BRENTUXIMAB VEDOTIN: FROM NAMED PATIENT PROGRAM (NPP) TO ITALIAN LAW 648/96

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Background

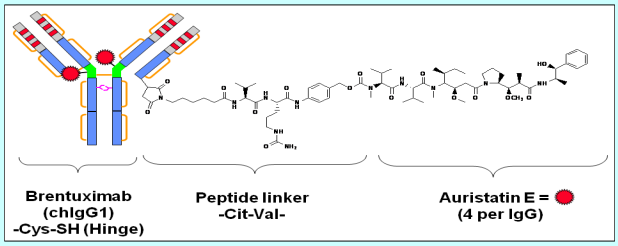
Brentuximab vedotin (BV) is an antibody-drug conjugate directed to the protein CD30, which is expressed in classical Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL). The drug received conditional marketing authorization from the European Medicines Agency (EMA) in October 2012 like *orphan drug* for relapsed or refractory HL CD30+ and relapsed or refractory sALCL. Since 01/11/2012, BV is reimbursable by the Italian National Health System (SSN) under Law 648/96 for these indications with specific Italian Medicines Agency (AIFA) monitoring initially through a tool excel and, since 15/02/2013, with the new AIFA Registry.

Purpose

To evaluate the efficacy and safety of BV in patients with relapsed or refractory HL CD30+ treated in our clinical center.

Materials and Methods

A total of 12 patients have been enrolled; therapies were carried out both in the Named Patient Program (NPP) and with BV as part of clinical program reimbursed by SSN. The drug was prepared at the Centralized Chemotherapy Preparation Unit of our Hospital Pharmacy.



SGN-35 treatment under NPP (period: September 2011-October 2012)	
Therapeutic indications	relapsed or refractory HL CD30+
Patients	4 (3F 1M); 3 from Hematology; 1 from Pediatric Oncohematology
Body weight	44-91 kg
Age at the starting therapy with SGN-35	13-40 years
N. of cycles	6-12
Previous treatments:	chemotherapy, autologous transplantation (+ allogenic in one case)

BV treatment under SSN (period: August 2012-October 2013)	
Therapeutic indications	relapsed or refractory HL CD30+
Patients	8 (3 F 5M); 7 from Hematology; 1 from Pediatric Oncohematology
Body weight	51-70 kg
Age at the starting therapy with BV	18-39 years
Previous treatments:	several lines of chemotherapy (ABVD, IGEV, bendamustine, etc), autologous transplantation

RESULTS

The responses observed after treatment with BV were: 2 complete remissions (CR), 1 stable disease (SD) and 1 progression disease (PD). There were no suspected adverse drug reactions (ADRs) during treatment with BV.

Of these, 2 patients are still 'ongoing' (not yet performed instrumental revaluation); 1 patient, after the 4th cycle (partial remission) has continued the therapy at another center and 2 patients died; we had 1 partial remission and 2 PD in other cases. With BV were notified as suspected ADRs two episodes of pulmonary toxicity and a case of severe infusion reaction with bronchospasm, but all with outcome improvement.

Conclusions

BV is the first monoclonal antibody available for HL therapy; we observed a homogeneous group of patients treated with classic chemotherapy, already receiving a bone marrow transplantation, in which overall survivals obtained with conventional therapies were greatly reduced. Clinical responses noted are substantially comparable to what is described in the literature, with complete responses in 2 patients, not achievable with other scheme of therapy. Based on the results obtained, are pending clinical studies with BV in the front line.