Clinical Trial Details (PDF Generation Date :- Sun, 13 Jun 2021 01:47:16 GMT)

CTRI Number	CTRI/2019/05/019044 [Registered on: 10/05/2019] - **Trial Registered Prospectively**
Last Modified On	09/06/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to compare the effects of two drugs DRL_RI and MabThera® for treatment in subjects with low tumor burden of follicular lymphoma (cancer of the immune system), who were not treated earlier.
Scientific Title of Study	A Randomised, Double-blind, Parallel-group, Phase III Study to Compare the Efficacy, Safety, and Immunogenicity of Proposed Rituximab Biosimilar (DRL_RI) with MabThera® in Subjects with Previously Untreated, Stage II-IV, Cluster of Differentiation (CD)20-Positive, Low Tumour Burden Follicular Lymphoma

Secondary IDs if Any

Secondary ID	Identifier
2018-004223-36	EudraCT
RI-01-006: Amendment 3 version 4 dated 04-Nov-2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Annappa Kamath
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Dr. Reddy's Laboratories S.A., Elisabethenanlage 11, CH-4051 Basel, Switzerland

Primary Sponsor

Primary Sponsor Details	
Name	Dr Reddys Laboratories SA
Address	Elisabethenanlage 11, CH-4051 Basel, Switzerland
Type of Sponsor	Pharmaceutical industry-Global

Details of Secondary Sponsor

Name	Address
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Countries of Recruitment

List of Countries
Belarus
Bosnia and Herzegovina
Bulgaria
Czech Republic
Georgia
Greece
India
Italy
Poland
Republic of Korea
Romania
Russian Federation
Serbia
Spain
Turkey
Ukraine
United States of America

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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		Kolkata WEST BENGAL	
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Dr Tanveer Mohibbhai Maksud	Unique Hospital Multispecialty and Research Institute	4th Floor, Chemo ward, Department of Oncology, Opp Kiran motor, Near Canal Road, Civil Char Rasta, Sosyo Circle Lane, Surat 395502 Surat GUJARAT	9909918887 tanveermasksud@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Amravati Ethics Committee, Sujan Surgical Cancer Hospital & Amravati Cancer Foundation,	Approved	23/10/2019	No
Ethics Committee – Unique Hospital	Approved	08/04/2019	No
Ethics Committee of KEM Hospital research centre	Approved	06/06/2019	No
GCRI /GCS Ethics Committee	Approved	22/05/2019	No
HCG - Central Ethics Committee	Approved	10/04/2019	No
HCG-BHIO Ethics Committee	Approved	17/12/2019	No
Institute Ethics Committee –HCG Curie Centre Vijayawada	Approved	18/04/2019	No
Institute Ethics Committee –Sparsh Hospital	Approved	21/05/2019	No
Institutional Ethics Committee - HCG NMR Cancer centre	Approved	30/11/2019	No
Institutional Ethics Committee – Apollo Gleneagles Hospital	Approved	06/04/2019	No
Institutional Ethics Committee – Clinical Studies Apollo Hospital Enterprises limited	Approved	30/07/2019	No
Institutional Ethics Committee – Erode Cancer Centre	Approved	17/03/2019	No
Institutional Ethics Committee – Gleneagles Global Hospital	Approved	17/09/2019	No
Institutional Ethics Committee – KGMU	Approved	20/05/2019	No
Institutional Ethics Committee – prince Aly Hospital	Approved	11/05/2019	No
Institutional Ethics Committee, AIIMS Bhubaneswar	Approved	23/11/2020	No
Institutional Ethics Committee, Aster Medcity,	Approved	28/08/2019	No
Institutional Ethics Committee, Government Medical College, Calicut	Approved	26/09/2019	No

Institutional Ethics Committee, Poona Medical Research Foundation, Ruby Hall Clinic	Approved	25/10/2019	No
Kailash Cancer and Medical Centre, Institutional Ethics Committee	Approved	03/08/2019	No
MAHE- Ethics Committee	Approved	11/06/2019	No
Manavata Clinical research Institutional Ethics Committee	Approved	09/04/2019	No
Mangala Institutional Ethics Committee	Approved	22/10/2020	No
Metro – ACRI Ethics Committee	Approved	25/04/2019	No
MVR Cancer centre & research Institute - Institute Ethics Committee	Approved	03/03/2020	No
Sahyadri Hospitals Ltd. Ethics committee, Sahyadri Clinical Research & Development Center	Approved	08/01/2020	No
Shettys Hospital Ethics Committee	Approved	18/04/2019	No
Shree Institutional Ethics Committee, Dhadiwal Hospital in Coalition with Shreeji HealthCare	Approved	24/10/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	29/04/2019

