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**EU CT number -** 2022-502660-20-00

**Date**: 16 Jun 2023

**Re: Submission of a Clinical Trial Application for A Phase 3, Open-label, Randomized Study To Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 x Anti-CD3 Bispecific Antibody, Versus Investigator's Choice in Previously Untreated Patients with Follicular Lymphoma (OLYMPIA-1)**

| | |
|---|---|
| **Investigational medicinal product (IMP)** | Odronextamab (REGN1979) |
| **Protocol number** | R1979-HM-2298 |
| **Protocol Title** | A Phase 3, Open-label, Randomized Study to Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 x Anti-CD3 Bispecific Antibody, Versus Investigator's Choice in Previously Untreated Patients with Follicular Lymphoma (OLYMPIA-1) |

| | |
|---|---|
| **Sponsor** | Regeneron Pharmaceuticals, Inc. |
| **EU Legal Representative** | Regeneron Ireland DAC |
| **Applicant** | Regeneron Ireland DAC |

| | |
|---|---|
| **Member States (MS)** | Austria (AT), Belgium (BE), Czech Republic (CZ), Germany (DE), Spain (ES), France (FR), Italy (IT), Poland (PL) |
| **Proposed Reference Member State (RMS)** | Spain (ES) |

Dear Sir/Madam,

Please find enclosed a Clinical Trial Application (CTA) dossier for your consideration, submitted under Regulation EU No 536/2014.

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## CLINICAL TRIAL DETAILS

This is an open-label, multi-centre, randomized phase 3 study to compare the efficacy and safety of odronextamab to investigator's choice of treatment (Rituximab-CHOP, Rituximab-CVP, or Rituximab-Bendamustine) in the participants with previously untreated follicular lymphoma (FL). In Part 1 (safety run-in), the intended dose of odronextamab monotherapy to carry forward to Part 2 (randomized phase) will be tested to assess safety. The efficacy and safety of odronextamab will be evaluated in Part 2, compared with investigator's choice of chemotherapy.

The primary objective of the Part 1 of the study is to assess the safety, tolerability, and dose-limiting toxicities (DLTs) as well as preliminary anti-tumor activity of odronextamab in participants with previously untreated FL. The study will enrol approximately 24 patients in the part I globally.

The primary objective of the Part 2 of the study is to compare the efficacy of odronextamab versus investigator's choice treatments in participants with previously untreated FL as measured by complete response at 30 months (CR30) per independent central review.

Study procedures include radiological examination for the patients.

The study will enrol approximately 446 participants in 200 sites globally randomized in a 1:1 ratio to receive either odronextamab followed by odronextamab maintenance or rituximab in combination with chemotherapy followed by rituximab maintenance. It is planned to include eligible participants aged 18 years or older with previously untreated $CD20^{+}$ FL based on World Health Organization (WHO) classification.

This proposed phase 3 trial is not a low-intervention clinical trial. The drug odronextamab has already been investigated in humans as part of Phase I First in Human trial and this is not the first administration of the active substance.

The study does not allow the inclusion of minors under the age of 18, pregnant or breastfeeding women. The patient who are not able to give informed consent can participate in the trial only if legally acceptable representative sign the ICF on behalf of the patient; however, patients must have the ability to understand the purpose and risks of the study.

Benefit Risk Assessment:

Please refer to Section 3.2.3 "Risk-Benefit" within the Protocol R1979-HM-2298.

## IMP/AXMP

Table 1 provides a comprehensive list of all IMPs and Auxiliary Medicinal Products (AxMPs), including the regulatory status of each compound as outlined in *Protocol Section 8. Study Treatments*.

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None of the investigational medicinal products or auxiliary medicinal products are a narcotic, psychotropic, radiopharmaceutical, nor do they contain GMO(s).

Further non-clinical and clinical information on the IMP can be found in the Investigator Brochure (IB) whilst CMC information can be found in the Investigational Medicinal Product Dossier (IMPD).

Additional information for IMP rituximab and below listed comparators can be found in the representative Summary of Product Characteristics (SmPC).

**Table 1: List of IMP(s) and AxMP(s) used in the proposed clinical study**

| **Compound** | **IMP or AxMP** | **Regulatory status (EU or ICH country)** |
|---|---|---|
| Odronextamab | IMP | Not authorized in EU |
| Rituximab | IMP | Authorized in EU |
| Cyclophosphamide | IMP | Authorized in EU |
| Doxorubicin | IMP | Authorized in EU |
| Vincristine | IMP | Authorized in EU |
| Prednisone | IMP | Authorized in EU |
| Bendamustine | IMP | Authorized in EU |

All comparators are authorized in all participating member states, therefore and based on CTR Annex 1 section H(55), no additional documentation is provided or included in CTIS.

