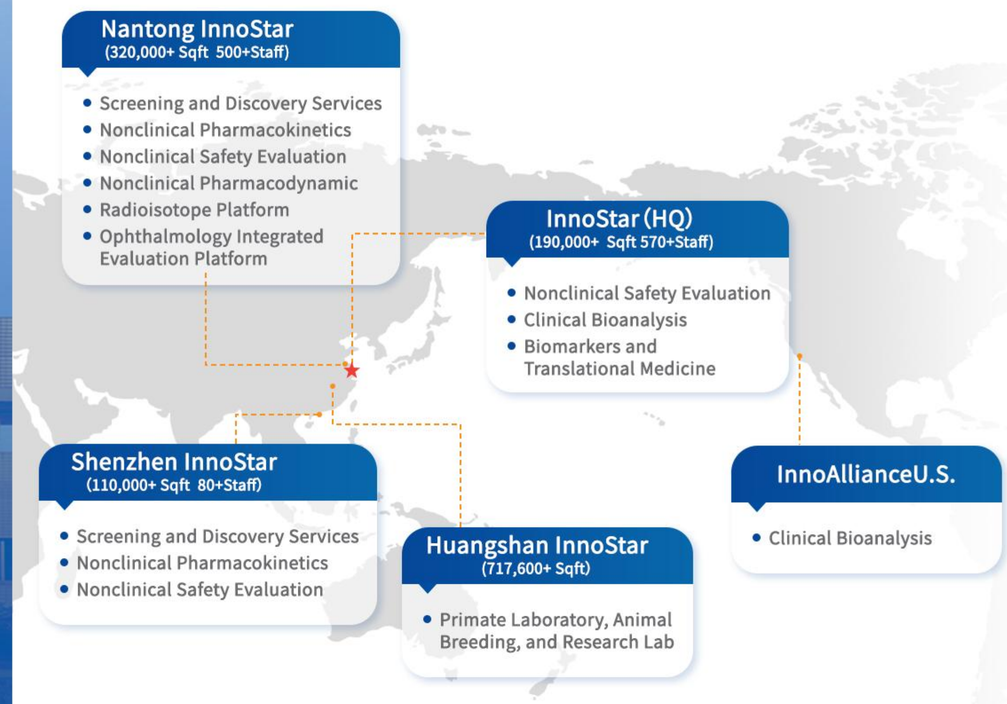
InnoStar

Isotopic Platform & Radiopharmaceuticals R&D Services

Focus on R&D services
Empowering the healthcare industry

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).



NMPA GLP AUT | U.S.FDA GLP INSP | OECD GLP AUT | AAALAC AUT | 美国CAP AUT

SCOPE OF BUSINESS

InnoStar Provides One-stop Service From Nonclinical to Clinical Translation

PCC
- Screening and Discovery Services

IND
- Nonclinical Pharmacodynamics
- Nonclinical Pharmacokinetics
- Nonclinical Safety Evaluation

NDA
- Clinical Biological Sample Testing
- Biomarkers and Translational Research

Services of differentiated solutions designed by experts covering the life cycle of drug development

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 and domestic "first-of-its-kind" innovative drug research and development projects.

140
Overseas IND Application Successful

3
FDA NDA/BLAs

注: 数据统计区间:2015-2024.12.31

Scan the QR code for more business inquiries

TOC

Main instruments and equipment

Radiopharmaceutical-labeled hot chambers

Radiopharmaceutical labeling hot chambers are used for the labeling of nuclides such as 68Ga、177Lu、89Zr, etc

Radioactivity assays

For radiochemical purity testing, and radiochemical purity stability testing after dosing preparation

Radio-HPLC: For Radiochemical purity testing and metabolites profiling study.

For the detection and analysis of radiopharmaceutical TK samples, tissue distribution samples, and material balance samples

For the detection and analysis of pure β-ray radiopharmaceutical TK samples, tissue distribution samples, and material balance samples

Micro-PET/MR: For the study of the distribution of positron nuclide drugs in rat tissues and pharmacodynamics

Radioprotection

Rigorous radiation protection and radiation detection system to ensure the safety of operators.

