

Non-clinical Safety Assessment

Scientific, Effective,
Coordinative, Comprehensive

- ▲ Expertise in ophthalmology / CNS / metabolic / autoimmune / oncology / rare diseases, etc.
- ▲ High success rate of drug R&D with lower R&D costs.

Founded in 2008
17+ years' leading
CRO experience

Core Science Team
20+ years'
toxicological
experience

Project Experience
900+ projects
in total

Regulatory Compliance
supporting NMPA/
FDA/OECD
submissions

Project Experience

900+ biologics, chemicals (including new modality), traditional Chinese medicines, some of them have been approved to market.

Type	Product/target	Indication	Advanced Status
Small nucleic acid drugs	siRNA: AGT, PCSK9, APOC3, etc., ASO	NASH	Phase I 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
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
Gene therapy	<ul style="list-style-type: none"> AAV2, AAV8, AAV9 VEGF, SMN 	Ophthalmology CNS	Phase I clinical trial
Peptide	GLP-1, Fc-GLP-1, Semaglutide, PEG-rhG-CSF, rhTPO	Diabetes Blood disease	Approved
Cell therapy	Stem cells, CAR-T	Tumors	Approved
Oncolytic virus	T601 (poxvirus), adenovirus	Tumors	Phase II clinical trial
Nano-drug	Liposome, albumin nanoparticles	Anesthesia Tumors	Approved

^ **Comprehensive non-clinical safety evaluation research methods to fulfill customized needs of each product**

Toxicology Service Category

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

- FEED, EFD and PPND in mice/rats/rabbits, EFD and ePPND in monkeys

Genotoxicity study

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



Carcinogenicity study

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

Abuse and dependence liability study

- psychic dependence, physical dependence

Immunotoxicity study

- TDAR, testing of immunotoxicity indicators

Immunogenicity study

Photosafety study

Administration Experience

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
- Immunodeficient mouse / transgenic mouse



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