Representative calculations on maximum daily and maximum total dose are included in CTIS, as the fields are defined as mandatory.

Please note that each investigator/clinical trial site will individually source authorised comparators as indicated by the active substance name or ATC code. However, where IMPs are sourced centrally via the sponsor, the product will be relabeled or repackaged in local language in line with the local regulation.

## Orphan designation status

The orphan designation was approved for odronextamab (REGN1979) for the treatment of follicular lymphoma (FL) on 18 July 2022, EU/3/22/2649.

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## Scientific Advice

Scientific advice has been sought from the European Medicines Agency (EMA) on 09 March 2021, EMA/SA/0000049550, Scientific advice discussion meeting for Odronextamab indolent lymphoma (iNHL) program in adult patients. The meeting minutes of the SA is provided is provided in this CTA dossier.

## Paediatric Investigation Plan

This clinical trial is not part or is not intended to be part of a Paediatric Investigation Plan (PIP) as referred to in Title II, Chapter 3, of Regulation (EC) No 1901/2006.

## IMPD

### Odronextamab (REGN1979)

Odronextamab will be supplied as a liquid in sterile, single-use vials. Two concentrations of odronextamab for intravenous (IV) administration will be used: 2 mg/mL and 20 mg/mL. The 100 mg/ml concentration listed in the IMPD is only used for subcutaneous administration which is not a proposed route of administration for this study.

There is no placebo control arm in this study. Odronextamab will be provided by the Sponsor as vials in cartons and labelled per country requirements.

Although only the liquid in sterile, single-use vials is intended for use in this study, the Sponsor is including all drug product presentations in the IMPD, in order to facilitate lifecycle management of the dossier going forward.

The accompanying Investigational Medicinal Product Dossier (IMPD) “odronextamab IMPD V 8.2” dated 10 Mar 2023 supports the use of odronextamab in this study. The odronextamab is currently being investigated in the EU under clinical studies R1979-HM-1333 and R1979-ONC-1625. The IMPD V 8.2 is approved in Germany on 24 April 2023 and in the France on 14 April 2023 for the study R1979-ONC-1625.

Please note that due to the restrictions caused by COVID-19, the period of validity for GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2023.

### Comparator treatment: Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, Prednisone and Bendamustine

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Rituximab used in this study, as outlined in the study protocol, is marketed authorized drug, and is either sourced locally by the investigational sites (which remains the preferred option), or supplied by the Sponsor centrally. Authorized product supplied by the Sponsor is over labelled and repackaged. A representative EU Summary of Product Characteristics (SmPC) is provided with this application, noting that products with the same strength and form may be used from different marketing authorization holders depending on the availability of the product at the time of sourcing. Rituximab is approved in the EU for the treatment of adult patients with CD20 positive follicular lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) chemotherapy.

Rituximab for this study will be QP released by Millmount Healthcare Limited, Ireland as required by local regulations. The supporting documents including manufacturers/importers authorizations, QP declarations and GMP certificates are included in this submission.

Please note that due to the restrictions caused by COVID-19, the period of validity for GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2023.

CHOP/CVP (Cyclophosphamide, Doxorubicin, Vincristine, Prednisone) as described in the protocol are approved standard of care treatments for the treatment of non-Hodgkin lymphoma.

The EU SmPCs of the comparator products are provided as examples only, since products with same pharmaceutical form and strength from different marketing authorisation holders may be used depending on availability of the product at the time of sourcing.

## REFERENCE SAFETY INFORMATION

The current reference safety information for Odronextamab is contained in section 6.6 of the Investigator's Brochure (IB) REGN1979 IB, Edition 9 dated 16 February 2023 attached to this submission.

The IB Edition 9 has already been approved in Germany on 24 April 2023 for the study R1979-ONC-1625 and on 28 April 2023 for the study R1979-HM-1333 under the clinical trial directives. The IB Edition 9 is also approved by France on 14 April for the clinical study, R1979-ONC-1625 under the clinical trial directives.

The RSI which will be used for the assessment of expectedness for safety reporting of Suspected Unexpected Serious Adverse Reactions (SUSARS) for each of the study IMPs is provided in the attached documents:

- Rituximab – 100 mg and 500 mg Concentrate for Solution for Infusion Injection – SmPC
- Cyclophosphamide – 500mg Powder for Solution for Injection/Infusion-SmPC
- Doxorubicin – 2mg Solution of Injection-SmPC
- Vincristine – 1mg Injection-SmPC
- Prednisone – 50mg Tablets-SmPC

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– Bendamustine – 25mg Solution for Injection-SmPC

## MEDICAL DEVICE STATUS

There are no medical devices, including in-vitro/companion diagnostics, which are to be investigated in the clinical trial

## LABELLING

In accordance with Annex VI, Particulars for the immediate and outer packaging are enclosed within this application along with translations into local languages.