L-type protective screen

Mobile lead protective screen

Lead trash cans

Whole body γ contamination monitor

Radiation protective clothing

Radiation resistant apron

Environmental monitors

Lead protective operating cabinet

Platform Introduction

Introduction to the Platform

The radioisotope platform provides comprehensive capabilities for the non-clinical and clinical evaluation of radiopharmaceuticals and radioisotope-labeled compounds. With the qualification to use 36 different radioisotopes, the platform supports a range of studies, including ADME research, human material balance studies, molecular imaging, and radiopharmaceutical evaluations. The platform is equipped with state-of-the-art experimental facilities and equipment, including a γ counter, liquid scintillation counter, QWBA, PET/MR imaging, and other advanced testing technologies. It supports a variety of animal models, including mouse, rat, rabbit, dog, pig, and non-human primates, and provides end-to-end analysis of radioactive biological samples.
Certified by NMPA, OECD, and FDA, the platform strictly follows GLP/GCP international standards, providing whole-process solutions that meet global standards for innovative drug development. The platform's capabilities are bolstered by its three-dimensional advantages of qualification, hardware, and technology.

Service content

Radioactive Laboratory Layout

Isotopic Laboratory Accreditation

Tissue distribution of ^{125}I -labeled macromolecule drugs

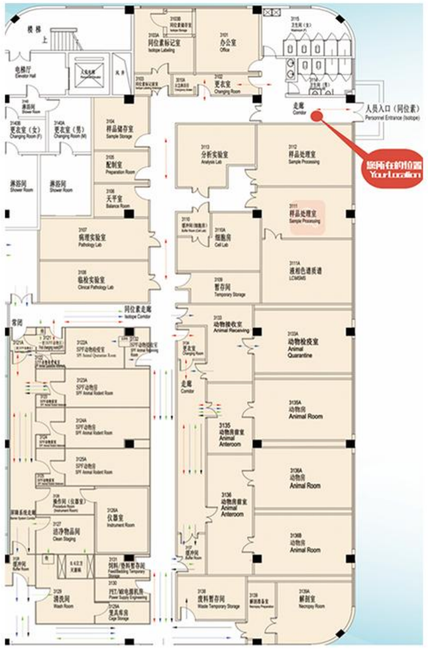
Tissue distribution study based on PET imaging

Positron nuclides commonly used for antibody labeling

A case of the distribution study on radioisotope-labeled cell therapy products

Radioactive Laboratory Layout

As one of the earliest preclinical CRO conducting radiopharmaceutical research, INNOSTAR has laboratory that is qualified for isotope and radiopharmaceutical study under GLP/GCP standards.



≈13,000 sqft
Total L
ayout

≈7,000sqft
radioactive animal facility

≈ 6,000sqft
Radioactive laboratory

Equipped with PET/MR imaging equipment for small animals

Lab Space Function

- Radioisotope labeling
- Quality control analysis
- Dispensing configuration
- Radiobiological sample testing room
- Radioisotope animal house
- Radiodissection room
- Radioactive waste room
- PET/MR room
- QWBA room

Isotopic Laboratory Accreditation

InnoStar’s isotopic platform is accredited for Class B radioactive studies and carrying out radioactive studies of 36 isotopes.

辐射安全许可证

根据《中华人民共和国放射性污染防治法》和《放射性同位素与射线装置安全和防护条例》等法律法规的规定，经审查准予在许可种类和范围内从事活动。

单位名称：益诺思生物技术南通有限公司

统一社会信用代码：91320684084399345l

地　　址：江苏省南通市海门区临江镇洞庭湖路100号A18楼

法定代表人：洪艳

证书编号：苏环辐证[F0510]

