The novel chemotherapeutic agent Bendamustine for indolent lymphomas and for Waldenström´s disease

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Results of a multicentre randomised phase III trial to compare the safety and efficacy of a novel chemotherapeutic agent, Bendamustine, will be presented from a study comparing Bendamustine combined with Rituximab (B-R) versus CHOP plus Rituximab (C-R) in patients with indolent lymphomas and Waldenström´s disease.

What is Bendamustine?

Bendamustine is a nitrogen-containing mustard compound that is chemically related to the alkylating agents chlorambucil and cyclophosphamide. The compound is water-soluble and exerts its anti-tumour effect via purine analogue and alkylating activities.

This bifunctional agent has similar, if not greater potency than cycloshosphamide, and has activity *in vitro* in cell lines that are resistant to other alkylating agents. It was developed in Germany in the 1960s where it has been used for the treatment of malignancies.

Study details

549 patients were randomised to receive Rituximab 375 mg/m^2 (day 1) plus either Bendamustine 90mg/m^2 (days 1 and 2) every 28 days or the standard CHOP regimen every 21 days for a maximum of six cycles.

This presentation is an preliminary interim analysis consisting of 454 patients evaluable for response and toxicity, and a subanalysis showing results of 40 patients treated for Waldenström´s disease

Primary endpoint: Progression-free survival (PFS); non-inferiority of B-R versus CHOP-R was defined as an PFS difference of less than 10% between the two treatment regimes after three years. An event was defined by a response less than a partial response, disease progression, relapse or death from any cause.

Results of the total patient group

	CHOP-R	**B-R**
ORR	94%	93%
CR	41%	32%
Stable disease	3%	4%
Primary refractory disease	3%	3%
No. with progressive/relapsed disease	63	89
No. of deaths	26	27

Abbreviations: ORR, overall response rate; CR, complete remission.

Adverse events

	CHOP-R	B-R
Alopecia	91%	0%
Infectious complications	41	27
Grade 3/4 leukocytopenia	38%	14%

Conclusions

It can be concluded from this preliminary Phase III analysis so far, that the B-R combination:

- appears not be inferior to CHOP-R, and
- is associated with less toxicity

Results in particular for the treatment of Waldenström´s disease will be presented at the meeting and are shown in the associated slides.