凯斯艾生物 KCI BioTech

珂玛麒生物 KMQ BioTech

凯灵生物 KAL BioTech

COMPREHENSIVE PRECLINICAL CRO

- ***In vivo* Pharmacology and Pharmacodynamics**
- **Oncology pharmacology and pharmacodynamic**
- **Pharmacokinetics & Early toxicology**
- **Pathogenic microorganism services platform**
- **Pathology**
- **Integrated Service Platform**
- **Preclinical veterinary medicine/pet drug research/GCP study platform**

KCI BioTech (Suzhou) Inc.

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KCI Biotech and its wholly-owned subsidiary, KMQ Biotech and KAL Biotech are CROs specializing in providing preclinical pharmacodynamics and durability evaluation services for pharmaceutical research and development. The company owns AAALAC-accredited state-of-the-art laboratory animal facilities in Suzhou and Nantong, with a total area of more than 40,000m², which can meet the needs of various types of preclinical research. The company has a full range of laboratory animal platforms including mice, hamsters, guinea pigs, rabbits, cats, ferrets, dogs, pigs, sheeps and non-human primates. The *in vivo* pharmacolofical department supplies more than 400 animal disease models for human medicine development research. The BSL2/ABSL2 department supplies more than 100 pathogenic microorganisms, including bacteria, viruses, and fungi for human medicine development research, veterinary medicine and pet medicine. The company also supplies pathology, toxicology, pharmacokinetics, cellular and molecular biology, and medical imaging services. The company has already cooperated with more than 1,000 famous domestic and international pharmaceutical companies , and completed more than 2000 domestic and international projects . With a professional R&D team, rich experience in *in vivo* pharmacology and pharmacodynamics evaluation, and a professional spirit of integrity and excellence, KCI/KMQ/KAL will provide a full range of preclinical drug discovery and development services for global pharmaceutical companies and research institutions, and establish a professional and efficient drug discovery and evaluation system.

Animal Facility
AAALAC

Laboratory Area
40000m²

Animal Disease Models
400+

The services including

01 Pharmacology & Pharmacodynamics services

02 Pathogenic microorganism Research services

03 Pharmacokinetics & Early toxicology services

04 Cellular and Molecular Biology Research services

05 Pathology services

40000m² Lab Site

400+ Disease Models

2000+ Number of clients

200+ Professionals

·Services·

Drug R&D

Vaccine R&D

TCM R&D

Medical devices

In vivo Pharmacology and Pharmacodynamics

- Cardiovascular disease models
- CNS disease models
- Inflammatory/Immune disease models
- Metabolic disease models
- Reproductive disease models
- Digestive disease models
- Urinary disease models
- Bone/joint / muscle disease models
- Model customization Service

Pathology

- Clinical pathology
- Histopathology
- Molecular pathology

Preclinical drug discovery

Oncology pharmacology

- CDX/PDX tumor models
- Orthotopic tumor models
- Metastatic tumor models

Early toxicology

- Toxic dose exploration
- Single/multiple dose toxicity study
- Acute/long-term toxicity study
- Toxicokinetic study

Pathogenic microorganism services

- Virus
- Bacteria
- Fungi

Pharmacokinetics

- Bioanalytical research
- Pharmacokinetic study
- PK/PD study
- Tissue distribution studies
- *In vivo* metabolism studies

Preclinical veterinary medicine/pet drug research Platform

- Non-infectious diseases
- Infectious diseases
- Veterinary pathology pharmacokinetics toxicology, GCP study

Integrated Service Platform

- Cellular Biology
- Medical imaging
- Molecular pharmacology
- Micro/organoid
- Medical devices

