AGMT_BV-NIS

Austrian Brentuximab Vedotin observational study

NIS Number: NIS005961

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Protocol Synopsis

Indication: Hodgkin's disease and PTCL (sub-entity sALCL)

Design: Retrospective and prospective, observational, multicenter research initiativey

Recruitment: 100 patients

Recruitment: First patient in (FPI): Q4 2017

Objectives:
The objective of this study is to evaluate the use, efficacy and toxicity of Brentuximab vedotin (BV) in Hodgkin´s disease (HD) and systemic anaplastic large cell lymphoma sALCL according to WHO 2008 in Austria and to identify the duration of therapy in these indications.

Further objectives are the evaluation of Progression free and Overall Survival (PFS and OS)

Background and Rationale

Brentuximab vedotin (Adcetris®) is an antibody-drug conjugate (ADC) directed to the protein CD30, which is expressed in classical Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL).

The drug was granted Marketing authorization from the European Medicines Agency in October 2012 for relapsed or refractory HL and relapsed or refractory sALCL. This medicinal product has been authorized under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited.

Brentuximab vedotin has been shown to offer a high overall response rate, including durable complete responses in both of its indications. This signifies an important advancement in the treatment of adult patients with these rare CD30 positive hematological cancers who are relapsed or refractory and previously had limited options.

This Brentuximab vedotin NIS is set up to collect real-world experience in the management of patients with Hodgkin's disease and PTCL (sub-entity sALCL) (according to the WHO 2008 classification) in Austria. The aim is to gain valuable insights on both efficacy and toxicity of this drug in a routine clinical setting in patients with various comorbidities.

Design

This non-interventional clinical study (NIS) is a prospective and retrospective, observational, multi-center research initiative. Data will be collected from all sites in Austria willing to participate.

100 patients in 5 years are planned. According to the Austrian office of statistic (Statistik Austria) this would be about 50% of the patients that qualify for BV treatment in this period.

To maintain patient confidentiality, each patient will be assigned a unique patient identifying number upon enrolment; this number will accompany the patient's medical and other information throughout the lifetime of the study.
Electronic Case Report Forms will be used for data collection.

Reporting of AEs
All SAEs and AESIs should be documented in the eCRF by the respective participating site

Adverse Events of Special Interest (AESI):
- Peripheral neuropathy (sensory, motor and other)
- Neutropenia (including febrile neutropenia)
- Infections (including opportunistic infections)
- Hyperglycemia
- Hypersensitivity reactions (including infusion-related reactions and allergic reactions)

Inclusion Criteria

Physicians will select appropriate patients for enrolment.

Appropriate patients are expected to:
Patients with Hodgkin's disease and PTCL (sub-entity sALCL) (according to the WHO 2008 classification) who are willing to participate and receive or qualify for BV therapy.

Due to the non-interventional design of the registry there are no exclusion criteria.

Status (as of March 2019)

Sites	Patients
PMU Salzburg / Innere Medizin III	29
Klinikum Wels-Grieskirchen / Innere Medizin IV	4
Kepler UK, Med Campus III. / UK Hämatologie	2
LKH Feldkirch / Innere Medizin II - Interne E	2
LKH Hochsteiermark / Dep. Hämato-Onkologie	7
TOTAL	**44**

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An academic registry
Sponsor: Arbeitsgemeinschaft medikamentöse Tumortherapie gemeinnützige GmbH,
Clinical-Scientific Director: R. Greil