

Non-clinical Safety Evaluation

Scientific, Effective,
Coordinative, Comprehensive

- ▲ Expertise in ophthalmology / CNS / metabolic / autoimmune / tumor / rare diseases, etc.
- ▲ Enabling high success rate of drug R&D, lower the R&D costs.

Founded in 2008
15 years' leading
CRO experience

Core Science Team
20+ years'
toxicological
experience

Project Experience
accumulation in
500+ projects
2000+ studies

Regulatory Compliance
supporting NMPA/
FDA/OECD
submissions

Project Experience

500+ biologics and new chemical entities (including innovative new modalities) that have advanced to various stages of approval.

Type	Product/target	Indications	Advanced Status
Gene therapy	<ul style="list-style-type: none"> • AAV2, AAV8, AAV9 • VEGF, SMN 	Ophthalmology CNS	Phase I clinical trial
Small nucleic acid drugs	siRNA, ASO	NASH	Phase I clinical trial
Cell therapy	Stem cells, CAR-T	Tumors	Approved
Oncolytic virus	T601 (poxvirus), adenovirus	Tumors	Phase II clinical trial
ADC	<ul style="list-style-type: none"> • Target: Her2, Trop2, CLDN18.2, CD30, CD70, DLL3 • Payload: DM1, DXd, DDxd, MMAE, SN-38 	Tumors	Phase II clinical trial
mAb/bispecific antibody	<ul style="list-style-type: none"> • EGFR, EGFR/MET, HER2, CLDN18.2, TNFα, VEGF, VEGFR, FLT3 • PD-(L)1, CTLA4, 4-1BB, NKG2A, CD3 TCE, CCR8, Siglec 15, SIRPα • TSLP, MASP-2, RANKL 	Tumors Ophthalmology Autoimmune disease Osteoporosis	Approved
Peptide	GLP-1, FC-GLP-1, Semaglutide, PEG-rhG-CSF, rhTPO	Diabetes Blood disease	Approved
Nano-drug	Lipidosome, albumin nanoparticles	Anesthesia Tumors	Approved
Innovative chemical drug	<ul style="list-style-type: none"> • FGFR, ALK, BTK, BCL-2, TRK, VEGFR, c-Met, PARP1, CDK4/6, CDK9, Syk, PI3K/mTOR, PRMT5 • DPP4, SGLT2, JAK, TYK, CCR2/5, RORγt, Capsid, FXR, PDE1/4 	Tumors Diabetes Autoimmune disease	Approved

Comprehensive drug non-clinical safety evaluation research methods
Satisfied with customized needs of each product

Studies

Single / Repeat dose toxicity study

- in rodent and non-rodent

Safety pharmacology study

- cardiovascular, central nervous and respiratory systems

Local toxicity study

- allergic reactions, hemolysis and local tolerance

Reproductive toxicity study

- Seg I/II/III in rats/rabbits; ePPND in monkeys



Genotoxicity studies

- Ames, micronucleus, chromosomal aberration, comet assay, etc.

Carcinogenicity study

- 2-year in rats, 6-month in transgenic mice, etc

Dependency study

- psychic dependence, physical dependence

Immunotoxicity study

- TDAR, testing of immunotoxicity indicators

Immunogenicity study

Administration Experiences

Systemic administration

- PO (gavage, capsules, tablet), intranasal
- Injection (intravenous, subcutaneous, intracutaneous, intramuscular)

Local administration

- Intra-articular injection
- Intraocular (eye drop, anterior chamber, subconjunctival, retrobulbar, intravitreal, SRI, SCS, anterior chamber, vitreous body slow implanted)
- CNS administration (ICV, striatum, foramen magnum, intrathecal, hippocampus injection)
- Cutaneous & mucosal administration
- Nasal drop/spray
- Intratumoral

Animal Species

- Mouse / rat / guinea pig
- New Zealand rabbit / blue rabbit / Dutch rabbit
- Beagle dog
- NHP (cynomolgus monkey, rhesus monkey)



- Mini pig
- Golden hamster, hamster
- Immunodeficient mouse / transgenic mouse



Thanks for
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