Full range of animal experimentation service capabilities


Rats


Mice

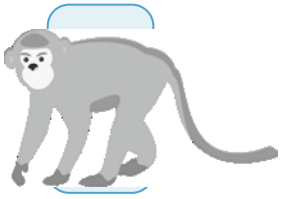

Guinea pigs


Hamsters


Cats


Ferrets


Rabbits


NHP

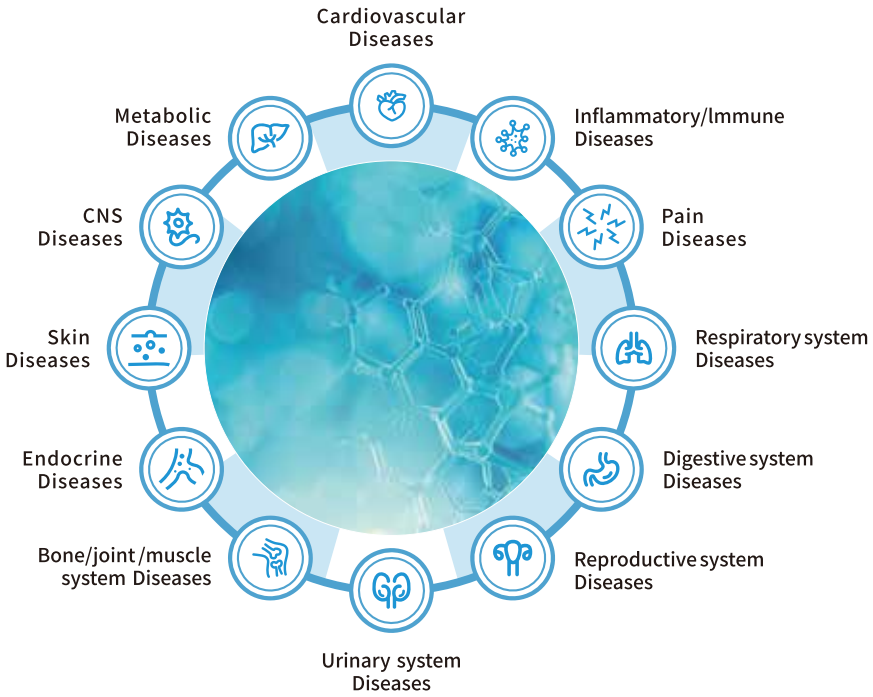

Dogs


Pigs

In vivo Pharmacology and Pharmacodynamics

KCI&KMQ have been deeply engaged in *in vivo* pharmacology and pharmacodynamics research for more than ten years. With professional and solid technical staff, advanced experimental equipment and facilities, and a comprehensive database of multiple disease models, KCI&KMQ have built a complete *in vivo* pharmacology and pharmacodynamics evaluation systems, which are capable of accurately analyzing the mechanism of action of the drug *in vivo*, pharmacology and pharmacodynamics.

Currently, we have served hundreds of well-known pharmaceutical companies and will continue to provide comprehensive, efficient and accurate services to our customers, helping pharmaceutical R&D to advance steadily.