种类和范围：使用Ⅴ类放射源；使用Ⅲ类射线装置；销售、使用非密封放射性物质，乙级非密封放射性物质工作场所（具体范围详见副本）。

有效期至：2028年07月19日

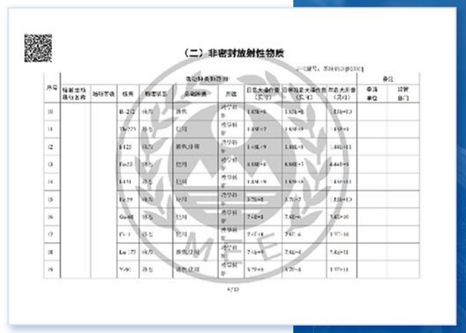
发证机关：南通市生态环境局

（公章）

发证日期：2025年04月02日

中华人民共和国生态环境部监制

（二）非密封放射性物质



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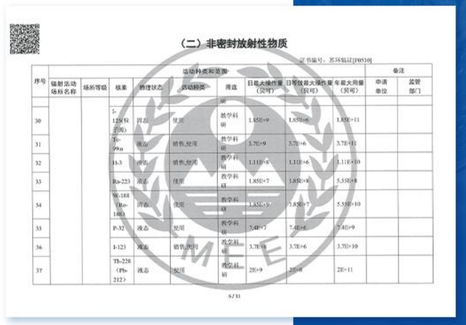


（二）非密封放射性物质

Radioisotope Platform

Radioisotope Class II Site Use Qualifications for 36 Isotopes

Radioactivity medicinal

- Nonclinical

-Radiopharmaceutical labeling: 68Ga/64Cu/177Lu/225Ac/212Pb…

-Early screening of radiopharmaceuticals

-Non-clinical ADME, efficacy and safety evaluation of radiopharmaceuticals

-Olinda Estimation of in vivo exposure dose for software

- Clinical

Clinical sample analysis

-Total radioactivity detection of clinical samples (γ counter, liquid scintillation counter)

-Detection of the proportion of clinical plasma and urine prototype drugs (Radio-HPLC method)

GLPconditions can be used to evaluate the safety of hot drugs

国家药品监督管理局 National Medical Products Administration

OECD BETTER POLICIES FOR BETTER LIVES

FDA

Radioactive Class II sites are qualified to use

37 isotopes

Non-radioactive medicinal

- Nonclinical

Compound labeling

-^{125}I/ ^{124}I/ ^{89}Zr labeled protein

-^{125}I/ ^{89}Zr labeled exosomes

-^{55}Fe/ ^{59} Fe labeling

ADME study

-Study on ADME of ^{3}H/^{14}C/^{125}I labeled compounds

-Study on the distribution of QWBA organizations

-Micro-PET/SPECT small animal imaging

-PET/SPECT large animal imaging (hospital scan)

- Clinical

-Radioactive drug preparation, stability, radiochemical purity detection

-Principle drug and major metabolites (LC-MS/MS)

-Total radioactivity detection of human plasma (liquid flash detection)

-^{14}C labeled compounds for human material balance

-Biotransformation (metabolite profile) and metabolic pathways of drugs in human body

Non-clinical studies ofradiopharmaceuticals

service content

- Types of radionuclides that can be released:

-^{18}F,^{68}Ga, ^{177}Lu, ^{89}Zr, ^{131}I, etc

- Radioactive drug synthesis:

-Synthesis of ^{68}Ga, ^{177}Lu and ^{89}Zr radiopharmaceuticals

- Early screening of radiopharmaceuticals:

-Compound labeling, cell experiments, tissue distribution, PET/SPECT/CT, pharmacodynamics

- Preclinical ADME studies of radiopharmaceuticals
- Olinda Estimation of in vivo dose of software

- Pharmacodynamics of radiopharmaceuticals:

-In vitro efficacy: cell uptake, intracellular ingestion, cell receptor binding, in vitro killing

-In vivo efficacy: PET imaging, in vivo antitumor pharmacodynamics

- Safety evaluation of radiopharmaceuticals:

-Study of single/ repeated extended toxicity of hot medicine

-Safety of hot medicine preparations: hemolysis, irritation, allergy

-Safety evaluation of cold drugs (precursors, cold labeled compo

One of the earliest CROs in China to conduct non clinical research on radiopharmaceuticals,Non clinical ADME providing one-stop radioactive diagnostic/therapeutic drugsSecurity Evaluation Research Service