No additional labels in French and Dutch language are provided for products rituximab, bendamustine, doxorubicin, vincristine and cyclophosphamide in line with the guidance provided in the Annex II Language requirement for Part I documents of Regulation (EU) No 536/2014 Questions and Answers February 2023. As per the guidance, English labelling is acceptable for an IMP that is only administered by the physician or qualified health professional in Belgium. The approach proposed for the IMP label in the guidance was additionally applied for the aforementioned comparators.

All the aforementioned comparators will be administered by physician only at the investigator site and will not be handed to patient for self-administration.

German labels are included in this application to support the investigator sites in Germany that do not accept English language labels even in instances where the drug is administered by the physician.

## COUNTRY-SPECIFIC INFORMATION

Proof of payment has been included in the application for the relevant countries.

**Germany (DE):**

Since an application procedure at the Federal Office for Radiation Protection (BfS) may be planned, we kindly ask you to release an EC vote in accordance with §36 of the Radiation Protection Act in case of a favorable opinion. Please send the EC vote acc. to §36 Radiation Protection Act to submissions.Germany@iconplc.com

The following CEC have been selected for countries listed below:

Italy: Comitato Etico della Fondazione IRCCS “Istituto Nazionale dei Tumori”, Via G. Venezian, 1 - 20133 Milano, Italy

Spain: CEIm Parc Tauli, Parc Taulí, 1 - Edifici Santa Fe, ala izquierda planta 2ª. 08208. Sabadell. Barcelona. Spain.

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## ANNUAL SAFETY REPORT

The anticipated date of first Annual Safety Report submission will be based on the Development International Birth Date (DIBD).

## CTA DOSSIER

### Deferral request

In this application, Regeneron Pharmaceuticals has requested a 5 (five) years deferral of the publication of applicable documents in accordance with EMA guidance. This is in line with its status as a category 2 (phase III study), with corresponding deferral justification as per EU Clinical Trial Regulation (CTR) deferral guideline.

### CTA content

Part I of the dossier consists of the supporting documents outlined in the table provided in Annex 1 of this cover letter. Redacted versions of these documents are also provided as outlined in the tables in the annex, for the purposes of public disclosure.

Part II of the dossier consists of the supporting country-specific documents outlined in the Annex II of this cover letter. Redacted versions of these documents are also provided as outlined in Appendix 1, for the purposes of public disclosure.

We trust that the information provided is sufficient. However, should you require any further information or clarification with regards to this submission package, please do not hesitate to contact us. EU CTIS will be monitored for notices and alerts related to this submission.

Sincerely,

*See appended e-signature page*

Regeneron EU Regulatory Affairs

*This submission contains confidential and proprietary commercial information and/or trade secrets which are subject to protection under laws and regulations worldwide including, but not limited to TRIPS Article 39 and regional, national or state laws whether by legislation or in equity. For the*

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*purposes of compliance with all applicable freedom of information laws, and regulations, and their equivalents anywhere in the world including but not limited to the US Freedom of Information Act 5 U.S.C. §552, Regeneron expects that, prior to disclosure to third parties of any information and/or data related to, or contained within, this submission, it will be given every opportunity under applicable laws to protect its commercial interests and/or its trade secrets including the opportunity to object to such disclosure and/or provide redaction proposals.*

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# ANNEX I

**Table 1: Part I supporting Documents:**

| Title | Version Number | Date | Redacted version provided (Y/N) |
|---|---|---|---|
| B1_Cover letter | 1.0 | 16 Jun 2023 | Y |
| D1_Protocol | 1.0 | 21 Dec 2022 | Y |
| D1_Protocol synopsis_EN | 1.0 | 21 Dec 2022 | N |
| D1_Protocol synopsis_AT | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_BE (fr) | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_BE (de) | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_BE (nl) | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_CZ | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_ES | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_FR | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_IT | 1.0 | 02 Jun 2023 | N |
| D1_Protocol synopsis_PL | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_EN (Plain Language Patient Summary) | 1.0 | 01 Feb 2023 | N |
| D1_PLPS_AT | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_BE (fr) | 1.0 | 02 Jun 2023 | N |