In vitro Pharmacology and Pharmacodynamics

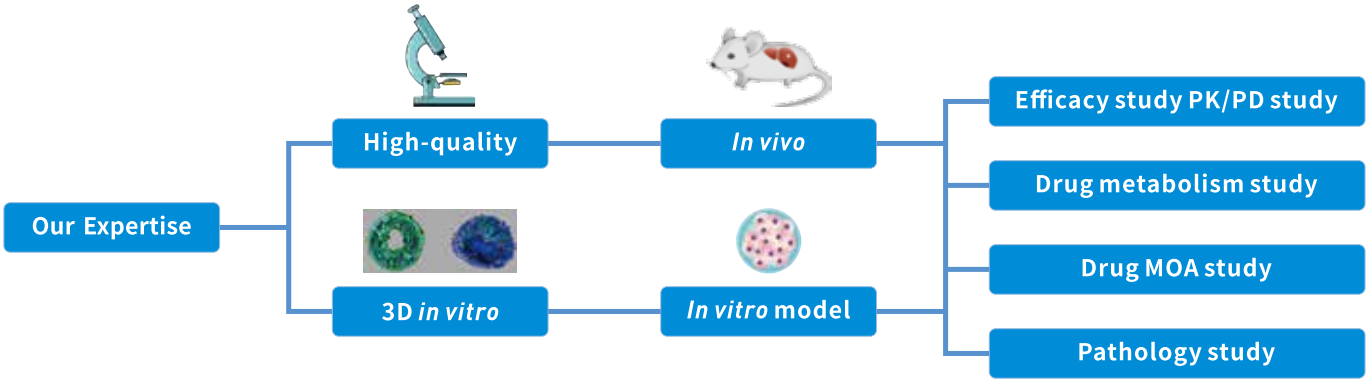
Services	Sample types	Testing technology	Applications
PCR&qPCR Assay	◉ Tissue ◉ cell culture	◉ Routine PCR ◉ RT-PCR ◉ Absolute Quantitative PCR ◉ Relative Quantitative PCR	◉ RNA/DNA gel electrophoresis, gene expression analysis ◉ AAV virus, influenza virus, etc. viral titer assay (qPCR method) ◉ Method development and validation
Elisa Assay	◉ Tissue ◉ Serum, plasma、Alveolar lavage fluid BALF, cerebrospinal fluid CSF ◉ cell culture	◉ Abs ◉ FI TRF ◉ Chemiluminescence	◉ Molecular biology: enzyme kinetic analysis, nucleic acid/protein quantification, detection of reporter genes ◉ Pharmacokinetic direction: cell proliferation, cytotoxicity and apoptosis studies. ◉ Aspects of cell signaling pathways: kinase, NFkB, CAMP, Ca2+ assays ◉ Microbiology: Bacterial endotoxin (LPS) detection
Western Blot Assay	◉ Tissue ◉ Cells ◉ Serum, plasma	◉ WB	◉ Protein Expression Analysis ◉ Phosphorylated protein expression analysis ◉ Customized Testing
Flow Cytometry	◉ Blood samples ◉ Tissue ◉ cell culture ◉ Fluids ◉ Other special samples	◉ Flow Cytometry	◉ Treg, Th cell secreted cytokine assay ◉ Apoptosis, cell cycle and proliferation ◉ TBNK cell fractionation, other cell typing, e.g., macrophages, DC cells ◉ Flow multifactor assays (CBA analysis) ◉ Phosphorylated protein (phos-Flow) analysis
Cell Construction	◉ Cell line	◉ NA	◉ Cell line construction and screening, cell transfection, etc.

