National Research Ethics Committee

NREC-CT A Meeting

**16th August 2023**

Attendance

|  |  |
| --- | --- |
| Name | Role |
| Prof. Alistair Nichol | Chairperson, NREC-CT A |
| Prof. Mary Donnelly | Deputy Chairperson, NREC-CT A |
| Prof. Tina Hickey | Committee Member, NREC-CT A |
| Mr Gerard Daly | Committee Member, NREC-CT A |
| Ms Muireann O’Briain | Committee Member, NREC-CT A |
| Prof. David Brayden | Committee Member, NREC-CT A |
| Dr Darren Dahly | Committee Member, NREC-CT A |
| Prof. Gene Dempsey | Committee Member, NREC-CT A |
| Prof. Austin Duffy | Committee Member, NREC-CT A |
| Ms Evelyn O’Shea | Committee Member, NREC-CT A |
| Ms Patricia Kenny | Project Officer, National Office for RECs |
| Dr Jane Bryant\* | Project Officer, National Office for RECs |
| Dr Laura Mackey | Programme Officer, National Office for RECs |
| Dr Susan Quinn | Programme Manager, National Office for RECs |
| Dr Emma Heffernan | Project Officer, National Office for RECs |
| Ms Rachel McDermott | Project Administrator, National Office for RECs |

\*Drafted minutes

**Apologies:** Dr Geraldine Foley, Prof. Catherine Hayes, Dr Heike Felzmann, Mr Gerard Eastwood, Ms Ann Twomey, Prof. John Wells, Mrs Erica Bennett

**Quorum for decisions:** Yes

Agenda

* Welcome & Apologies
* 2022-501606-35-01
* 2022-500537-84-01
* 2023-503697-21-00
* 2022-501980-42-00
* AOB
* The Chair welcomed the NREC-CT A.
* The minutes from the previous NREC-CT A meeting on 26th July 2023 were approved.
* The NREC Business Report was discussed and noted.

Applications

**2022-501606-35-01**

Dossiers: Part I

Study title: Randomized, multicenter, open-label, Phase 3 study of mirvetuximab soravtansine in combination with bevacizumab versus bevacizumab alone as maintenance therapy for patients with FRα-high recurrent platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancers who have not progressed after second-line platinum-based chemotherapy plus bevacizumab (GLORIOSA)

EudraCT: 2022-501606-35-01

* NREC-CT comments:
* The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.
* NREC-CT Decision:
* Request for further information
* Additional Information Required
* The Sponsor is requested to provide information on the frequency of ocular toxicity for participants in the treatment group.

**2022-500537-84-01**

Dossiers: Part I and II

Study title: A randomized, double-blind, multicenter Phase 3 study to evaluate the long-term efficacy and safety of ABX464 25mg or 50mg once daily as a maintenance therapy in subjects with moderately to severely active ulcerative colitis.

Sites and Principal Investigators: St. Vincent’s University Hospital (Prof. Glen Doherty), Connolly Hospital (Dr Orlaith Kelly), Regional Hospital Mullingar (Dr Murat Kirca), University Hospital Galway (Prof. Laurence Egan), Portiuncula Hospital (Dr Gerard Clarke), Our Lady of Lourdes Hospital (Dr John Keohane)

