



*POST-ASH* Issue 7, 2015

# Final Results from the Phase II Trial of Brentuximab Vedotin in Mycosis Fungoides or Sézary Syndrome

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## CME INFORMATION

### OVERVIEW OF ACTIVITY

Each year, thousands of clinicians, basic scientists and other industry professionals sojourn to major international oncology conferences, like the American Society of Hematology (ASH) annual meeting, to hone their skills, network with colleagues and learn about recent advances altering state-of-the-art management in hematologic oncology. As such, these events have become global stages where exciting science, cutting-edge concepts and practice-changing data emerge on a truly grand scale. This massive outpouring of information has enormous benefits for the hematologic oncology community, but the truth is it also creates a major challenge for practicing oncologists and hematologists.

Although original data are consistently being presented and published, the flood of information unveiled during a major academic conference is unprecedented and leaves in its wake an enormous volume of new knowledge that practicing oncologists must try to sift through, evaluate and consider applying. Unfortunately and quite commonly, time constraints and an inability to access these data sets leave many oncologists struggling to ensure that they're aware of crucial practice-altering findings. This creates an almost insurmountable obstacle for clinicians in community practice because they are not only confronted almost overnight with thousands of new presentations and data sets to consider but they are also severely restricted in their ability to review and interrogate the raw findings.

To bridge the gap between research and patient care, this CME activity will deliver a serial review of the most important emerging data sets on novel agents and salvage therapeutic options for the management of previously untreated or relapsed/refractory follicular lymphoma (FL), mantle-cell lymphoma (MCL), diffuse large B-cell lymphoma (DLBCL) and T-cell lymphoma (TCL) from the latest ASH meeting, including expert perspectives on how these new evidence-based concepts may be applied to routine clinical care. This activity will assist medical oncologists, hematologists, hematology-oncology fellows and other healthcare professionals in the formulation of optimal clinical management strategies and the timely application of new research findings to best-practice patient care.

### LEARNING OBJECTIVES

- Evaluate the efficacy and safety of rituximab and bortezomib as maintenance therapies for patients with MCL.
- Assess the results of recent Phase II studies evaluating the immunotherapeutic agents brentuximab vedotin and blinatumomab for the treatment of DLBCL.
- Appraise emerging clinical data from early-phase studies evaluating novel chemobiologic combination regimens for the treatment of TCL.
- Compare and contrast the benefits and risks of the novel up-front treatment approaches of rituximab combined with lenalidomide and obinutuzumab alone or in combination with CHOP for patients with FL.

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**Hardware/Software Requirements:**

A high-speed Internet connection

A monitor set to 1280 x 1024 pixels or more

Internet Explorer 7 or later, Firefox 3.0 or later, Chrome,

Safari 3.0 or later

Adobe Flash Player 10.2 plug-in or later

Adobe Acrobat Reader

(Optional) Sound card and speakers for audio

Last review date: May 2015

Expiration date: May 2016

To go directly to slides and commentary for this issue, [click here](#).

To begin a recent interview for our *Hematologic Oncology Update* audio series, Dr Jeff Sharman presented from his practice the fascinating and highly instructive case of a 57-year-old yoga instructor and motivational speaker with follicular lymphoma (FL). He started by noting that after migrating from Stanford to his current location in Eugene, Oregon, he quickly learned that a lot of people in the Pacific Northwest don't much like chemotherapy. I have heard this comment from others who practice in the area, and as



**Jeff Sharman, MD**

as a fan of the TV show *Portlandia* — where the characters regularly inquire about the detailed life histories of the chicken they are about to eat in a restaurant and the like — it really resonated. More importantly, however, this case relates to a critical issue in contemporary oncology: When is it acceptable to reach for an investigational therapy with encouraging Phase II data?

This patient — described as charismatic and dynamic — presented with bulky inguinal and cervical adenopathy and increased abdominal girth. She had previously consulted her naturopath, who palpated an enlarged spleen, and this led to a “second opinion” from Jeff.

Massive splenomegaly, hepatomegaly and extensive bulky adenopathy were observed on CT, and excisional biopsy of an inguinal node revealed Grade 3a FL. Flow cytometry confirmed peripheral blood involvement with mild anemia and thrombocytopenia. Because of the high tumor burden by GELF criteria and the possibility of occult transformation, Dr Sharman recommended R-CHOP (rituximab [R]/cyclophosphamide/doxorubicin/vincristine/prednisone). However, the patient absolutely refused chemotherapy, stating, in essence, “There’s no way you’re going to do that to me. I would rather die of my disease than go through what you’re talking about.”