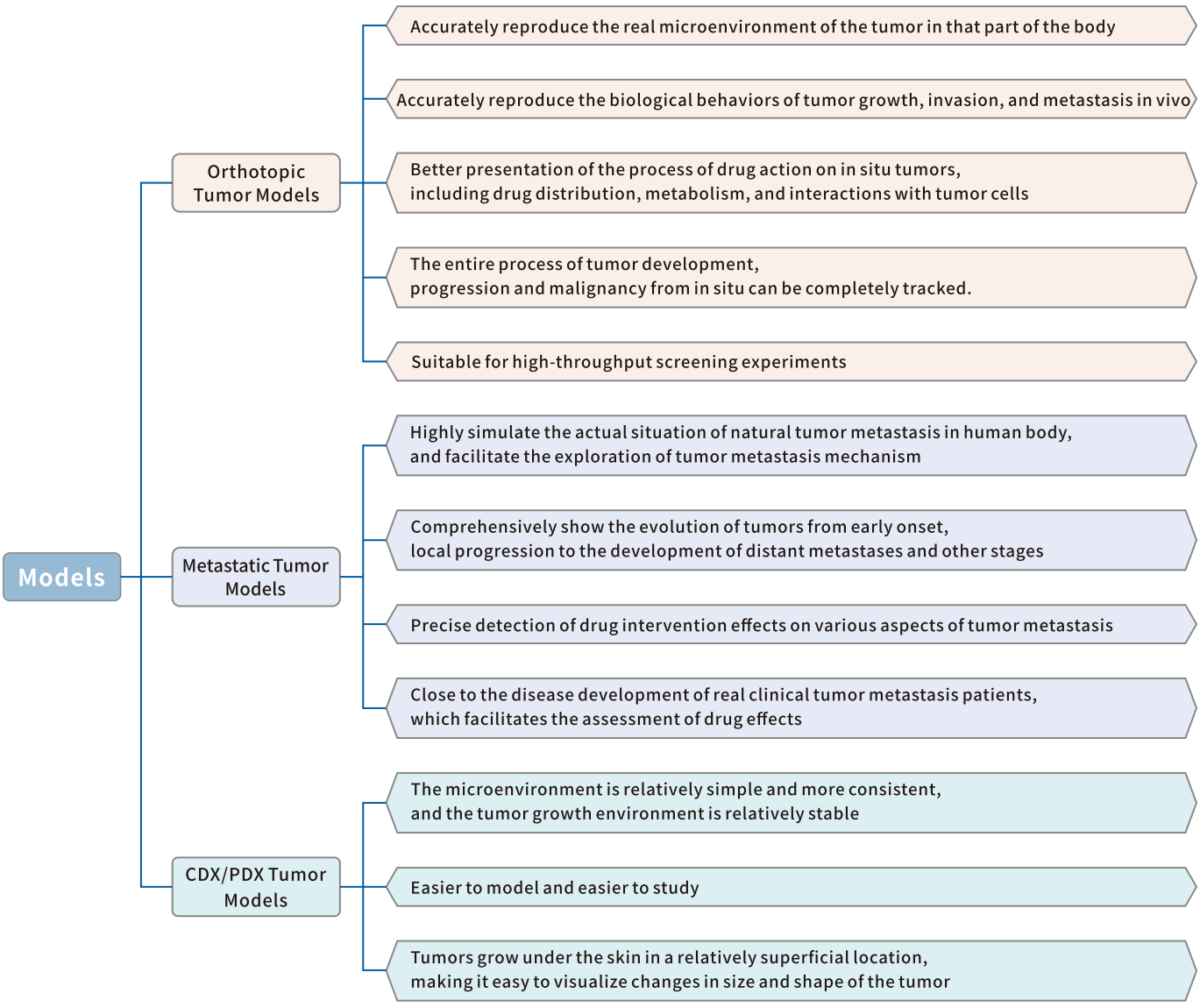
Animal Diseases Models

Cardiovascular Diseases	Stroke
	Acute myocardial infarction
	Heart failure
	Atherosclerosis
	Coronary artery disease
	Hypertension
	Pulmonary arterial hypertension
	Deep-vein thrombosis
	Arterial thrombosis
	Peripheral vascular disease
	Atrial fibrillation
	Ventricular tachycardia
	Diffuse intravascular coagulation
	Pericarditis
	Myocarditis
Metabolic Diseases	Obesity
	Diabetes
	Complications of diabetes
	Hyperlipidemia
	NASH
	Acute liver injury
	Liver fibrosis/cirrhosis
	Gout
	Sarcopenia
Respiratory system Diseases	Acute lung injury
	Cough
	COPD
	Idiopathic pulmonary fibrosis
	Acute/Chronic asthma
	Silicosis
	Pulmonary nodular disease
	Bronchiectasis
Endocrine system Diseases	Hyperthyroidism
	Hypothyroidism
	Thyroiditis
	SHPT
	Bulging eyes

Inflammatory and Immunological Diseases	Rheumatoid arthritis
	Inflammatory bowel disease
	Atopic dermatitis
	Psoriasis
	Systemic lupus erythematosus
	Septicemia
	Systemic sclerosis
	Skin scar
	Skin burns
	Healing of skin defects
	Pressure ulcer
Renal/Urological Diseases	Acute kidney injury
	Subacute/chronic renal failure
	Hypertensive nephropathy
	Metabolic nephropathy
	Immune-mediated nephropathy
	Acute/Chronic cystitis
CNS Diseases	Pain disorder
	Parkinson's disease
	Alzheimer's disease
	Autism
	Huntington's disease
	Cerebral palsy
Gastrointestinal Diseases	Gastric ulcer
	Atrophic gastritis
	Primary biliary cholangitis
	Primary sclerosing cholangitis
	Acute pancreatitis
	Chronic pancreatitis
	Diarrhea
	Vomit
Bone, joint and muscle Diseases	Osteoarthritis
	Osteoporosis
	Rheumatoid arthritis
	Joint fibrosis
Reproductive system Diseases	Endometriosis
	Hysteromyoma

