Clinical effectiveness and safety of CT-P10 in patients with diffuse large B-cell lymphoma: an observational study in Europe

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Study Ongoing

Administrative details

EU PAS number

EUPAS25317

Study ID

29188

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

☐ Spain

☐ United Kingdom

Study description

Celltrion manufacture CT-P10, the first monoclonal antibody biosimilar version of rituximab to be approved by the European Medicines Agency (EMA) for the treatment of rheumatic diseases and specific blood cancers including NHL and CLL (4). In France, Germany, Italy, the Netherlands, Spain and the United Kingdom (UK) it is licensed as TruximaTM for intravenous use in adults with rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukaemia (CLL). Diffuse large B-cell lymphoma (DLBCL) represents 30 to 58% of NHL, with the crude incidence in Europe being 3.8 per 100,000 patient years (5). Patients with DLBCL are often treated with a combination of four chemotherapy drugs, plus rituximab immunotherapy, known by the acronym R-CHOP (6). Clinical similarity between CT-P10 and rituximab has been accepted by the EMA (7). It has been reported that the introduction of CT-P10 in Europe will be associated with significant budget savings, with the reallocation of such enabling more patients to access treatment (8). However, there are currently no studies investigating the effectiveness or safety of CT-P10 treatment in patients with DLBCL in the real world clinical setting. This study will therefore address this evidence gap by collecting real world data on the effectiveness and safety of CT-P10 treatment in patients with DLBCL in European countries.

Study status

Ongoing

Research institutions and networks

Institutions

Celltrion

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pier Luigi Zinzani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2017

Actual: 06/02/2018

Study start date

Planned: 02/04/2018

Actual: 31/07/2018

Date of final study report
Planned: 01/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion Healthcare Hungary Kft.

Study protocol

PASS DLBCL Apr 2018.pdf(814.66 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To describe the clinical effectiveness of CT-P10 for the treatment of DLBCL.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC02) rituximab

rituximab

Medical condition to be studied

Diffuse large B-cell lymphoma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

500

Study design details

Outcomes

• OS, defined as the time from index until death from any cause.• PFS, defined as the time from index until the first documented evidence of disease progression or death from any cause. • Summary of best response to CT-P10 • Time to complete or partial response, defined as the time from index until first documentation of complete or partial response by the local investigator. o Any IRR, Any grade 3 or grade 4 IRRs (according to the Common Terminology Criteria for Adverse Events CTCAE version 4), Any other AE (excluding IRR), Any other grade 3 or grade 4 AE (excluding IRR), Any serious adverse event (SAE).o Demographic and clinical characteristics o DLBCL disease characteristicso Treatment patterns

Data analysis plan

For the primary analyses, the time-to-event clinical effectiveness endpoint analyses (OS, PFS, time to complete or partial response) will be displayed descriptively using Kaplan Meier plots from the index event until the date of the event (or censoring, which will occur at the date of the last hospital visit for OS, where patient is lost to follow-up, the date of data collection for OS, where patient is known to be alive, the date of the last hospital visit at which the patient was known to be free from disease progression for PFS, or the date of

the last recorded known response for time to complete or partial response. Absolute counts and the percentages of these events will be reported. The proportion of patients assessed as having a best response of complete response, partial response, stable disease or progressive disease within the 12-, 18-, and 30- months post-index based the documented assessment of the local investigator will be presented with 95% CI.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Patient-based medical records in medical centers

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No