Key points	Content
Type of medication	▪ Radioactive diagnostic drugs ▪ Radiotherapy drugs
Test form	▪ Hot drugs: Clinically intended preparations ▪ Cold drugs: Drugs in non-radioactive or decay form, including unlabeled ligands or carriers, ligands or carriers containing stable isotopes, products after decay of radioactive molecules
radioactive nuclide	▪ Nuclides that can be carried out: ^{18}F、^{68}Ga、^{89}Zr、$^{125/131}$I、^{177}Lu、^{90}Y、etc ▪ Self-labeling radiopharmaceutical synthetic nuclide species: ^{68}Ga、^{89}Zr、^{177}Lu、^{90}Y、etc
Non-radioactive part	▪ Ligands or carriers: Peptides, proteins, liposomes, and small molecules, etc ▪ Excipients, impurities, residual solvents, etc
Pharmacodynamic studies	▪ Efficacy in vitro: cellular uptake, endocytosis, cell receptor binding, in vitro killing ▪ Efficacy in vivo: PET imaging, anti-tumor efficacy evaluation
Characteristics of the test sample	▪ Drug composition, impurities ▪ Metabolites ▪ Biological half-life, physical half-life ▪ Progeny decay and radioactive decay products
GLP	▪ Toxicology studies should generally be conducted in a GLP-accredited institution and comply with GLP ▪ Considering the particularity of radiopharmaceuticals, when GLP cannot be complied with, the test should be carried out in accordance with the principles of GLP to ensure the authenticity, completeness and traceability of the test quality and data

Tissue distribution of ^{125}I - labeled macromolecule drugs

Animal Species:

- Rodent: mice, rats, rabbits
- Non-rodent: Canine, NHP

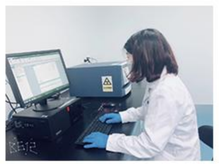
Macromolecular Drug Categories:

- Proteins, ADCs, peptides, polysaccharides, etc


Protein purification instrument

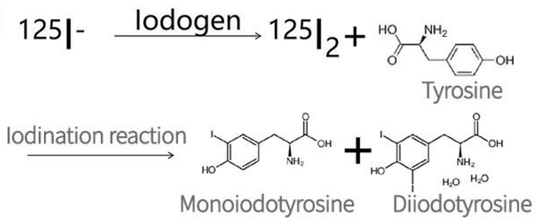

Ridio-HPLC/TLC


γ counter

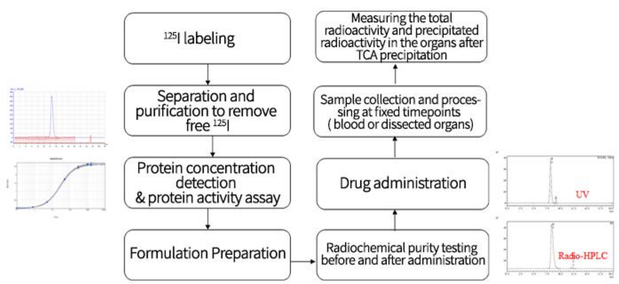

ELISA

^{125}I Labeling Mechanism

Iodogen method is commonly used to label protein, antibody and polypetides or amino acid residue with ^{125}I



Flow chart of tissue distribution of ^{125}I labeled proteins

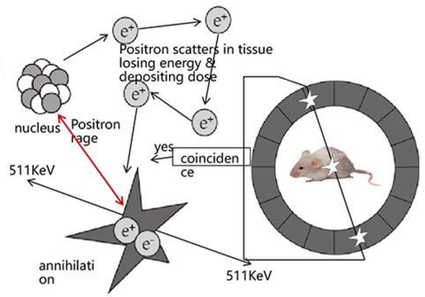


Tissue distribution study based on PET imaging

Pioneering Micro-PET/SPECT/PET in vivo imaging platforms in China.
The research team has rich project experience in IND filing of radioactive diagnostic and therapeutic drugs, 89Zr labeled antibody distribution research , migration and homing research of cell products, etc.