Oncology pharmacology and pharmacodynamics





CDX/PDX tumor models	
Genus	Type
Human	Human colon cancer cells
	Human pancreatic cancer cells
	Human breast cancer cells
	Human macrophage lung cancer cell
	Human lung cancer cells (lymph node metastasis)
	Human non-small cell lung cancer cells
	Human small cell lung cancer cells
	Human lung adenocarcinoma cells
	Human liver cancer cells
	Human highly metastatic liver cancer cell Line
	Human gastric cancer cells
	Human brain astrocytoblastoma cells
	Human glioblastoma cells
	Human bladder cancer cells, or human bladderMigratory cell carcinoma
Rodent	Mouse colon cancer cells
	Mouse lung cancer cells
	Mouse breast cancer cells
	Mouse liver cancer cells

Orthotopic tumor models			
Genus	Type	Cell name	Model type
Human	Gastric cancer	NCI-N87-luci	Gastric cancer in situ and spontaneous metastasis
	Breast cancer	MDA-MB-231-LUC; MCF-7	Breast cancer in situ and spontaneous metastasis
	Liver cancer	MHCC97H-LUCI; SNU-739; SK-hep1	In situ and spontaneous metastasis of hepatocellular carcinoma
	Brain glioma	U87 MG-LUC; U251-LUC	Glioma in situ
	Pancreatic	PANC-1; MIAPaCa-2; CFPAC-1	Pancreatic cancer in situ
Rodent	Breast cancer	4T1-LUC	Breast cancer in situ and spontaneous metastasis
	Liver cancer	Hepa 1-6	Hepatocellular carcinoma in situ and spontaneous metastasis

Metastatic tumor models			
Genus	Type	Cell name	Model type
Human	Lung cancer	NCI-H446; HCC827; NCI-H292	Brain metastasis
			Liver metastasis
	Colorectal cancer	SW620	Brain metastasis
			Liver metastasis
	Prostate cancer	22RV1	Bone metastasis
	Breast cancer	MDA-MB-231-LUC	
			Bone metastasis
Rodent	Lung cancer	LLC	Liver metastasis
			Liver metastasis
	Colorectal cancer	CT26.WT; MC38	Brain metastasis
			Liver metastasis
	Breast cancer	4T1-LUC	Lung metastasis
			Bone metastasis

Pathogenic microorganism services platform

Human vaccines and anti-infective drugs, veterinary vaccines and anti-infective drugs

01 In vitro anti-infective efficacy tests: antiviral effect-EC50/CC50 assay; MIC drug sensitivity test; FIC determination; biological properties.

02 In vivo immunogenicity tests for vaccines: neutralization test, hemagglutination inhibition test, cellular immunity, etc...

03 Protective tests for animal attack: vaccines, antiviral drugs.

04 Infectious animal testing.

Types	Name	Sub type	Model	Animal species							
				Mice	Rats	Cotton mice	guinea pig	Pigs	Cats	Ferrets	Rabbits
Virus	RSV	A2/9320/18537	Virus attack model	✓		✓					
	HBV		AAV-HBV1.3 infection model	✓							
	Influenza virus	H1N1/H3N2 B Victoria B Yamaga	Virus attack model	✓						✓	
	HSV-2	MS	Reproductive Tract Infection Model	✓			✓				
	VZV	Oka	Neuropathic pain\skin herpes		✓		✓				
	FIPV	FCoV II	FIPV Model						✓		
	Rabbit papilloma skin lesion model	NA	Rabbit CRPV virus skin papilloma								✓
	PRRSV	High fever type	PRRSV Model					✓			
Bacteria	staphylococcus aureus	Seattle 1945	Skin wound infection model					✓			
			Sepsis model	✓							
		Seattle 1946	Sepsis model	✓							
	Enterobacter cloacae	Clinical strain	Thigh muscle infection model	✓							
	Acinetobacter baumannii	Clinical strain	Vaginitis model		✓						
			Thigh muscle infection model	✓							
	Klebsiella pneumoniae	C122	Vaginitis model	✓							
	Pseudomonas aeruginosa	ATCC9027	Vaginitis model	✓							
			Sepsis model	✓							
			Thigh muscle infection model	✓							
Fungi	Candida albicans	3147	Pneumonia model		✓						
			Sepsis model	✓							
			Vaginitis model								
	Aspergillus	Aspergillus fumigatus/Aspergillus flavus	Pneumonia model	✓							

