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| **Protocol number:** |  |
| **Version (date):** |  |
| **Sponsor:** | Company name  Address |
| **Emergency contact:** | Email: [xxx@companyname.com](mailto:xxx@companyname.com)  Telephone: +xx.xx.xxx.xx.xx |
| **Investigational therapy:** |  |
| **Development phase:** |  |
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Sponsor signature page

This clinical trial protocol was subjected to critical review and has been approved by the sponsor. By my signature, I confirm that the information it contains is consistent with current risk/benefit evaluation of the investigational therapy as well with moral, ethical, and scientific principles governing clinical research set out in the current version of the Declaration of Helsinki, the International Council for Harmonisation (ICH) Good Clinical Practices Guidelines, and local regulations.

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|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Signature** |  | **Date** |

Investigator signature page

I have read this study protocol, including all appendices. By my signature, I agree to personally supervise the conduct of this clinical study at my study site and to ensure its conduct is in compliance with the protocol, informed consent, Institutional Review Board (IRB)/Ethics Committee (EC) procedures, the current version of the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practices Guidelines, and local regulations governing the conduct of clinical studies.

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| **Name, Degree(s)**  **Title**  **Institution name** |  | **Signature** |  | **Date** |

Protocol amendment history

Document history

|  |  |
| --- | --- |
| **Protocol version** | **Date** |
| Amendment N | DD-Mmm-YYYY |
| Amendment N-1 | DD-Mmm-YYYY |
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| Amendment 1 | DD-Mmm-YYYY |
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Amendment N (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

Amendment N-1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

Amendment 1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

Protocol Summary

Synopsis

Study rationale and purpose

Objectives, endpoints, and estimands

Population

Key inclusion/exclusion criteria

Investigational and reference therapy

Study design

Graphical study design

Study flow

Study and treatment periods

Efficacy assessments

Safety and tolerability assessments

Other assessments

Statistical methods

Committees

Visit and assessment schedule

Table of contents

[Sponsor signature page 2](#_Toc93071821)

[Investigator signature page 3](#_Toc93071822)

[Protocol amendment history 4](#_Toc93071823)

[Document history 4](#_Toc93071824)

[Amendment N (DD-Mmm-YYYY) 4](#_Toc93071825)

[Amendment N-1 (DD-Mmm-YYYY) 4](#_Toc93071826)

[Amendment 1 (DD-Mmm-YYYY) 4](#_Toc93071827)

[Protocol Summary 5](#_Toc93071828)

[Synopsis 5](#_Toc93071829)

[Visit and assessment schedule 6](#_Toc93071830)

[List of figures 10](#_Toc93071831)

[List of tables 11](#_Toc93071832)

[List of abbreviations 12](#_Toc93071833)

[1. Background and rationale 13](#_Toc93071834)

[1.1. Background 13](#_Toc93071835)

[1.2. Rationale 13](#_Toc93071836)

[1.2.1. Study rationale and purpose 13](#_Toc93071837)

[1.2.2. Rationale for the study design 13](#_Toc93071838)

[1.2.3. Rationale for the endpoints 13](#_Toc93071839)

[1.2.4. Rationale for the investigational therapy 13](#_Toc93071840)

[1.2.4.1. Rationale for the dose and regimen selection 13](#_Toc93071841)

[1.2.4.2. Rationale for the combination treatments 13](#_Toc93071842)

[1.2.5. Rationale for the reference therapy 13](#_Toc93071843)

[2. Objectives, endpoints, and estimands 14](#_Toc93071844)

[3. Study design 15](#_Toc93071845)

[3.1. Description of the study design 15](#_Toc93071846)

[3.2. Definition of end of study 15](#_Toc93071847)

[3.3. Early study termination 15](#_Toc93071848)

[4. Population 16](#_Toc93071849)

[4.1. Patient population 16](#_Toc93071850)

[4.2. Eligibility criteria 16](#_Toc93071851)

[4.2.1. Inclusion criteria 16](#_Toc93071852)

[4.2.2. Exclusion criteria 16](#_Toc93071853)

[4.3. Screen failure 16](#_Toc93071854)

[4.4. Patient numbering, treatment assignment and blinding 16](#_Toc93071855)

[4.4.1. Patient numbering 16](#_Toc93071856)

[4.4.2. Treatment assignment 16](#_Toc93071857)

[4.4.3. Blinding and unblinding 16](#_Toc93071858)

[5. Treatments 17](#_Toc93071859)