PET (Positron emission tomography)

(1) Most advanced nuclear medicine imaging equipment available in the industry;
(2) By injecting specific positron developer into animals or human, the physiological, pathological, biochemical, metabolic features and the in vivo distribution of receptors can be shown;
(3) By labeling compounds with positronium, the resulting characteristics such as pharmacokinetics and tissue distribution of compounds in animals or human can be obtained.



Schematic diagram of PET imaging

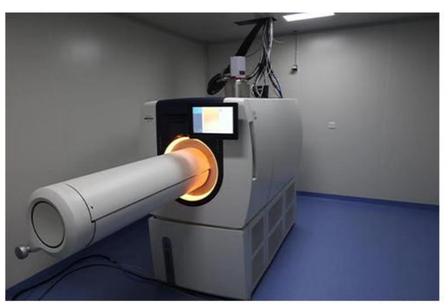
The main features of PET

- Perform on living model animals with noninvasive manners, obtaining dynamic results. Hence, reduce the use of animals;
- Self-control study with repeatability
- Highly sensitive and accurate quantification;

PET/MR imaging on living animals.
Drug categories applicable: Antibodies, stem cells, and positron radiopharmaceuticals

Service Content

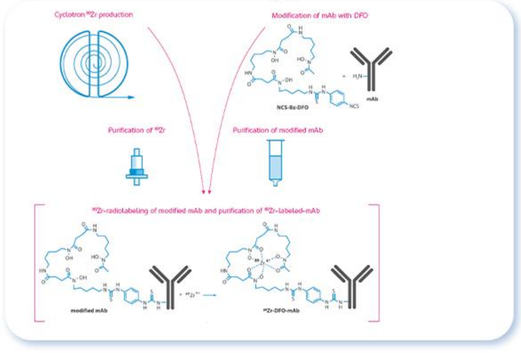
- PET imaging of various species of animals (we cooperate with the First Affiliated Hospital of Suzhou University on the study of large animals. Scans are performed by clinical PET)
- ^{89}Zr、^{68}Ga、^{124}I labeling
- ^{89}Zr、^{124}I -labeled macromolecule drug distribution in vivo
- Isotope (^{89}Zr) labeling of stem cells, in vivo distribution imaging studies
- Tissue distribution study of ^{18}F and ^{68}Ga radiopharmaceuticals


Micro-PET/MR

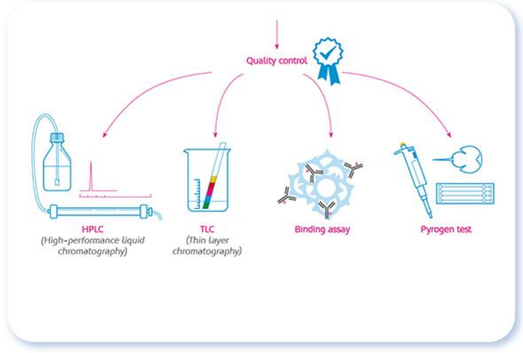
Positron nuclides commonly used for antibody labeling

Nuclide	Half-life (h)	Pros & Cons
^{68}Ga	1.1	Pros: ▪ Easily applicable Can be washed with germanium and gallium generators at any time; Cons: ▪ Short half-life (68 min)
^{64}Cu	12.7	Pros: ▪ Moderate energy; Cons: ▪ Relatively short half-life Isotopic sources are scarce in China
^{89}Zr	78.4	Pros: ▪ Simple production process with low cost and high purity; ▪ Moderate energy and good imaging quality from PET.
^{124}I	100.3 (4.18d)	Pros: ▪ Easy labeling; Cons: ▪ High cost ▪ Strong energy ▪ Scarce sources ; ▪ Deiodination causing high thyroid uptake hence lowering resolution; ▪ Quick excretion of 124I-labeled antibody for its quick degradation into tyrosine in cell.