Tests	Bacterial / Fungal / Viral isolation and culture		
	In vitro antiviral CC50 and EC50 tests		
	In vitro antimicrobial sensitization	MIC	Micro broth dilution method
			Paper Amplification
		FIC assay - Checkerboard method to determine combined antimicrobial capacity	
		Biological Characterization	Growth Curve
			Motility
			Biofilm
			Adhesion invasion
	Evaluation of vaccine immunogenicity	Evaluation of humoral immunity	Binding antibody Ig G and different subtype detection
			Neutralization test\hemagglutination inhibition test
		Cellular immunity evaluation	ELISOPT-IFN-γ\IL-2\IL-4\IL-6 assay
			Flow Test-CD4+\CD8+\IFN-γ+\TNF-α+\IL-2+\IL-4+\IL-6+ and other tests
	Attack protection assay		
	Evaluation of therapeutic anti-infective drugs		

Preclinical veterinary medicine/pet drug research Platform

Preclinical research of pharmacology & pharmacokinetics: Non-infectious disease models

Field of Diseases	Canine-related animal models	Cat-related animal models
Cardiovascular diseases	Canine hypertension model Canine heart disease model (cardiomyopathy)	Spontaneous HCM, RCM, DCM
Digestive diseases	Canine pancreatitis model Canine gastroenteritis model Canine gastric ulcer model	Feline pancreatitis
Endocrine diseases	Drug-induced canine hypothyroidism model	Drug-induced feline hyperthyroidism model
Inflammatory/Immune diseases	Canine allergic dermatitis model Canine rheumatoid arthritis model	Dust mites-induced feline allergic dermatitis model
Metabolic diseases	High-fat diets-induced canine obesity models and canine diabetes models	High-fat diets-induced feline obesity model ALX/ surgically-induced feline diabetes model
Bone/joint/muscle diseases	MIA-induced canine osteoarthritis model Surgery-induced canine osteoarthritis model Fracture healing and cartilage injury repair model	MIA-induced feline osteoarthritis model
CNS diseases	Drug-induced canine epilepsy model Kaolin-induced joint pain model Incision pain model	Feline neuroinflammation model Kaolin-induced joint pain model
Reproductive diseases	Hormone-induced canine endometritis model Surgically-induced canine infertility model Drug-induced contraceptive model	Feline ovarian cyst model Endometritis model
Respiratory diseases	Drug-induced canine allergic airway inflammation model	Feline asthma model Feline COPD model
Urinary diseases	Canine acute renal injury model Canine uremia model Canine urinary calculi model	Feline acute renal injury model Feline uremia model Feline cystitis model

Species	Infection types	Animal disease name	Biosafety level	Drug R&D types
Cat	Viral infection	FPV	BSL-2	Common feline trivalent vaccines R&D
		FHV-1	BSL-2	
		FCV	BSL-2	
		FIPV	BSL-2	Vaccines or antiviral drugs, commonly GS-441524 treatment used in clinical practice
		FeLV	BSL-2	Vaccines Antiretroviral drugs (such as zidovudine) Immunomodulator
		FIV	BSL-2	
Dog	Bacterial fungal infection	Canine bronchogenic Bordetella disease	BSL-2	Mucosal immune vaccine Attenuated live vaccine
		Canine leptospirosis	BSL-2	Multivalent vaccine
		Microsporum Canis skin infection	BSL-2	Antifungal topical preparations
	Viral infection	Canine distemper	BSL-2	Vaccines, therapeutic monoclonal antibodies long-acting interferons
		CPVD	BSL-2	Vaccines, therapeutic monoclonal antibodies
Pig	Viral infection	PRRS	BSL-2	Main focus on Vaccine R&D
		TGE	BSL-2	
		PED	BSL-2	
		Porcine circovirus related diseases	BSL-2	

Pharmacokinetics & Early toxicology

ANIMAL STRAIN

ROUTE OF ADMINISTRATION

Gavage, intraperitoneal injections, intravenous injections (tail vein, femoral vein, facial vein, posterior eye socket vein), intramuscular injections, myocardial injections, airway nebulization administration, skin application, nasal drip administration, and stereotactic brain injections.

