PHARMACOKINETIC STUDIES
SAMPLE DESIGNS

- Single Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs (Parallel Session)
- Single Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs (4 crossover Sessions)
- Repeat Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs
**PHARMACOKINETIC STUDIES: SAMPLE DESIGNS**

**Single Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs (Parallel Session)**

<table>
<thead>
<tr>
<th>Groups</th>
<th>Test material</th>
<th>Animals per group</th>
<th>Dose Group</th>
<th>Dose Route</th>
<th>Approx. Time points</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>TBD</td>
<td>2M/2F</td>
<td>xx mg/kg</td>
<td>TBD</td>
<td>Approximately 8 time points up to 24 post-dose</td>
</tr>
<tr>
<td>B</td>
<td>TBD</td>
<td>2M/2F</td>
<td>xx mg/kg</td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>

- **Total Animals**: 8 beagle or mixed breed dogs (non-naïve)
- **No. of Dose Sessions**: One session does in parallel
- **Dose Frequency**: Single dose
- **Dose Route**: To be specified (ex. oral, bolus iv, infusion, subcutaneous injection, intraperitoneal injection, topical ocular, etc.)
- **Dose Formulation**: Per Sponsor specifications
- **Collection Times**: Standard collection time points are within normal working hours, 8:00am-5:00pm Monday through Friday. Sponsor-specified collections (i.e. 12 or 18 hour) outside of standard business hours will incur additional charges.
- **Blood Processing**: Whole blood samples will be collected and immediately placed on wet ice until processed. A portion of each blood sample will be processed as specified by Sponsor. Samples will be directly transferred to appropriate tubes and stored at -80 ± 10°C. Samples will be shipped to Sponsor for analysis.
- **Compliance**: Non-GLP
- **Deliverables**: Summary table with animal designation of dose group and collection time points
### Single Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs (4 Crossover Sessions)

<table>
<thead>
<tr>
<th>Species</th>
<th>Dosing Session</th>
<th>Nº of animals</th>
<th>Dose Route</th>
<th>Dose Frequency</th>
<th>Dose (mg/kg)</th>
<th>Blood Collection Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beagle or mixed breed Dogs</td>
<td>1</td>
<td>3M/3F</td>
<td>TBD</td>
<td>1x</td>
<td>TBD</td>
<td>Approximately 8 time points up to 24 post-dose</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>1x</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td>1x</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td>1x</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Total Animals**: Estimated 6 dogs (non-naïve)
- **No. of Dose Sessions**: 4 Sessions
- **Washout Period**: As specified by Sponsor; minimum of 48 hours between doses
- **Dose Frequency**: Single dose
- **Dose Route**: To be specified (ex. oral, bolus iv, infusion, subcutaneous injection, intraperitoneal injection, topical ocular, etc.)
- **Dose Formulation**: Per Sponsor specifications
- **Collection Times**: Standard collection time points are within normal working hours, 8:00am-5:00pm Monday through Friday. Sponsor-specified collections (i.e. 12 or 18 hour) outside of standard business hours will incur additional charges.
- **Blood Processing**: Whole blood samples will be collected and immediately placed on wet ice until processed. A portion of each blood sample will be processed as specified by Sponsor. Samples will be directly transferred to appropriate tubes and stored at -80 ± 10°C. Samples will be shipped to Sponsor for analysis.
- **Compliance**: Non-GLP
- **Deliverables**: Summary table with animal designation of dose group and collection time points
Repeat Dose PK Study in Non-Naïve Beagle or Mixed Breed Dogs

- **Total Animals:** 8 Dogs (non-naïve)
- **Dose Frequency:** Daily for 5-7 days Dose
- **Route:** To be specified (ex. oral, bolus iv, infusion, subcutaneous injection, intraperitoneal injection, topical ocular, etc.)
- **Dose Formulation:** Per Sponsor specifications Clinical Pathology: As specified by Sponsor. Options include clinical chemistry, hematology, coagulation, and/or reticulocytes.
- **TK Blood Processing:** Whole blood samples will be collected and immediately placed on wet ice until processed. A portion of each blood sample will be processed as specified by Sponsor. Samples will be directly transferred to appropriate tubes and stored at -80 ± 10°C. Samples will be shipped to Sponsor for analysis.
- **Compliance:** Non-GLP
- **Deliverables:** Report with observations and dose administration table for in-life phase.

<table>
<thead>
<tr>
<th>Species</th>
<th>No. of animals</th>
<th>Dose Route</th>
<th>Dose Frequency</th>
<th>Sample Collection</th>
<th>Collection Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beagle or mixed breed dogs</td>
<td>4M/4F</td>
<td>As requested</td>
<td>Once daily for 5-7 days</td>
<td>Clinical Pathology</td>
<td>Pre-dose and post-final dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TK</td>
<td>Post-final dose for approximately 6 time points (ex. 0.5, 1, 2, 4, 8 and 24 hours)</td>
</tr>
</tbody>
</table>
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