Investigator-Initiated Study Proposal Form

Please complete all applicable sections of this form and provide a copy of the Principal Investigator's CV to Medical Affairs at: IISRequests.NA@kyowakirin.com.

General information

Kyowa Kirin drug products

☐ Burosumab (Crysvita®)

☐ Istradefylline (Nourianz™)

☐ Mogamulizumab (Poteligeo®)

Study title

Sponsor-investigator information

Principal investigator

Principal investigator name: _____

Credentials: ☐ MD ☐ DO ☐ PhD ☐ Other: _____

Institution: _____

Address: _____

Phone: _____ Email: _____

Primary site information (if different than above)

Contact name: _____

Institution: _____

Address: _____

Phone: _____ Email: _____

Institution type:

☐ Academic

☐ Government

☐ Other (please specify): _____

Contact information:

Contact name: _____

Role: _____

Address: _____

Phone: _____ Email: _____

Is this a multi-site study?

☐ Yes (If yes, please complete the below.) ☐ No

Number of planned sites: _____

Site names and locations:

Please list previous collaborations/partnerships with Kyowa Kirin below.

Study description

Background/Rationale

Please provide a brief summary of the overall study purpose and rationale for this proposed study, including an explanation of clinical significance.

Additional documentation may be provided as separate attachments in your email submission.

Study objectives

Please provide a description of the key study objective(s) or research question(s), including hypothesis if applicable.

Primary objectives

Secondary objectives

Study design

Study type

Select all that apply.

☐ Clinical ☐ Interventional ☐ Registry ☐ In vitro
☐ Non-Clinical ☐ Observational ☐ Retrospective ☐ Biomarkers
☐ Pre-Clinical ☐ HEOR/RWE ☐ Exploratory
☐ Other: _____

Study Phase

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
If Phase IV, will this be a post-marketing study? ☐ Yes ☐ No

Design and methods

Please provide the procedures, methods, and measurements to be used during the study. Study schema can be included as a separate document.

Design and methods (cont.)

Target enrollment/sample size

Study population

Please provide a general description of the study population (e.g., demographics such as age, sex, and other key characteristics).

Inclusion criteria

Exclusion criteria

Study drug regimen

Please provide dosage, frequency, route of administration, and duration for both investigational drug and any comparative drug.

Statistical plan or data analysis

Please specify power, sample size calculations, and statistical plan and list criteria for evaluability including intent-to-treat, per protocol, and safety population.

Preliminary publication plan

Please give a brief description of the expected date of publications and presentations that may result from this data, as well as target journals and/or conferences.

Study timelines

Estimated study duration/ timelines

For clinical studies	Months
Contract execution to first patient in:	_____
Enrollment period (first patient in to last patient in):	_____
Follow-up period (last patient in to last patient, last visit):	_____
Last patient, last visit to final study report:	_____

For non-clinical studies	Months
Contract execution to study start:	_____
Study start to study completion:	_____
Study completion to final study report:	_____

Total study duration: _____
(contract execution to final study report)

Target study start date: _____
Target study completion date: _____
Target date for data analysis completion: _____

Estimated monthly patient accrual

Support requested

Request type
Select all that apply.

☐ Funding
☐ Study drug *(Please note we are unable to provide matching placebo at this time.)*

Study budget
Please give an estimated breakdown of the funding request by completing the table provided and specify any additional request for funding.

Patient costs	$
Per patient cost	$
Total number of patients	
Study task/personnel costs	$
Site costs	$
Pass-through costs	$
TOTAL	**$** 0

Comments:

Quantity of product per patient

Please list exact numbers of tablets or vials per patient and dosage required.

Total quantity of product requested

Special requirements

(e.g., labeling, blinding, etc.).

If commercial product is supplied, will insurance payments be required?

☐ Yes
☐ No

Will the study involve on-label or off-label use of a Kyowa Kirin product?

☐ On-label
☐ Off-label

Do you plan to submit an IND for this study?

☐ Yes
☐ No

Will support be requested from other companies to run this study?

☐ Yes
☐ No

If yes, please specify type and amount of support.

Will any collaborative groups, research bodies or other organizations be involved in running this study?

☐ Yes
☐ No

Are there any actively competing studies being conducted at your institution?

☐ Yes
☐ No
☐ Prefer not to answer

References

Investigator Acknowledgment

By accepting this agreement, I confirm that the information provided above and/or attached is complete and accurate to the best of my knowledge. I agree that any amount awarded will be subject to further terms and conditions to be included in a written clinical study agreement. I, the study investigator, attest that Kyowa Kirin has not unduly influenced the submission of this IIS proposal.

Name: _____

Signature: _____

Date: _____