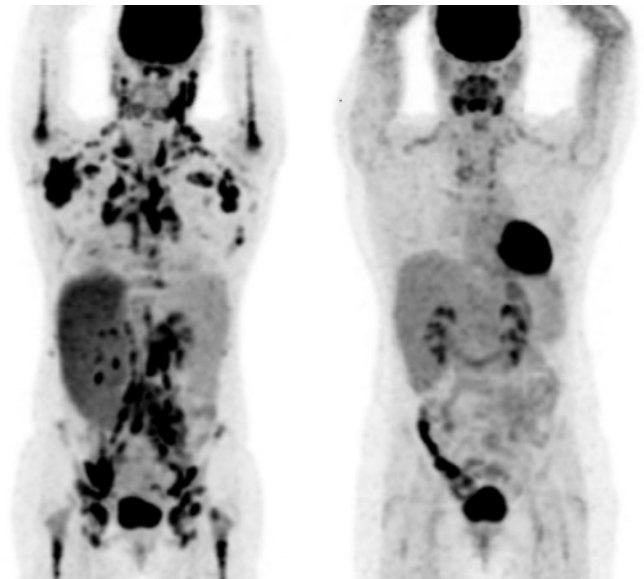
Taking a deep breath, Jeff brought up the possibility of treatment without chemotherapy and the patient listened with rapt attention. R monotherapy seemed suboptimal given the extent of the disease, and he reluctantly raised the possibility of a regimen that is currently being studied by many research entities, the so-called “R squared” (R<sup>2</sup>) combination of the immunomodulatory agent lenalidomide (len) with R.

The patient was more than interested, and Dr Sharman initiated 4 weekly doses of R followed by 4 more doses every 2 months as per the SAKK regimen along with len at 25 mg PO daily for 21 out of 28 days. In Jeff's words, here is what happened: "She did develop some cytopenias, had a little bit of fatigue, but the disease simply melted away. It was really a quite stunning response. Her adenopathy resolved within the first 8 weeks of therapy, and when we repeated the PET scan, she'd actually had a PET-negative complete response (CR). We even redid her marrow, which had cleared as well. Len was discontinued about the same time she completed R, and currently she's still in a CR and feeling great more than 4 years later."

As part of last week's email focused on multiple myeloma, we discussed the immune effects of len creating synergy with elotuzumab, and Dr Sharman suggests that a similar dynamic may be in play with R. He notes the suboptimal function of T cells in patients with B-cell cancers and emerging data suggesting that malignant cells are able to induce T-cell anergy/apathy.

Because the activity of R is in part through antibody-dependent cellular cytotoxicity, the effect may be blunted with a poorly functional T-cell component. For this reason, Jeff describes the R<sup>2</sup> combination as planning a road trip with a map (R) and a highly synergistic pot of coffee (len) — an analogy perhaps prompted by the beautiful outdoor scenes nearby. This combination is now being studied in the Intergroup Phase III RELEVANCE trial with the challenging randomization comparing R<sup>2</sup> to R-chemotherapy. The study is not restricted to patients with low tumor burden, and Dr Sharman hopes the result will be a new paradigm in this disease.

At a more macro level, this case illustrates the continuing dilemma that occurs every day in oncology practice — whether to recommend an intervention that involves the use of approved therapies but is the subject of ongoing investigation. In terms of Dr Sharman's yoga teacher, it could be that the same benefit would have accrued had only R been used, and it is also possible that in the long run she would have been better off embarking initially on an R-chemotherapy regimen, although that seems unlikely given what happened. It is also true that patients ideally should receive new therapies as part of clinical trials, but that is not always feasible, and in the end, the clinician evaluating the patient hopefully makes the optimal recommendation for that individual. Any way you look at it, though, Dr Sharman's case is compelling, thought provoking and may be a sign of what is to come in the near future.



**Before and after treatment with lenalidomide/rituximab**

With that said, on this final ASH review we profile new data with R<sup>2</sup> as well as a number of other intriguing papers focused on the management of FL, mantle-cell lymphoma (MCL), diffuse large B-cell lymphoma (DLBCL) and T-cell lymphoma (TCL).