SAMPLE COLLECTION

Tail vein, dorsal foot vein and femoral vein blood collection, orbital blood collection, cheek blood collection, cerebrospinal fluid collection, lacrimal fluid collection, lymphatic fluid collection, bile collection, urine collection, fecal collection and all other tissue collection.

BIOLOGICAL MATRIX

Whole blood, plasma, serum, urine, feces, tissues of all parts, ocular tissues (sclera, iris, cornea, aqueous humor, ciliary body, choroid, retina, etc.), cerebrospinal fluid, brain, nerves and ganglia of all parts, lymph nodes, and bone marrow.

In Vivo Pharmacokinetics

Type of surgeries

Intubation of jugular veins, carotid arteries, portal veins, bile ducts, duodenum, and lymphatics

Type of experiment

- 01. Rapid drug screening, simultaneous administration of multiple drugs detection
- 02. PK test of drugs in different dosage forms/salt forms/crystal forms
- 03. Single-dose, single-administration PK test
- 04. Gradient dose (low, medium, high) single/multiple administration PK test
- 05. Gradient dose (low, medium, high) single/multiple administration tissue distribution test
- 06. Gradient dose (low, medium, high) single/multiple administration excretion test
- 07. Conventional efficacy trials: combining PK data results for specific models
- 08. Customized Experimental Solutions

(Overall strategy for IND filing available)

Bioanalytical

Type of articles

Small molecules, large molecules (peptides, ADCA, proteins, XDC, PROTAC), liposomes, nucleic acids etc.

Sample types

Whole blood, plasma, serum, urine, feces, tissues from various sites, ocular tissues, cerebrospinal fluid, brain, nerves and ganglia from various sites, lymph nodes, bone marrow, clinical samples, etc.

Type of test methods

LC/MS/MS method development/validation and sample analysis, immunological assay method development/validation and sample analysis, etc.

Early toxicology

- DRF
  Toxicokinetics (7、14、28 Days)
- Single/multiple dose toxicity studies
- Acute/long-term toxicity studies
- Local toxicity studies
  (sensitization, irritation studies)
- MTD
- Histopathology/Clinical Pathology
  (serum chemistry, hematology and coagulation)

Others

Formulation analysis, biomarker testing, etc.