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| D1_PLPS_ BE (de) | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ BE (nl) | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ CZ | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ ES | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ FR | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ IT | 1.0 | 02 Jun 2023 | N |
| D1_PLPS_ PL | 1.0 | 02 Jun 2023 | N |
| D3_DSMB Charter | 1.0 | 05-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_EN | 1.0 | 06-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _EN | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_AT | 1.0 | 07-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _AT | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_BE (de) | 1.0 | 07-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _BE (de) | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_BE (fr) | 1.0 | 07-Jun-2023 | N |

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|---|---|---|---|
| D4_Patient facing documents_eCOA screen report _BE (fr) | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_BE (nl) | 1.0 | 06-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _BE (nl) | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_CZ | 1.0 | 07-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _CZ | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_DE | 1.0 | 06-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _DE | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_ES | 1.0 | 06-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _ES | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_FR | 1.0 | 07-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _FR | 1.0 | 06-Jun-2023 | Y |
| D4_Patient facing documents_subject quick reference guide_IT | 1.0 | 07-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _IT | 1.0 | 06-Jun-2023 | Y |

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| D4_Patient facing documents_subject quick reference guide_PL | 1.0 | 06-Jun-2023 | N |
| D4_Patient facing documents_eCOA screen report _PL | 1.0 | 07-Jun-2023 | Y |
| E1_IB (REGN1979) | 9.0 | 16 Feb 2023 | Y |
| F1_GMP declaration_Regeneron Declaration | 1.0 | 11 May 2023 | Y |
| F1_GMP declaration_Fisher Clinical Services, UK | 2.0 | 19 Dec 2022 | N |
| F1_GMP declaration_ Fisher Clinical Services, Germany | 2.0 | 30 Nov 2022 | N |
| F1_GMP declaration_Yourway Transport Limited, UK | 2.0 | 19 Dec 2022 | N |
| F1_GMP declaration_Sanaclis s.r.o, Slovakia | 1.0 | 21 Dec 2021 | N |
| F1_GMP declaration_Anderson Brecon Limited, UK | 1.0 | 09 Dec 2020 | N |
| F1_GMP declaration_Biotec Services International Limited, UK | 1.0 | 19 Nov 2021 | N |
| F1_GMP declaration_Millmount Healthcare Limited, Ireland | 1.0 | 17 Aug 2021 | N |
| F1_GMP declaration_Yourway Transport Biopharma Services, USA | 1.0 | 28 Feb 2022 | Y |
| F1_GMP declaration_Anderson Brecon Inc., US | 1.0 | 28 Feb 2023 | N |
| F1_GMP declaration_Baxter Pharmaceutical Solution, LLC, US | 1.0 | 28 Feb 2023 | N |
| F1_GMP declaration_Catalant Indiana, LLC, US | 1.0 | 28 Feb 2023 | N |
| F1_GMP declaration_Fisher Clinical Services Inc, US | 1.0 | 01 Mar 2023 | N |

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| F1_GMP declaration_Nelson Laboratories, LLC, US | 1.0 | 28 Feb 2023 | N |
| F1_GMP declaration_Regeneron Pharmaceuticals, Inc, US | 1.0 | 19 May 2017 | N |
| F1_GMP declaration_Nitto Avecia Pharma Services, US | 1.0 | 28 Feb 2023 | N |
| F1_GMP declaration_Fisher Clinical Services, MtProspect, US | 1.0 | 14 Oct 2019 | N |
| F2_QP declaration_Millmount Healthcare Ltd.-odronextamab | 1.0 | 02 Mar 2023 | Y |
| F2_QP declaration_millmount pharma services - AxMPs | 1.0 | 05 Apr 2023 | Y |
| F3_Manufacturing licence (MIA)_Fisher Clinical Services, UK | 2.0 | 16 Dec 2022 | N |
| F3_Manufacturing licence (MIA)_Fisher Clinical Services, Germany | 1.0 | 28 Jul 2022 | N |
| F3_Manufacturing licence (MIA)_Yourway Transport Limited, UK | 2.0 | 28 Oct 2022 | N |
| F3_Manufacturing licence (MIA)_Sanaclis s.r.o, Slovakia | 2.0 | 08 Feb 2022 | N |
| F3_Manufacturing licence (MIA)_Anderson Brecon Limited, UK | 2.0 | 16 Dec 2022 | N |
| F3_Manufacturing licence (MIA)_Biotec Services International Limited, UK | 2.0 | 16 Dec 2022 | N |
| F3_Manufacturing licence (MIA)_Millmount healthcare Limited, Ireland | 3.0 | 27 Feb 2023 | N |
| G1_IMPD_Q | 8.2 | 10 Mar 2023 | N/A |