## FL

### More on R<sup>2</sup>

Whether trials like RELEVANCE will establish equal or greater efficacy of R<sup>2</sup> versus R-chemotherapy, it seems clear that len adds substantially to the benefit of R monotherapy. At ASH the randomized [Phase II SAKK 35/10 study](#) comparing R to R<sup>2</sup> as up-front therapy in 154 patients with FL mirrored the results of previous trials demonstrating a substantial improvement in overall response rate (45% versus 75% at week 10), although the impact on progression-free survival (PFS) and overall survival has not been established.

### Obinutuzumab (O) with CHOP or bendamustine (benda) in untreated FL

Not many people expected another anti-CD20 antibody to outperform R in any disease, but the encouraging results and FDA approval of O in chronic lymphocytic leukemia (CLL) led to the hope that similar benefits will be observed with other B-cell cancers. As such, the [Phase 1b GAUDI study](#) investigated O-CHOP and O-benda with 2 years of O maintenance in 81 patients with FL. Although much of the emphasis of this effort was on safety, perhaps the most interesting finding was that the CR rate increased substantially during the 2 years of O maintenance (O-benda: 37% to 61%; O-CHOP: 35% to 70%).

Phase III research is ongoing to define not only the efficacy but also the tolerability of these regimens compared to R-based approaches — particularly with the prolonged B-cell depletion during maintenance O. In a related manner, next week at ASCO we will see the results from the Phase III GADOLIN study evaluating O-benda versus benda alone in patients with R-refractory indolent non-Hodgkin lymphoma. A press release has already hinted that the data will be positive, but what that means for clinical practice remains unknown.

Over the past year there has been a great deal of understandable excitement about the rapid changes that have occurred in the management of CLL, but it seems that a similar upheaval will soon take place in FL, for which O and len may join the recently approved PI3 kinase delta inhibitor idelalisib (Id) in the clinical algorithm. Interestingly, it is Dr Sharman's impression that many clinicians mistakenly believe that ibrutinib has good activity in FL despite the documented modest benefit and fail to realize that Id — the first agent in 6 years approved in FL — on the other hand is for real and has sparked a number of combination trials up front.

In this vein, although [one ASH paper](#) reported durable responses with BR-Id, another data set is a [cautionary tale](#) of the potential dangers of empiric attempts to combine agents outside a trial setting, specifically Phase I research evaluating Id with R<sup>2</sup> that had to be discontinued for unacceptable toxicity after 4 of the first 8 patients developed rash, fevers and hypotension suggestive of a cytokine release syndrome.



## **MCL**

### **R maintenance after autologous stem cell transplant (ASCT)**

Previous work had demonstrated the benefit of R maintenance in older patients receiving induction therapy. However, the role of this approach in younger individuals undergoing ASCT was poorly understood, and at ASH we saw data from the **Phase III LYMA trial** evaluating 3 years of R maintenance in 257 patients who received 4 cycles of R-DHAP followed by ASCT. At 2 years, R maintenance increased the event-free survival from 81.5% to 93.2%, but no overall survival benefit has yet been observed, although the influx of new and effective therapies for relapsed/refractory (R/R) MCL will complicate the evaluation of this important endpoint. However, from a clinical perspective these findings are likely to be practice changing as many investigators view the delay in disease progression as enough benefit to justify the use of this strategy for many/most patients with MCL.

### **SWOG trial of R-CHOP/bortezomib (bor) with bor maintenance**

At ASH we saw the results of a **Phase II trial** in 65 evaluable patients exploring the role of the proteasome inhibitor bor (which now has a limited approval as up-front therapy in the disease) as maintenance treatment. The activity of this approach was viewed as encouraging (PFS: 2 years 62%; 5 years 28%) with acceptable tolerability, but how this will fit into the increasingly crowded MCL "space" remains to be determined.

## **DLBCL**

### **Brentuximab vedotin (BV) with R-CHOP**

BV has demonstrated compelling activity as a single agent in R/R DLBCL even in patients with low CD30 expression, and this has led to interest in its use up front. A Phase II trial reported at ASH evaluated the **addition of BV to R-CHOP** in 33 patients with newly diagnosed DLBCL and reported excellent activity (overall response rate: 92%; CR: 58%) with an acceptable tolerability profile. Peripheral neuropathy (PN) was about what is typically observed with BV alone and only 5 patients required dose reductions as a result. Further research will define the future role of BV up front (as is being studied in Hodgkin lymphoma), probably without the concurrent use of vincristine, and how CD30 expression relates to treatment benefit.

