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Observing the effectiveness and safety of Reditux and Reference Medicinal Product(s) to treat Diffuse Large B-Cell Lymphoma and Chronic Lymphocytic Leukaemia

Submission date
23/08/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Completed

Last Edited
25/06/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The most common B cell sub-type is diffuse large B-cell lymphoma (DLBCL), accounting for 30% of B-cell NHL. Chronic lymphocytic leukaemia (CLL) is the most common type of leukaemia in adults. The rise in DLBCL and CLL incidence and mortality has been observed worldwide including India.

DLBCL is an aggressive lymphoma with an expected survival of less than 1 year if untreated and advances quickly, requiring immediate treatment. The current standard-of-care (SoC) for DLBCL is a combination of cyclophosphamide, hydroxydoxorubicin, vincristine, and prednisolone (CHOP) chemotherapy and rituximab, the latter being a chimeric monoclonal antibody against the CD20 B-cell antigen. This regimen is also known as R-CHOP (rituximab + CHOP).
CLL is slow-progressing and often goes untreated in the early stages. In intermediate stages of CLL, treatment typically consists of chemotherapy (fludarabine and cyclophosphamide [FC]) alone or in combination with rituximab (R-FC).
The aim is to conduct Reditux™ Registry study to observe Effectiveness and Safety, of Reditux™ and the Reference Medicinal Product to Treat Diffuse Large B-Cell Lymphoma (DLBCL) and Chronic Lymphocytic Leukaemia(CLL) in Routine Clinical Practice.

Who can participate?
Patients aged 18 and over with DLBCL or CLL requiring immediate treatment

What does the study involve?
After collection of the data, we will analyze such data by valid scientific methods. This will, in turn, help us to understand how effective and safe the drug is. By participating in this study you will contribute to the better understanding and knowledge of the use of this medicine and thus benefit the patients in future for effective, safe, quality of life and economic use of this medicine.

What are the possible benefits and risks of participating?
You will not be exposed to any kind of risk or discomfort due to this study. Foreseeable risks and discomforts remain the same as mentioned in the information leaflet given with Reditux™, MabThera®, or Ristova®. By being part of this study, you will not receive any additional benefits apart from the ones associated with the use of Reditux™, MabThera®, or Ristova®.

Where is the study run from?
Approximately 60 clinical study sites, across India.

When is the study starting and how long is it expected to run for?
Mar 2015 to April 2022

Who is funding the study?
Dr. Reddy's Laboratories Ltd., Hyderabad, India.

Who is the main contact?
Mr. Rakesh Naranbhai Dadhania (rakeshnd@drreddys.com).

Contact information

Type(s)
Public

Contact name
Mr Rakesh Naranbhai Dadhania

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RI-02-003

Study information

Scientific Title
An observational study to collect data of real-world experience in India with Reditux™ or RMP to observe clinical effectiveness and safety in DLBCL and CLL patients

Study objectives
A proposed a non-interventional study (NIS) which aims to collect data reflecting the real-world experience in India with Reditux™ (biosimilar rituximab) and RMP rituximab in the post-approval setting to expand their understanding of its effectiveness and safety in DLBCL and CLL patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 28/02/2015, HCG Central Ethics Committee (HCG Tower # 8, P. Kalinga Rao Road Sampangiram Nagar, Bengaluru - 560027, Karnataka; radheshyam_n@yahoo.com).
2. Approval pending, Narayana Health Medical Ethics Committee (No. 258/A, Bommasandra Indl Area, Hosur Road, Bengaluru – 560099; nataraj.ks.dr@nhhospitals.org).
3. Approved 25/03/2015, Ethics Committee Manipal Hospitals (The Annexe, 98/2, Rustom Bagh Road, Off HAL Airport Road, Bangalore 560017; poonam.patil@manipalhospitals.com).
4. Approved 02/11/2015, Ethics committee Sir Gangaram Hospital (Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060; drshyam_aggarwal@yahoo.com).
5. Approval pending, Ethics Committee Jehangir Clinical Development Centre (Jehangir Hospital Premises 32, Sassoon Road, Pune 411 001, Maharashtra; dockannan@gmail.com).
6. Approval pending, Jaslok Hospital and Research Centre Ethics Committee (15 - Dr Deshmukh Marg, Pedder Road, Mumbai, Maharashtra 400026; shadvani2000@yahoo.com).
7. Approved 09/07/2015, Tata Medical Centre Institutional Review Board (14 MAR (E-W), New Town, Rajarhat, Kolkata, West Bengal 700156; reena.nair@tmckolkata.com).
8. Approved 03/06/2015, Institutional Ethics Committee Nightingale Hospital (11 Shakespeare Sarani, Kolkata, West Bengal 700071; shibashishbhattacharya@ymail.com).
9. Approved 29/09/2015, Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre (Near West Rohini Metro Station, Rohini, New Delhi, Delhi 110085; narendra_ag1@rediffmail.com).
10. Approval pending, Institutional Ethics Committee Basavatarakam Indo American Cancer Hospital & Research Institute (Road #10, Banjara Hills, Hyderabad - 500034, Telangana; senthiljrajappa@gmail.com).
11. Approval pending, Institutional Ethics Committee Omega Hospital (Road No.12, Banjara Hills, Hyderabad, Telangana – 500034; satya_palanki@rediffmail.com).
12. Approved 12/01/2016, Ethics Committee Apollo Hospital (320, Padma Complex, Anna Salai, Chennai – 600035, Tamil Nadu; -drmaraja@gmail.com).
13. Approval pending, Artemis Health Sciences Institutional Ethics Committee (Sector - 51 Gurgaon – 122001, Haryana; drdivsb@gmail.com).
14. Approval pending, Apollo Gleneagles Institutional Ethics Committee (58-Canal Circular Road, Kolkata – 700054; soumya_bhattacharya@rediffmail.com).
15. Approval pending, Tata Memorial Hospital Institutional Ethics Committee (Dr E Borges Road, Parel, Mumbai – 400012; manjusengar@gmail.com).