Health Condition / Problems Studied

Health Type	Condition
Patients	Follicular lymphoma grade I
Patients	Follicular lymphoma grade II
Patients	Follicular lymphoma grade IIIa

Intervention / Comparator Agent

Type	Name	Details
Intervention	DRL_rituximab (DRL_RI)	DRL_rituximab (DRL_RI) will be administered as an intravenous (i.v) infusion, at a dose of 375 mg/m2 of Body Surface Area.
Comparator Agent	MabThera®	MabThera® will be administered as an intravenous (i.v) infusion, at a dose of 375 mg/m2 of Body Surface Area.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both

Details	1)Subject is Male or female subjects aged greater than or equals to 18 years of age. 2)Subject is histologically confirmed, Grade 1-3a, previously untreated, CD20-positive. 3)Subject has Ann Arbor Stage II to IV and ECOG status of 0 to 1. 4)Subject has Low tumor burden follicular lymphoma as per Groupe dEtude des Lymphomes Folliculaires (GELF) Criteria 5)Subject has at least 1 measurable tumor mass in 2 dimensions, and the mass must be: a)Nodal lesion greater than 15 mm in the longest dimension; or b)Nodal lesion greater than 10 mm to the longest dimension; dimens ion and greater than 10 mm in the shortest dimension; or c)Extra-nodal lesion with both long and short dimensions greater than or equals to 10 mm. 6)Subject has Life expectancy greater than or equals to 3 months. 7)If female subject, then subject should be non pregnant, non lactating.

Exclusion Criteria

Exclusion Criteria	
Details	1)Subject with prior use of rituximab or any CD20 monoclonal antibody for any reason. 2)Subjects with known hypersensitivity to rituximab or its excipients, or to proteins of murine or other foreign origin. 3)Any prior therapy for follicular lymphoma (including but not limited to chemotherapy, radiotherapy) or subjects on chronic supra-substitutive doses of systemic gluco-corticosteriods. 4)Subjects who, in the opinion of the Investigator, require additional concomitant treatment for lymphoma. 5)Evidence of histologic transformation to high grade lymphoma or diffuse large B-cell lymphoma. 6)Subjects with known sero-positivity for or history of active viral infection with human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg) positive or hepatitis B core antibody positive, hepatitis C virus (HCV) antibody positive. 7)Subjects who have received a live vaccine within last 3 months of the first administration of study drug. 8)Subjects with history or presence of a medical condition or disease that in the Investigators opinion would place the subject at an unacceptable risk for study participation. 9)Participation in any clinical study or having taken any investigational therapy (within 2 months of the first dose of study drug). 10)Women of childbearing potential who do not consent to use highly effective methods of birth control

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
To demonstrate the equivalent efficacy of DRL_RI and MabThera® in subjects as measured by Overall Response Rate evaluated in accordance with published response criteria for malignant lymphoma.	Week 28

Secondary Outcome

Outcome	Timepoints
Progression-free survival (PFS)	Week 52/ till progressive disease/ death
Overall Response Rate	Week 12
Overall Survival	Week 52/ End of study
Duration of response	Week 52/ End of study
Safety, tolerability, and immunogenicity of	Week 52

	DRL_RI and MabThera®
Target Sample Size	**Total Sample Size=**284 **Sample Size from India=**66 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	20/05/2019
Date of First Enrollment (Global)	20/05/2019
Estimated Duration of Trial	**Years=**2 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Open to Recruitment
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	None Yet
Brief Summary	The primary objective of the current study is to demonstrate the equivalent efficacy of DRL_RI and MabThera® in subjects with cluster of differentiation (CD)20-positive, low tumour burden follicular lymphoma (LTB-FL) in the first-line treatment setting, as measured by overall response rate (ORR).