### **Blinatumomab**

A recent issue of this series focusing on acute leukemias discussed the profound clinical activity with this bispecific T-cell engager antibody in acute lymphoblastic leukemia. However, the benefits of this novel agent — which engages CD3-positive cytotoxic cells leading to T-cell expansion and lysis of CD19-positive B cells — appears not to be confined solely to that disease, as objective responses have been previously reported in a number of patients with DLBCL. At ASH we saw **more evidence to substantiate** that claim as a Phase II study of 21 patients with R/R DLBCL demonstrated responses in 43%. More to come.

## TCL

### **BV in mycosis fungoides (MF) and Sézary syndrome (SS)**

Although much has been previously made of the activity of BV in peripheral TCL (PTCL) — most relevantly anaplastic large cell lymphoma — it appears that this agent may also have utility in cutaneous TCL. Notably, we saw data from a [Phase II trial](#) of 30 evaluable patients, the majority of whom had advanced-stage MF or SS, that demonstrated a 70% response rate (mostly partial responses) with acceptable toxicity (mainly PN). While there was a suggested correlation of activity with CD30 levels and it remains to be seen whether an antitumor effect occurs without CD30 expression, these results will likely lead to the use of BV in these patients.

### **Romidepsin/CHOP in PTCL**

For quite some time investigators have been struggling to develop more impactful long-term treatment strategies for patients with PTCL, who generally face a bleak prognosis even with postinduction ASCT. In this regard there has been significant interest in moving novel agents with activity in the R/R setting into up-front regimens. This dynamic was on full display at ASH as we saw final results from a [Phase Ib/II report](#) of 35 evaluable patients who received romidepsin-CHOP as up-front therapy with a CR rate of 51% and 17% partial responses. These data are far from definitive but suggest the combination is safe, providing additional support for ongoing Phase III studies.

This concludes our ASH series, and as we saddle up and head out to the Windy City we encourage you to stay tuned this summer for virtual replays of the 4 evening satellite symposia focused on [lung cancer](#), [GI cancers](#), [myeloma/lymphoma](#) and [breast cancer](#) we will be hosting at the annual ASCO extravaganza.

Neil Love, MD

[Research To Practice](#)

Miami, Florida

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# Final Results from the Phase II Trial of Brentuximab Vedotin in Mycosis Fungoides or Sézary Syndrome

Presentation discussed in this issue

Kim YH et al. **Phase II investigator-initiated study of brentuximab vedotin in mycosis fungoides or Sezary syndrome: Final results show significant clinical activity and suggest correlation with CD30 expression.** *Proc ASH 2014*; **Abstract 804.**

Slides from a presentation at ASH 2014 and transcribed comments from a recent interview with Craig Moskowitz, MD (1/6/15)

## Phase II Investigator-Initiated Study of Brentuximab Vedotin in Mycosis Fungoides or Sezary Syndrome: Final Results Show Significant Clinical Activity and Suggest Correlation with CD30 Expression

**Kim YH et al.**

*Proc ASH 2014*; Abstract 804.

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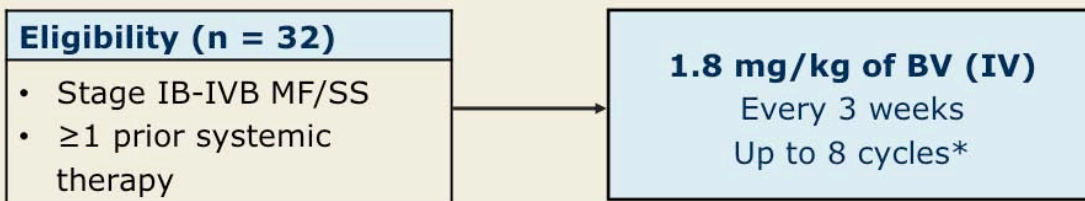
# Background

- While CD30 expression on malignant cells in Hodgkin lymphoma and anaplastic large cell lymphoma is uniform, in mycosis fungoides/Sézary syndrome (MF/SS), the CD30 expression is more variable.
- Previously, we reported that brentuximab vedotin (BV), an anti-CD30 antibody-drug conjugate, has clinical activity in MF/SS across all CD30 expression levels (*Proc ASH 2012;Abstract 797*).
- **Study objective:** To report the updated clinical data and present new biomarker and correlative tissue analyses from the study of BV in MF/SS.

Kim YH et al. *Proc ASH 2014;Abstract 804*.