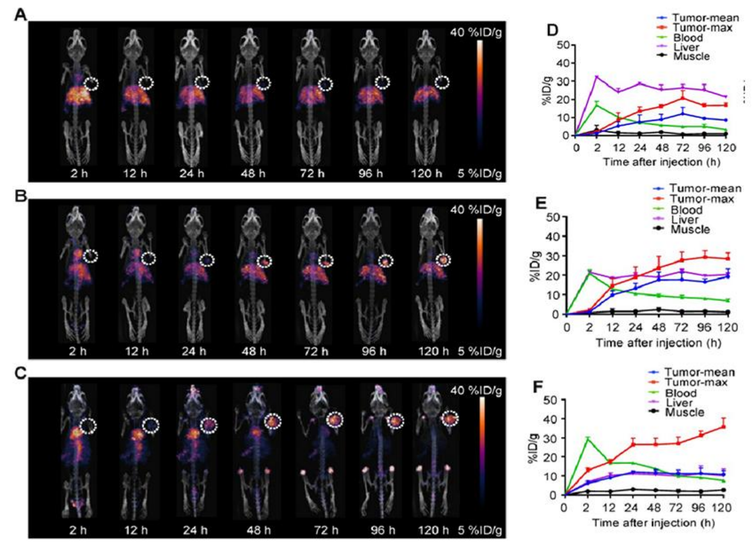
Schematic diagram of the ^{89}Zr labeling



Quality control after ^{89}Zr labeling

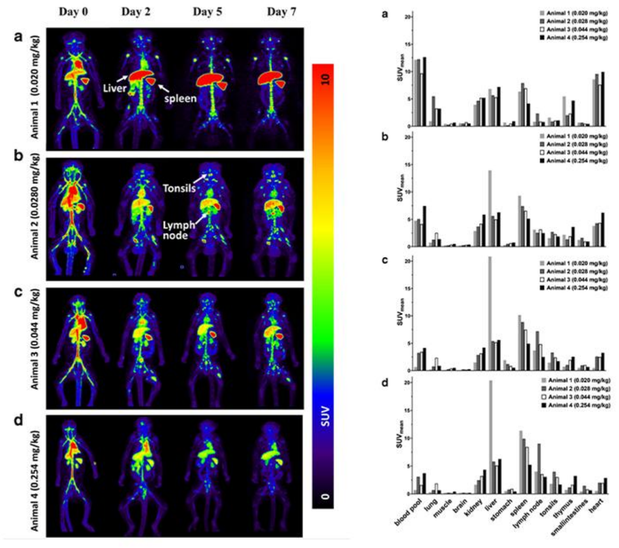


Distribution of ^{89}Zr labeled antibody in tumor-bearing mice



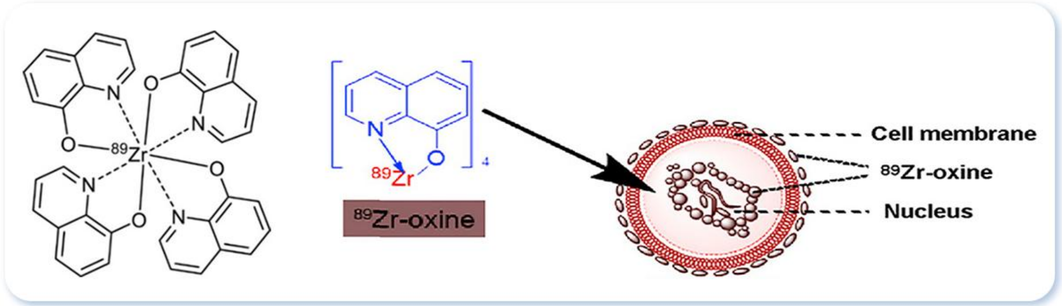
Data source: Theranostics 2021, Vol. 11, Issue 1

