CANCER IMMUNOTHERAPIES

Immuno-oncology • GLP Safety and Toxicology • Clinical Trial Support

Recent advances in cancer immunotherapies such as checkpoint inhibitors, cancer vaccines, oncolytic viruses, and CAR-T cell therapies have refocused the oncology drug development landscape from traditional chemotherapeutics to immuno-oncology therapeutics. Preclinical efficacy, safety and toxicology studies for regulatory submissions must include the monitoring of immune responses in addition to traditional toxicology endpoints since adverse events from exaggerated pharmacology may occur.

At IITRI, the cornerstone of our immuno-oncology capabilities is a strong scientific foundation in immunology and cancer biology. We offer preclinical services for cancer immunotherapy development from preclinical translational models and full characterization of immune responses to IND-enabling GLP toxicology and safety studies.

IMMUNOPROFILING

Screening new therapies and developing translational animal models is an essential component of a preclinical program for new antitumor immunotherapies. IITRI now offers immunoprofiling services to support efficacy screening of new therapies in xenograft and syngenic mouse tumor model proof of concept studies.

IITRI's immunoprofiling services include:

- Immunophenotyping with multi-color FACS
- Cytokine panels
- ELISpot assays
- *In vitro* and *in vivo* T cell exhaustion models

IMMUNO-ONCOLOGY TOXICOLOGY

IITRI offers the capability to conduct GLP toxicology studies in mouse tumor models to mimic the physiologic environment of the patient. We also can accommodate BSL-2 viral vectors for oncolytic viral vector efficacy through toxicology studies, and offer scientific support of PhD-level immunologist, virologist and microbiologist study directors.

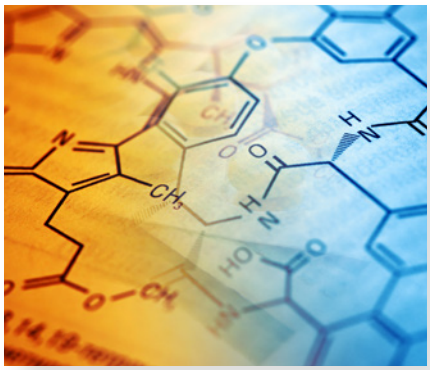
- Toxicology and safety studies
- Histopathology services
- Small molecule and biologic bioanalytical
- Immunogenicity laboratory support
- Rodent, non-rodent and NHP studies

MOUSE TUMOR MODELS

As the leading preclinical contractor to the National Cancer Institute (NCI) for over 10 years, IITRI has conducted preclinical toxicology studies supporting the successful filing of over 20 INDs for the NCI. We work hand-in-hand with our sponsors to design experiments and select the appropriate xenograft or syngeneic model to evaluate new investigational agents. Below is a list of available mouse tumor models:

CANCER TYPE	CELL LINES	MOUSE STRAIN
XENOGRAFT MODELS		
Lung	NCI-H522,NCI-H460, A549, NCI-H1975	Nude
Colorectal	COLO-205, HT29, HCT116, Caco-2, RKO	Nude
Breast	MCF-7, T47D, MDA-MB-231	Nude, SCID
Prostate	PC-3, DU-145	Nude
Ovarian	OVCAR-3, OVCAR-5	Nude, SCID
Renal	RXF-393, Cakl-1, A498	Nude
Melanoma	MDA-MB-435	Nude
Pancreatic	PANC-1	Nude
SYNGENEIC MODELS		
Lung	Lewis Lung Cancer (LLC)	C57BL/6
Colorectal	CT26	BALB/c
Breast	4T1	BALB/c
Melanoma	B16-F10	C57BL/6

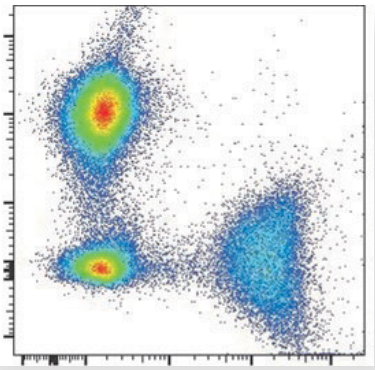
CANCER IMMUNOTHERAPEUTIC DRUG DEVELOPMENT



DRUG DISCOVERY

Efficacy studies
- Cancer cell lines
- Xenograft mouse models
- Transgenic / syngeneic mouse models

Mechanism of action studies
- Gene expression studies
- Cancer cell line-based studies



IMMUNE RESPONSE CHARACTERIZATION

Immunoprofiling
- Immunophenotyping: multi-color FACS
- T-cell characterization
- Cytokine panels

Immunogenicity
- ADA ELISA
- NAb assays
- Rodents, non-rodents, NHPs

GLP SAFETY & TOXICOLOGY

Repeat-dose GLP toxicology studies
- All relevant routes including inhalation
- Rodent, non-rodent, NHP
- ABSL 2

Biodistribution (qPCR)

Safety pharmacology

Reproductive toxicology

CLINICAL TRIAL SUPPORT

Bioanalytical support
- Method cross-validation
- Tissue and fluid matrices

Tissue cross-reactivity

Cytokine panels

Assessment of biomarkers

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