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# Phase II Trial Design



\* Optional extension of up to 2 cycles if complete response or 8 cycles if partial response and ongoing clinical improvement

- **Primary endpoint:** Overall response rate
- **Secondary endpoints include:** Time to response, duration of response, progression-free survival (PFS) and safety
- CD30 expression and clinical response were confirmed by independent review.
- Tumor microenvironment was assessed using immunohistochemical (IHC) staining for CD8, CD20, CD163, FoxP3 and PD-1.
- Multispectral image analysis was used to evaluate CD30 antigen coexpression.

Kim YH et al. *Proc ASH 2014;Abstract 804*.

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# Response Rates by Category

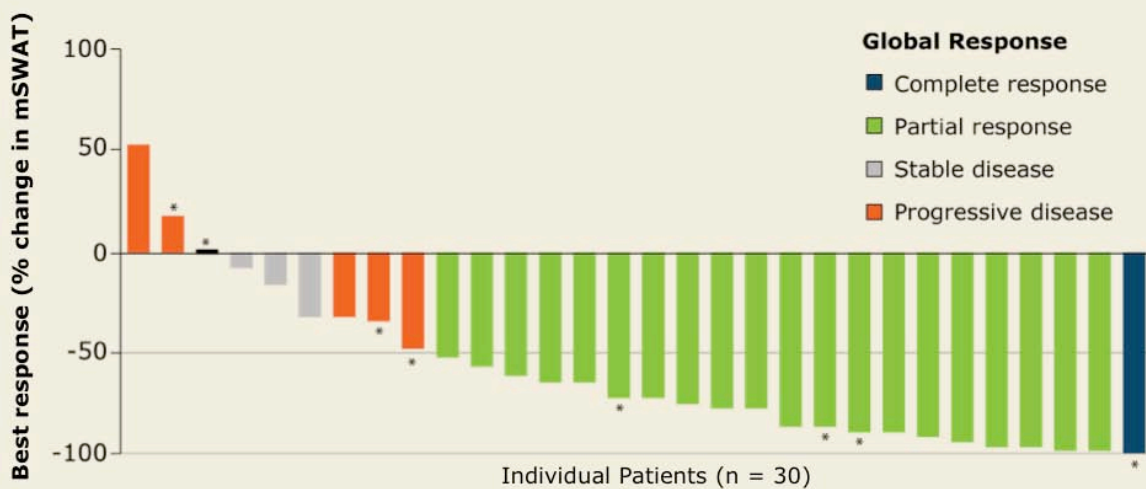
Category (n)	ORR	CR	PR	SD	PD
All patients (30)	70%	3.3%	66.7%	13.3%	16.7%
Stage IB (4)	75%	0%	75%	25%	0%
Stage IIB (18)	78%	0%	77.8%	11.1%	11.1%
IV/SS (8)	50%	12.5%	37.5%	12.5%	37.5%

ORR = overall response rate; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease

Kim YH et al. *Proc ASH* 2014;Abstract 804.

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# Percent Change in Skin mSWAT Score at Best Skin Response



\* Stage IV

mSWAT = modified severity weighted assessment tool

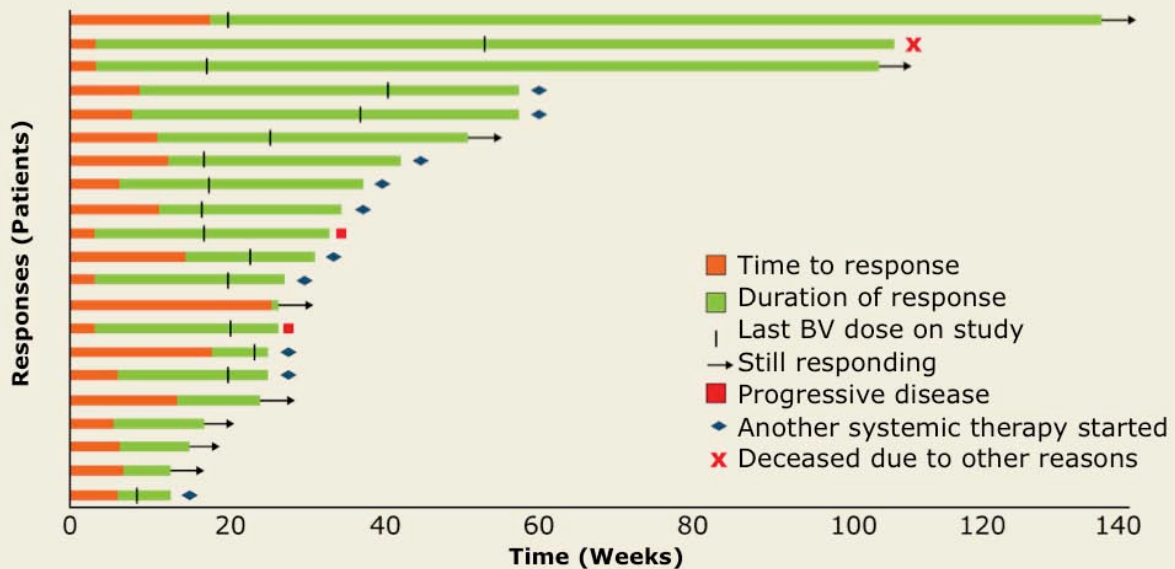
- Medium best mSWAT reduction: 73% (100% to -54%)
- Patients with mSWAT reduction >90%: 8