EudraCT: 2022-500537-84-01

* NREC-CT comments:
* The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.
* NREC-CT Decision:
* Request for further information
* Additional Information Required
* The NREC-CT notes that participants with limited understanding of English, the ability to read, and those lacking capacity to consent are excluded from the study. The Committee requests justification for the exclusion of these cohorts.
* The NREC-CT would also like to clarify whether the exclusion of participants unable to read includes those with a visual impairment, and if not, what provisions will be in place for these participants.
* The NREC-CT requests that all reimbursed expenses that participants are entitled to should be clearly stated in the Participant Information and Consent Form document, and that the wording is changed from ‘may be reimbursed’ to ‘will be reimbursed’ (Page 14 of the Participant Information Leaflet), with a brief outline of the process and frequency of payment of such reimbursements over the course of the study.
* The NREC-CT requests that an estimate of the planned recruitment number of participants in Ireland is added to the total number worldwide on Page 2 of the Participant Information and Consent Form document.
* The NREC-CT notes that information on reproductive risks (Page 12 of the Participant Information Leaflet) relates to both participants and partners of participants who become pregnant, but this information is not summarized as a bullet point under ‘What will I have to do’ on page 9. The NREC-CT requests that a bullet-point item on the need to avoid pregnancy for both male and female Ps is added near to the list (e.g. “Because of the risk of fetal malformations, you must not become pregnant if you are a female participant, and you must not father a baby if you are a male participant taking the study drug and for at least x days after”. The NREC-CT also recommends that this is added as an explicit clause for consent for both male and female participants in the Consent document, to highlight its salience.
* The Committee notes that female participants will be administered pregnancy tests at study visits, which acts as a reminder of the need to avoid pregnancy. The NREC requests confirmation that male participants will also be reminded formally at every visit of the risks of the study drug causing abnormality in partners’ pregnancies, and the importance of avoiding pregnancy.
* The NREC-CT notes that anti-diarrhoea medication is prohibited during the study (Page 9 of the Participant Information Leaflet), but is listed as among the most common side-effects of the study drug on Page 11. The NREC-CT requests clarification on whether any form of rescue medicine for treatment of diarrhoea will be allowed for participants who may require it during the study.
* The NREC-CT requests clarification on whether only the code to link participant ID with their personal data will be destroyed, rendering them unidentifiable, or whether the intention is that all participants’ personal data will be destroyed after 25 years. The Committee suggests that destruction of the code alone may be sufficient.
* The NREC-CT notes the inclusion of the NREC-CT in the list of who will have access to participants’ medical records. The Committee advises that the NREC-CT will not request this access and that this should be removed from the PISCF documents.

**2023-503697-21-00**

Dossiers: Part I and II

Study title: A multicenter, randomized, double-blind, placebo-controlled, Phase 3 study to evaluate the efficacy, safety, and tolerability of BMS-986278 in participants with idiopathic pulmonary fibrosis

Sites and Principal Investigators: Our Lady Of Lourdes Hospital (Dr Tidi Hasan), Connolly Hospital (Prof Eoin Judge)

EudraCT: 2023-503697-21-00

* NREC-CT comments:
* The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.
* NREC-CT Decision:
* Request for further information
* Additional Information Required
* The NREC-CT requests clarification that insurance will be in place for the full duration of the trial.
* The NREC-CT requests that all details of reimbursement of expenses are added to the ICF documents, in line with those detailed in the document P1\_Compensation for clinical trial participants.
* The NREC-CT requests that further information is provided to participants on any process in place for communication of incidental findings from the genetic analyses of samples. If no process if available, clarification should also be made to this effect in the ICF documents.
* The NREC-CT requests further information on Prof. Hassan’s previous clinical trial experience, if available.

**2022-501980-42-00**

Dossiers: Part I

Study title: A Phase 3, Open-label, Uncontrolled Study to Evaluate the Activity, Safety, Pharmacokinetics and Pharmacodynamics of Roxadustat for the Treatment of Anemia in Pediatric Participants with Chronic Kidney Disease

EudraCT: 2022-501980-42-00

* NREC-CT comments:
* The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.
* NREC-CT Decision:
* Request for further information
* Additional Information Required
* The Sponsor is requested to clarify how any discrepancies between central and Haemocue readings will be handled.
* The Sponsor is requested to provide copies of validated questionnaires when available.
* The Sponsor is requested to provide further information on who will review and advise on dose changes when they need to occur.
* AOB:
* The Expression of Interest Campaign for new members was discussed and the Committee updated on the recruitment process.
* A lunch and learn session was suggested to focus on statistical methodology.