A long term prospective observational study of the safety and tolerability of Bramitob® administered twice daily over three 28-day “on”/28-day “off” cycles to patients with cystic fibrosis having severely compromised lung function (Bethkis study)

First published: 04/02/2016

Last updated: 17/12/2018

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27095

EU PAS number

EUPAS12292

Study ID

27095

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Slovakia

Study description

This will be a long-term observational, non-interventional, multi-center study in approximately 30 Bramitob-exposed patients and 30 TOBI-exposed patients who meet all inclusion/exclusion criteria, e.g., have a stable baseline FEV1 ≥25% and <40% predicted and are not candidates for lung transplantation.The study will be conducted via a medical chart review in a prospective fashion. Due to the study's observational nature, the decision to treat with Bramitob® or TOBI®, the medical care given to patients, and the monitoring and assessments of the patients will not be scripted. Data obtained during routine clinic visits occurring during the observational period will be collected via a medical chart review and will be used to evaluate efficacy, safety, and tolerability. The end of the trial is defined as the last visit recorded after completion of three nebulized tobramycin inhalation solution treatment cycles of the last patient included in the study.

Study status

Ongoing

Research institutions and networks

Institutions

Chiesi Farmaceutici

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Guido Varoli

Study contact

g.varoli@chiesi.com

Primary lead investigator

Guido Varoli

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2015

Actual: 31/07/2015

Study start date

Planned: 14/12/2015

Actual: 16/12/2015

Date of final study report
Planned: 15/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Farmaceutici S.p.A.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Safety and tolerability of Bramitob

Main study objective:

To describe the following in patients suffering from CF and receiving Bramitob®, who have severely compromised pulmonary function:• Risk of upper airway and bronchial hypersensitivity/irritation, • Efficacy in terms of FEV1, pulmonary exacerbations, anti-pseudomonal use, hospitalizations and death.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

prospective, observational study

Study drug and medical condition

Name of medicine, other

Bramitob

Medical condition to be studied

Cystic fibrosis lung

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

50

Study design details

Outcomes

Efficacy Variables• FEV1 (expressed as liters and % predicted), • Number of pulmonary exacerbations as defined by Fuchs,• Anti-pseudomonal use, • Number of planned and unplanned hospitalizations,• Death.Safety Variables• AEs and ADRs, • AEs of special interest which will be queried for will include: acute, decreases in FEV1, bronchospasm, wheezing, dyspnea, cough, hemoptysis

Data analysis plan

Descriptive analysis of efficacy and safety variables

Data management

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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