Distribution of ^{89}Zr labeled antibodies in large animals



Data source: Mol Imaging Biol (2021) 23:250 –259

A case of the distribution study on radioisotope-labeled cell therapy products

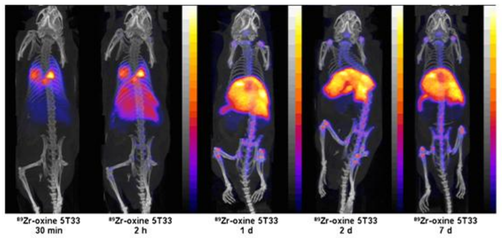


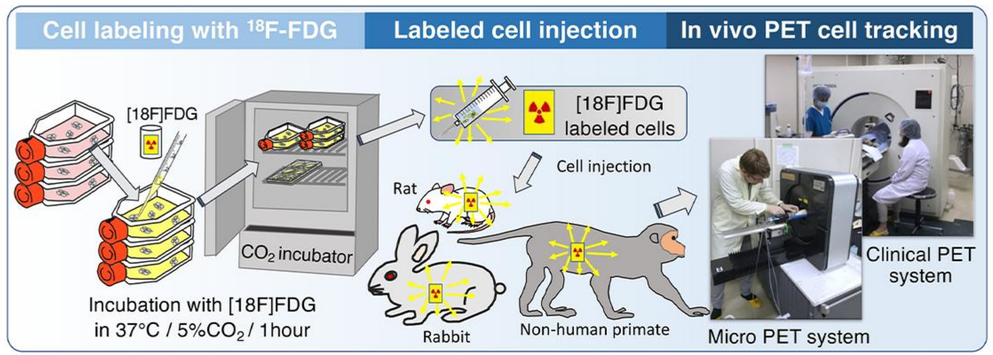
- **Labeling principle of ^{89}Zr-Oxine**

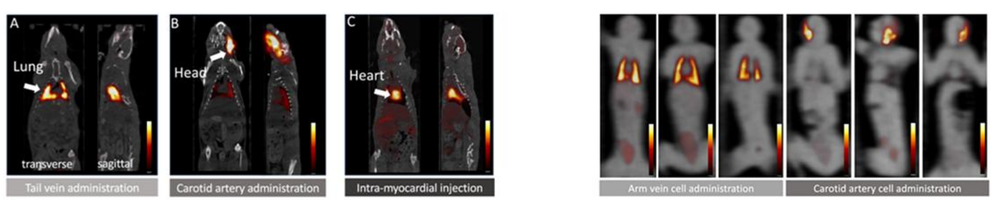
-Oxine, as the 89Zr vector, is highly fat-soluble

-It enters the cells by passive diffusion

-After entering the cell, the vector flows out and ^{89}Zr remains in the cell to bind cytoplasm







doi: 10.1038/s41598-021-90383-4

Non-clinical 3H/14C ADME & clinical sample mass balance study

Non-clinical ^{3}H/^{14}C labeled compound ADME study

- **Service Content:**

-Rodent tissue distribution of ^{3}H/^{14}C labeled compounds

-Biliary excretion and mass balance study in the rat BDC models

-Mass balance study in normal rats

-In vivo biotransformation (metabolite profile) and metabolic pathway study

-Estimation of intrabody Olinda-radiation dose

Mass balance study in clinical samples

- **Service Content:**

-Radioactive drug delivery preparation configuration、stability、radiotherapy purity testing.

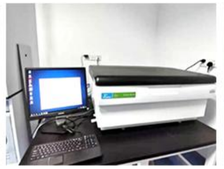
-Prototype drug and major metabolites (LC-MS/MS)

-Detection of total radioactivity in human plasma (Liquid scintillator)

-^{14}C -labeled compounds for human mass balance

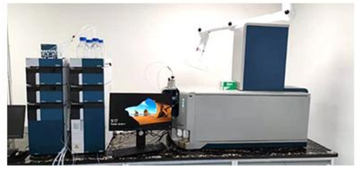
-Biotransformation (metabolite profile) and metabolic pathways of drugs in the human body