[5.1. Study treatment 17](#_Toc93071860)

[5.2. Dose modifications and delay 17](#_Toc93071861)

[5.2.1. Dose modification 17](#_Toc93071862)

[5.2.2. Dose delay 17](#_Toc93071863)

[5.3. Treatment preparation and dispensation 17](#_Toc93071864)

[5.3.1. Study drug packaging and labeling 17](#_Toc93071865)

[5.3.2. Drug supply and storage 17](#_Toc93071866)

[5.3.3. Study drug compliance and accountability 17](#_Toc93071867)

[5.3.4. Study drug disposal and destruction 17](#_Toc93071868)

[5.4. Concomitant medications, therapies, and procedures 17](#_Toc93071869)

[5.5. Prohibited concomitant medications, therapies, and procedures 17](#_Toc93071870)

[6. Visit and assessment schedule 18](#_Toc93071871)

[6.1. Study flow and visit schedule 18](#_Toc93071872)

[6.1.1. Screening phase 18](#_Toc93071873)

[6.1.2. Pre-treatment phase 18](#_Toc93071874)

[6.1.3. Treatment phase 18](#_Toc93071875)

[6.1.4. Efficacy follow-up phase 18](#_Toc93071876)

[6.1.5. Survival follow-up phase 18](#_Toc93071877)

[6.1.6. Discontinuation of study treatment 18](#_Toc93071878)

[6.1.7. Withdrawal of consent 18](#_Toc93071879)

[6.1.8. Follow-up for safety evaluations 18](#_Toc93071880)

[6.1.9. Loss to follow-up 18](#_Toc93071881)

[6.1.10. Unscheduled assessments 18](#_Toc93071882)

[6.2. Assessment types 18](#_Toc93071883)

[6.2.1. Efficacy assessments 18](#_Toc93071884)

[6.2.2. Safety and tolerability assessments 18](#_Toc93071885)

[6.2.3. Translational assessments 18](#_Toc93071886)

[6.2.4. Patient reported outcomes 18](#_Toc93071887)

[6.2.5. Healthcare resource utilization 18](#_Toc93071888)

[7. Safety monitoring and reporting 19](#_Toc93071889)

[7.1. Adverse events 19](#_Toc93071890)

[7.1.1. Definition 19](#_Toc93071891)

[7.1.2. Grading and relationship to study drug 19](#_Toc93071892)

[7.1.3. Reporting 19](#_Toc93071893)

[7.1.4. Laboratory and other assessments abnormalities 19](#_Toc93071894)

[7.1.5. Adverse events of special interest 19](#_Toc93071895)

[7.2. Serious adverse events 19](#_Toc93071896)

[7.2.1. Definition 19](#_Toc93071897)

[7.2.2. Reporting 19](#_Toc93071898)

[7.3. Emergency unblinding 19](#_Toc93071899)

[7.4. Pregnancies 19](#_Toc93071900)

[7.5. Contraception and barrier guidance 19](#_Toc93071901)

[8. Committees 20](#_Toc93071902)

[8.1. Scientific steering committee 20](#_Toc93071903)

[8.2. Data monitoring committee 20](#_Toc93071904)

[8.3. Safety review committee 20](#_Toc93071905)

[8.4. Independent review committee 20](#_Toc93071906)

[9. Data collection, monitoring and management 21](#_Toc93071907)

[9.1. Data confidentiality 21](#_Toc93071908)

[9.2. Data collection 21](#_Toc93071909)

[9.3. Database management and quality control 21](#_Toc93071910)

[9.4. Data monitoring 21](#_Toc93071911)

[10. Statistical method 22](#_Toc93071912)

[10.1. Estimands and statistical hypotheses 22](#_Toc93071913)

[10.2. Sample size 22](#_Toc93071914)

[10.2.1. Sample size determination 22](#_Toc93071915)

[10.2.2. Robustness of the sample size 22](#_Toc93071916)

[10.3. Analysis sets 22](#_Toc93071917)

[10.4. Statistical analyses 22](#_Toc93071918)

[10.4.1. General considerations 22](#_Toc93071919)

[10.4.2. Primary evaluation 22](#_Toc93071920)

[10.4.2.1. Definition 22](#_Toc93071921)

[10.4.2.2. Main analytical approach 22](#_Toc93071922)

[10.4.2.3. Sensitivity analyses 22](#_Toc93071923)

[10.4.2.4. Supplementary analyses 22](#_Toc93071924)