16. Approval pending, CMC Institutional Ethics Committee (CMC Campus, Near Calvary Church, Ludhiana, Punjab-141008; mjosephjohn@gmail.com).
17. Approval pending, Yashoda Academy of Medical Education and Research (YAMER), Yashoda Group of Hospitals (Behind Hari Hara Kalabhavan, S.P. Road, Secunderabad – 500003; bharatvaswanidm@yahoo.co.in).
18. Approval pending, Ethics Committee Sahyadri Hospitals Ltd (Plot no.30-C, Erandwane, Deccan Gymkhana, Pune - 411004, Maharashtra; shashikant.apte@gmail.com).
19. Approved 06/01/2018, Institutional Ethics Committee of PGIMER, Chandigarh (PGI Road, Sector 12, Chandigarh – 160012; malhotrapankaj@yahoo.com).
20. Approved 06/05/2015, Institutional Ethics Committee of SGPGI, Lucknow (Raebareli Road, Lucknow-226014; soniya_nityanand@yahoo.co.in).

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Diffuse large B-cell lymphoma and chronic lymphocytic leukaemia

Interventions
The study will enroll patients who recently started treatment with Reditux™ or the RMP for previously untreated DLBCL or CLL in routine clinical practice. All treatment decisions (Reditux, Ristova & MabThera) will have already been made by the patient's physician by the time the patient provides consent for the study. Patients meeting eligibility criteria will be enrolled and each patient will ideally be observed and followed for a minimum of 2 years & Maximum of 3 years after the first dose of Treatment (Rituximab).

The study involves data collection twice in a year at 6 monthly intervals (Jan – Jun and Jul – Dec format). During those data collection time points, patient information pertaining to the previous 6- month interval of visits to the doctor and other important information will be collected as indicated in the eCRFs.

Intervention Type
Biological/Vaccine

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Rituximab

Primary outcome measure
Progression-free survival at 2 years.

Secondary outcome measures
1. Event-free survival at 2 years.
2. Objective response rate (complete remission and partial remission) is determined using “CT /PET/MRI/Bone Marrow/Physical Examination/CBC reports” at “2 years”.
3. The incidence of safety events is determined using “Adverse Events reported” at “2 years”.
4. Quality of Life will be measured using the EQ-5D at 2 years.

Overall study start date
30/01/2015

Completion date
30/04/2022

Eligibility

Key inclusion criteria
1. Age ≥ 18;
2. Willing and able to provide written informed consent.
3. Previously untreated DLBCL or CLL.
4. Was recently administered first cycle of Reditux™ or the RMP (before the administration of 2nd cycle), at any dose, either in monotherapy or part of a combined treatment regimen, in routine clinical practice.
5. Participating in other non-interventional studies or registries as long as their participation does not interfere with this protocol or likely to affect the patient’s ability to comply with this protocol can be included in this study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 2000

Key exclusion criteria

1. Concurrent participation in an investigational study in which treatment, procedures, patient assessments are dictated by a protocol;
2. Starting treatment with a rituximab product other than Reditux™, MabThera®, or Ristova®

Date of first enrolment
25/03/2015

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
India

Study participating centre
Tata Medical Centre
14 MAR (E-W), New Town, Rajarhat
Kolkata
India
700156

Study participating centre
Rajiv Gandhi Cancer Institute and Research Center
Sector 5, Near West Rohini Metro Station, Rohini
New Delhi
India
110085

Study participating centre
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road
Lucknow
India
226014

Study participating centre
HCG Hospital
HCG Tower # 8, P. Kalinga Rao Road Sampangiram Nagar
Bangalore
India
560027

Study participating centre
Narayana Health Hospital, (Mazumdar Shaw Medical Center)
No. 258/A, Bommasandra Indl area, Hosur road
Bangalore
India
560099

Study participating centre
Manipal Hospital
The Annexe, 98/2, Rustom Bagh Road, Off HAL Airport Road
Bangalore
India
560017

Study participating centre
Gangaram Hospital
Sir Ganga Ram Hospital Marg, Rajinder Nagar
New delhi
India
110060

Sponsor information

Organisation
Dr. Reddy's Laboratories

Sponsor details
Biologics
Survey No. 47, Bachupally,
Qutbullapur, Medchal Malkajgiri District,
Telangana
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500 090
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Sponsor type
Industry

Website

https://www.drreddys.com/

ROR
https://ror.org/01rkxa860

Funder(s)

Funder type
Industry

Funder Name
Dr. Reddy’s Laboratories

Results and Publications

Publication and dissemination plan
The publication of the results from this study must be consistent with Dr.Reddy’s publication policy and guided by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication of the International Committee of Medical Journal Editors (ICMJE), updated April 2010.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/10/2023	19/10/2023	Yes	No
Results article		06/06/2025	25/06/2025	Yes	No