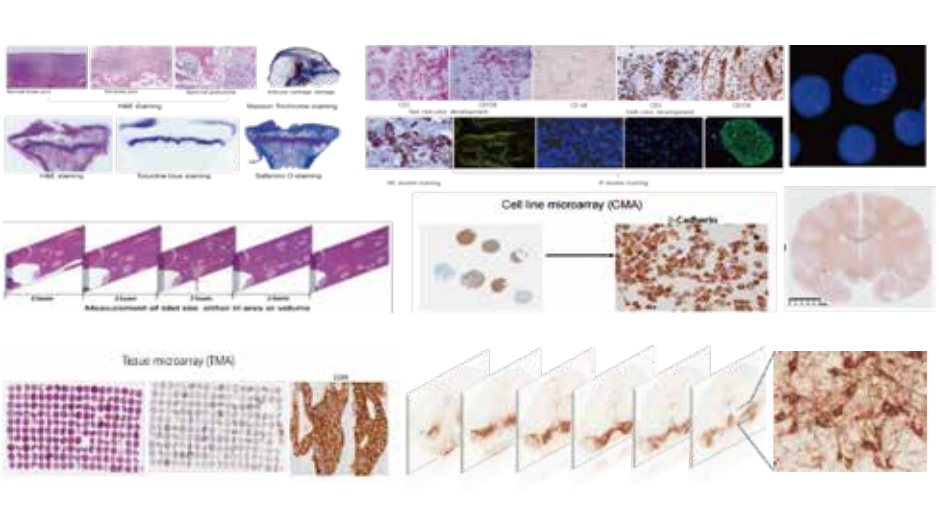
Pathologies

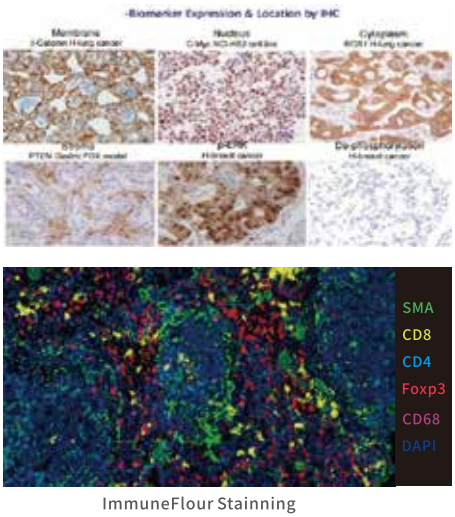
Histopathology

Experiment	Content	Description
Sections	Decalcification of bone tissue	Slow stripping, fast stripping
	Paraffin Embedding	Fixed Sample
	0CT Embedding	Fresh/fixed sample
	Paraffin sectioning	Fixed Sample
	Frozen section	Fresh/fixed sample
	Large Tissue	Brain/Heart/Kidney/Lung
Staining	HE staining	
	Special Staining	Masson Trichrome、Oil red 0、Sirius Red、PAS、IHC、Multiplex Immunofluorescent、Masson-Fontana、Golgi stain
	IHC staining	IHC/IF/MF staining
	Large Tissue staining	HE/Special/IHC/IF staining
Pathological imaging	Full Slice Scanning (Bright Field)-20X/40X	
	Immunofluorescence Full Section Scan-20X	Single and Multi Label
	Morphologic Description	

Clinical pathology

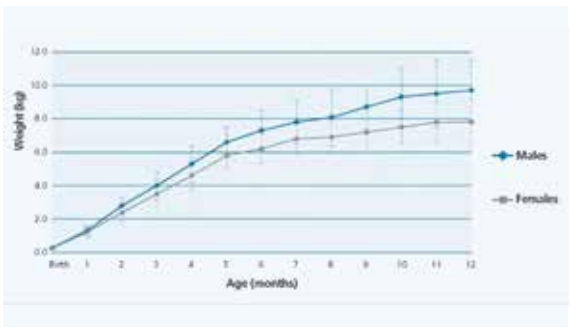
Experiment	Content	Description
Clinical pathology	Biochemical Analysis	Lipids, lipoprotein metabolism, cardiovascular classes, liver function classes, renal function classes, myocardial function and myocardial enzyme profiles, glucose metabolism classes, gastric function, pancreatic function classes, rheumatologic markers infection markers, metabolic classes, specific proteins (D-Dimer, FDP, IgE, Ferritin, TRF), ionic classes (CO2, Ca, Mg, P, Fe)
	Hematology Analysis	CBC, DIFF, RET (reticulocyte measurable)
	Coagulation Analysis	Prothrombin time, activated partial thromboplastin time, fibrinogen, prothrombin time
	Urinalysis	Color, appearance, pH, glucose, bilirubin, ketone bodies, specific gravity, protein, occult blood, urobilinogen, nitrite and leukocytes, vitamin C





ImmuneFlour Stainning

Animal Breeding Center



Equipment

SHIMANZU UHPLC LC-30AD

LC-MS AB Sciex 5500

Flow cytometer

B-ultrasound

Blood Coagulation Analyzer

Biochemical analyzer

General PCR instrument

Blood analyzer

Enzyme marker

High-order Imager

QMR06-090H

MESO QuickPlex SQ 120

Real-time fluorescence quantitative PCR instrument

CT

MRI

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