	circRN	IA s	iRNA	•
radiophar- maceuticals	•••••	For diagnostic only radioph maceutical	ar- radiop	rapeutic use harmaceu- cicals				•
traditional Chinese medicine	•••••	Ancient class prescription Chinese medic compound preparation	n compo cine prepara	und ation	aditional Chinese nedicine roved new drugs		medicine cion drugs	•

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■First ADC Targeting GPRC5D with IND Approved

◆ Other New Modalit

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FirstAnti-PD1Monoclonal Antibody (LOQUORZIFY), BLAS **Approved by NMPA and FDA**



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- First MET Inhibitor with NDA Approved by NMPA

First BCL-2 Inhibitor with IND Approved
 First Long-acting FGF21 Fusion Protein with IND Approved

■ First BCL-2 Inhibitor with IND Approved

Other New Modalit

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Telline SIOPHIME	Syncromune	YH-002	Anti-OX40 Antibody
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