TOXICITY

ACUTE TOXICITY - SAMPLE DESIGNS

- Single-Dose Toxicity Study in Beagle or Mixed Breed Dogs
- MTD Determination with Repeat Dose Range-Finding in Beagle or Mixed Breed Dogs

REPEAT DOSE TOXICOLOGY STUDIES - Non GLP

- 14- Day Repeat Toxicity Study in Beagle or Mixed Breed Dogs

ACUTE TOXICITY - SAMPLE DESIGNS

Single-Dose Toxicity Study in Beagle or Mixed Breed Dogs

Acute Toxicity: Single Dose	
Number of Animals	4 Dogs (2 M/2F)
Treatment Frequency	Single dose
Dose Route	To be specified by sponsor (ex. oral, bolus iv, infusion, subcutaneous injection, intraperitoneal injection, topical ocular, etc.)
Study Duration	48 hours Clinical
Observation Frequency	Daily
Body Weight	Pre-dose and study end Clinical Pathology: Collection pre-dose, 24 and 48 hours post-dose. Options include clinical chemistry, hematology, and/or coagulation parameters.
Necropsy	Gross
Organ Weight	As specified by Sponsor
Histopathology	As specified by Sponsor (ex. Lesions only, target organs, or main organs); Standard histology includes paraffin embedding and slides prepared with H&E
Deliverables	Report with observations and dose administration table for in-life phase, as well as any clinical pathology, gross observations, and pathology results, as applicable.
Compliance	Non-GLP

ACUTE TOXICITY-SAMPLE DESIGNS (1)

MTD Determination with Repeat Dose Range-Finding in Beagle or Mixed Breed Dogs

Phase I: Single Acute Dose	
Animals	4 dogs (2/sex)
Study Duration	Approximately 9 days
Dosing	Up to 4 dose administrations of a single dose with a sponsor-specified washout period between escalating doses
Dose Route	As specified by Sponsor (i.e. Oral, iv, ip)
Clinical Observation	Twice Daily Body Weights and all other observations specified by the sponsor (Prior to dose administration)
Blood Sampling	One sample per treatment for TK

ACUTE TOXICITY - SAMPLE DESIGNS (2)

Phase II: 7-Day Repeat Dose Range-Finding Study	
Animals	24 dogs (3/sex/group)
Study Duration	7 days
Dosing	Daily for 7 days
Dose Route	As specified by Sponsor (i.e. Oral, iv, ip)
Clinical Observation	Twice Daily
Body Weight	Daily
Blood Sampling &TK	Pre-dose and at the end of the study (for clinical chemistry and hematology) TK (6 to 9 time points per day)
Gross Necropsy Organ Weight	Standard by ICH/OECD guidelines
Histopathology	Lesions as applicable; additional charges will be incurred for preservation, processing, and evaluation

REPEAT DOSE TOXICOLOGY STUDIES - Non GLP (1)

14- Day Repeat Toxicity Study in Beagle or Mixed Breed Dogs

		Main Study		Optional Recovery	
	Group	**Male**	**Female**	**Male**	**Female**
Dog	Control	4	4	3	3
	Low	4	4	0	0
	Mid	4	4	0	0
	High	4	4	3	3
Total animals		N= 32		N= 12	
Dose Route	Specified by the sponsor (ex. oral, bolus IV, infusion, subcutaneous injection, intraperitoneal injection, topical ocular …)				
Dose Frequency	Daily				
In-Life Study Duration	14 days dosing plus Recovery Period (i.e. 7 or 14 days)				
Dose Formulation	As specified by Sponsor				
Dose Sampling	Sampling on first and last dose days for dose verification				

REPEAT DOSE TOXICOLOGY STUDIES - Non GLP (2)

14- Day Repeat Toxicity Study in Beagle or Mixed Breed Dogs

Dose Route	To be specified (ex. oral, bolus IV, infusion, subcutaneous injection, intraperitoneal injection, topical ocular …
Clinical Observation	Daily
Food Consumption	Weekly
Body Weight	Weekly
Ophthalmic examination	As specified by sponsor. Suggested prior to first dose and during week 2
Clinical Pathology	All animals, pre-dose and at sacrifice: standard panels for clinical chemistry, hematology, and coagulation, terminal collection for urinalysis
TK Blood sampling	Approximately six time points on day 1 and day 14
TK Blood Processing	A refrigerated centrifuge will used to process whole blood to plasma. Plasma samples will be directly transferred to appropriate tubes and stored at -80. Samples will be shipped to sponsor on dry ice upon receipt of shipping request,
Necropsy	Main and recovery animals
Organ Weight	Standard tissues per ICH/OECD guidelines
Tissue Preservation	Mid and low level group tissues stored in formalin
Histology/Pathology	Standard tissues on high and control animals in main and recovery groups: Sponsor to specify request for histopathology on all tissues or preserved tissues

Contact us:

SPM BIOCAMLETEC
Mal: majd.biocameltec@gmail.com
Phone: +33 6 22 02 59 82
www.biocameltec.com