Biological oxidation burner



Liquid scintillation counter

Solid scintillation counter



AB 7600 High Resolution Mass Spectrometry

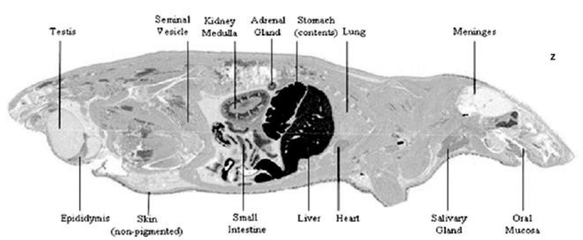
Non-clinical ^{3}H/^{14}C ADME & clinical sample mass balance study

- **Service Content:**

-tissue distribution of ^{3}H/^{14}C compounds in rodents (QWBA)

-Placental barrier permeability study (QWBA)

-Estimation of internal radioactive exposure in human



Freezing microtome

Phosphor screen exposure instrument

Project experience

58+
Serviced radiopharmaceuticals R&D projects

17+
INDs approved by NMPA / FDA / TGA

Cover indications

- diagnose:
  - -Tumor diagnosis
  - -AD diagnose
  - -nervous system
  - -.....
- treat:
  - -Bone cancer metastasis
  - -prostatic carcinoma
  - -solid tumor
  - -.....

Covering the mode of administration

- -Intraperitoneal and intravenous injection
- -venoclysis
- -hypodermic injection
- -Muscle puncture implantation
- -Intravenous injection through the tail vein
- -.....

Covering targets

- -18F, Tau protein
- -Ga68
- -Technetium [99mTc]
- -Carbonic anhydrase IX (CAIX)
- -68Ga/68Ga-FAPI/68Ga-GPC
- -^{68}Ga-PSMA, ^{99}Tm, PSMA
- -Ga^{68}, carbonic anhydrase IX (CAIX)
- -.....

Diagnostic Radiopharmaceuticals	
^{18}F	**Tumor diagnosis and treatment**
^{68}Ga	PSMA
^{99m}Tc	**Tumor diagnosis and treatment**
Therapeutic Radiopharmaceuticals	
^{103}Pd	tumor
^{177}Lu	Targets are involved: PSMA、SSTR、FAPI、$\alpha v\beta_3$, etc
Integrated Radiopharmaceuticals	
^{177}Lu& ^{68}Ga	Oncology diagnosis and treatment

Representative Projects

- The first diagnostic radiopharmaceutical targeting Tau protein in China with an IND approved. (currently advancing to Phase 3 clinical trials)
- The first positron emission computed tomography (PET) tracer for diagnosis of primary and metastatic brain tumors in China with INDs approved by NMPA and FDA.
- Theragnostic products (68Ga-NYM032, 177Lu-NYM032) with INDs approved by NMPA.

Service Experience

Tissue Distribution utilizing ^{125}I labeling

- Antibody
  - -Monoclonal antibody
  - -Bispecific antibody
  - -Multi-specific antibody (tri-specific, tetra-specific)
- ADC
- Fusion protein
- Recombinant protein
- Nanobody
- Polypeptide drug

Tissue Distribution utilizing Micro-PET imaging

- Stem cell therapy
  - -iPSC, MSC,.....
- Antibody drug
  - -Monoclonal antibody
  - -Bispecific antibody
- Diagnostic radiopharmaceuticals

Radiopharmaceuticals IND Enabling

- Diagnostic radiopharmaceuticals
  - -^{18}F
  - -^{68}Ga
  - -^{99}mTc
- Radiotherapeutic drugs
  - -^{103}Pd
  - -^{177}Lu

^{3}H/^{14}C ADME

- Chemical drugs
- ADC

Clinical mass balance study

- Chemical drugs

INNOSTAR

益诺思 INNOSTAR

Shanghai InnoStar Biotechnology Co., Ltd

SHANGHAI HEADQUARTERS
No. 199 Guoshoujing Road, China (Shanghai) Pilot Free Trade Zone
BUSINESS CONSULTING
Tel:+86-21-60211999
Email: services@innostar.cn marketing@innostar.cn

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