[10.4.3. Secondary evaluation 22](#_Toc93071925)

[10.4.4. Exploratory evaluation 22](#_Toc93071926)

[10.4.5. Safety evaluation 22](#_Toc93071927)

[10.5. Interim analyses and timing of analyses 22](#_Toc93071928)

[11. Ethical considerations and administrative procedures 23](#_Toc93071929)

[11.1. Regulatory and ethical compliance 23](#_Toc93071930)

[11.2. Responsibility of the investigator and IRB/IEC/REB 23](#_Toc93071931)

[11.3. Informed consent procedures 23](#_Toc93071932)

[11.4. Discontinuation of study 23](#_Toc93071933)

[11.5. Publication of study protocol and results 23](#_Toc93071934)

[11.6. Study documentation, record keeping and retention of documents 23](#_Toc93071935)

[11.7. Confidentiality of study documents and patient records 23](#_Toc93071936)

[11.8. Audits and inspections 23](#_Toc93071937)

[11.9. Financial disclosures 23](#_Toc93071938)

[11.10. Protocol adherence 23](#_Toc93071939)

[11.11. Amendment to the protocol 23](#_Toc93071940)

[12. References 24](#_Toc93071941)

[13. Appendices 25](#_Toc93071942)

List of figures

**No table of figures entries found.**

No numbered figure in the document

List of tables

No numbered table in the document

List of abbreviations

| **Acronym** | **Definition** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

# Background and rationale

## Background

## Rationale

### Study rationale and purpose

### Rationale for the study design

### Rationale for the endpoints

### Rationale for the investigational therapy

#### Rationale for the dose and regimen selection

#### Rationale for the combination treatments

### Rationale for the reference therapy

# Objectives, endpoints, and estimands

| **Objective** | **Endpoint** | **Condition of evaluation** |
| --- | --- | --- |
| **Primary objective(s)** |  |  |
|  |  |  |
| **Key secondary objective(s)** |  |  |
|  |  |  |
| **Secondary objectives** |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Exploratory objectives** |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Study design

## Description of the study design

## Definition of end of study

## Early study termination

# Population

## Patient population

## Eligibility criteria

### Inclusion criteria

### Exclusion criteria

## Screen failure

## Patient numbering, treatment assignment and blinding

### Patient numbering

### Treatment assignment

### Blinding and unblinding

# Treatments

## Study treatment

## Dose modifications and delay

### Dose modification

### Dose delay

## Treatment preparation and dispensation

### Study drug packaging and labeling

### Drug supply and storage

### Study drug compliance and accountability

### Study drug disposal and destruction

## Concomitant medications, therapies, and procedures

## Prohibited concomitant medications, therapies, and procedures

# Visit and assessment schedule

## Study flow and visit schedule

### Screening phase

### Pre-treatment phase

### Treatment phase

### Efficacy follow-up phase

### Survival follow-up phase

### Discontinuation of study treatment

### Withdrawal of consent

### Follow-up for safety evaluations

### Loss to follow-up

### Unscheduled assessments

## Assessment types

### Efficacy assessments

### Safety and tolerability assessments

### Translational assessments

### Patient reported outcomes

### Healthcare resource utilization

# Safety monitoring and reporting

## Adverse events

### Definition

### Grading and relationship to study drug

### Reporting

### Laboratory and other assessments abnormalities

### Adverse events of special interest

## Serious adverse events

### Definition

### Reporting

## Emergency unblinding

## Pregnancies

## Contraception and barrier guidance

# Committees

## Scientific steering committee

## Data monitoring committee

## Safety review committee

## Independent review committee

# Data collection, monitoring and management

## Data confidentiality

## Data collection

## Database management and quality control

## Data monitoring

# Statistical method

## Estimands and statistical hypotheses

## Sample size

### Sample size determination

### Robustness of the sample size

## Analysis sets

## Statistical analyses

### General considerations

### Primary evaluation

#### Definition

#### Main analytical approach

#### Sensitivity analyses

#### Supplementary analyses

### Secondary evaluation

### Exploratory evaluation

### Safety evaluation

## Interim analyses and timing of analyses

# Ethical considerations and administrative procedures

## Regulatory and ethical compliance

## Responsibility of the investigator and IRB/IEC/REB

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## Study documentation, record keeping and retention of documents

## Confidentiality of study documents and patient records

## Audits and inspections

## Financial disclosures

## Protocol adherence

## Amendment to the protocol

# References

# Appendices