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|---|---|---|---|
| G1_sIMPD_Q | 2.0 | 06 Mar 2023 | N/A |
| G2_SmPC_rituximab | 1.0 | 22 May 2023 | N/A |
| G2_SmPC_bendamustine | 1.0 | 07 Jun 2023 | N/A |
| G2_SmPC_cyclophosphamide | 1.0 | 22 May 2023 | |
| G2_SmPC_doxorubicin | 1.0 | 10 May 2023 | |
| G2_SmPC_prednisone | 1.0 | 10 May 2023 | |
| G2_SmPC_vincristine | 1.0 | 10 May 2023 | |
| J1_Label IMP_vial_160 mg | 1.0 | 10 May 2023 | Y |
| J1_Label IMP_carton_160 mg | 1.0 | 10 May 2023 | Y |
| J1_Label IMP_vial_2mg | 1.0 | 10 May 2023 | Y |
| J1_Label IMP_carton_2mg | 1.0 | 10 May 2023 | Y |
| J1_Label comparator_carton_DE | 1.0 | 19 May 2023 | Y |
| J1_Label comparator_vial_DE | 1.0 | 19 May 2023 | Y |
| J1_Label comparator_carton_PL | 1.0 | 19 May 2023 | Y |
| J1_Label comparator_vial_PL | 1.0 | 19 May 2023 | Y |
| J1_Vial Label AxMP _cyclophosphamide_DE | 1.0 | 19 May 2023 | Y |
| J1_Vial Label AxMP _cyclophosphamide_PL | 1.0 | 19 May 2023 | Y |
| J1_Carton Label AxMP _cyclophosphamide_DE | 1.0 | 19 May 2023 | Y |
| J1_Carton Label AxMP _cyclophosphamide_PL | 1.0 | 19 May 2023 | Y |
| J1_Vial Label AxMP _doxorubicin_DE | 1.0 | 19 May 2023 | Y |

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| J1_Vial Label AxMP _ doxorubicin _PL | 1.0 | 19-May-2023 | Y |
| J1_Carton Label AxMP _ doxorubicin _DE | 1.0 | 19-May-2023 | Y |
| J1_Carton Label AxMP _ doxorubicin _PL | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_AT | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_CZ | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_BEde | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_BEfr | | | |
| J1_Label AxMP prednisone_BEnl | | | |
| J1_Label AxMP prednisone_DE | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_FR | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_ES | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_IT | 1.0 | 19-May-2023 | Y |
| J1_Label AxMP prednisone_PL | 1.0 | 19-May-2023 | Y |
| J1_Vial Label AxMP _vincristine_DE | 1.0 | 19-May-2023 | |
| J1_Vial Label AxMP _vincristine_PL | 1.0 | 19-May-2023 | |
| J1_Carton Label AxMP _vincristine_DE | 1.0 | 19-May-2023 | |
| J1_Carton Label AxMP _vincristine_PL | 1.0 | 19-May-2023 | |
| J1_Vial Label AxMP _bendamustine_DE | 1.0 | 19-May-2023 | |
| J1_Vial Label AxMP _ bendamustine _PL | 1.0 | 19-May-2023 | |
| J1_Carton Label AxMP _ bendamustine _DE | 1.0 | 19-May-2023 | |

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| J1_Carton Label AxMP _ bendamustine _PL | 1.0 | 19-May-2023 | |
| I1_Scientifica advice EMA | 1.0 | 07-Jun-2023 | |
| Q1_Proof of payment<br><br>Proof of Payment Statement (BEL, FRA)<br><br>Proof of Payment – RA (POL, DE, CZ, Austria, ES)<br><br>Proof of payment – RA/EC (IT)<br><br>Proof of payment – EC (ES)<br><br>Proof of Payment – Clinical Trials Compensation Fund (POL) | N/A | N/A | N/A |
| R1_Declaration of Compliance with Data Protection | 1.0 | 30-Mar-2023 | Y |

**Table 2: List of Part II supporting documents – country specific list available in Annex 2:**

| **Part II Documents** |
|---|
| Recruitment Arrangements |
| Subject information and informed consent form |
| Suitability of the investigator |
| Suitability of the facilities |
| Proof of insurance cover or indemnification |
| Financial and other arrangements |
| Compliance with national requirements on Data Protection |
| Compliance with use of biological samples |

Signature Page for VV-RIM-00305248 v2.0

| | |
|---|---|
| Approval/eSignature | Jacqueline Campbell<br>jacqueline.campbell@regeneron.com<br>Regulatory<br>16-Jun-2023 09:19:59 GMT+0000 |

Signature Page for VV-RIM-00305248 v2.0 Approved