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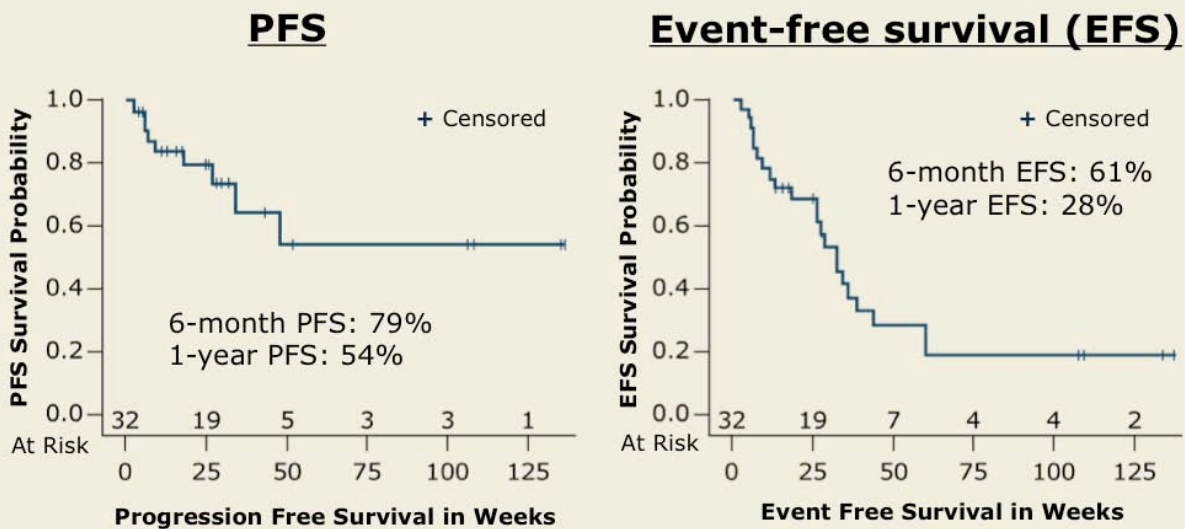
## Time Course for Patients with Objective/Global Clinical Response (N = 21)



- Medium time to response: 6.6 wk
- Patients with continued response at 6 and 12 mo: 90% and 79%, respectively

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## Survival Outcomes



- Event-free survival event: PD, early termination, death or initiation of other significant treatment

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## CD30 Expression and Treatment Outcomes

Outcome	Value
Median maximum CD30 expression level in all patients (range)	13% (0%-100%)
Median maximum CD30 expression level in responders (CR/PR) vs nonresponders (SD/PD) <i>p</i> -value	15% vs 3% 0.037

- The correlation with CD30 level was greatest in the IIB/skin tumor subset ( $p = 0.0072$ ).
- Patients with CD30 level <5% had a lower likelihood of clinical response (17% vs 83%;  $p = 0.0046$ ).

Kim YH et al. *Proc ASH* 2014;Abstract 804.

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## Assessment of the Tumor Microenvironment

- No correlation of pretreatment tissue-infiltrating CD8-positive, Foxp3-positive or PD-1-positive T cells with clinical response
- No correlation of soluble CD30 between responders and nonresponders ( $p = 0.92$ )
- No correlation of pretreatment tissue-infiltrating CD20-positive B cells or CD163-positive macrophages with clinical response
- Tumor-associated CD163-positive macrophages were the most abundant.
  - Median of total infiltrate: 40% (range 5-80%)

Kim YH et al. *Proc ASH* 2014;Abstract 804.

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## Select Adverse Events

N = 32	All grades	Grade 3/4
Peripheral neuropathy (PN)	66%	3%
Fatigue	47%	0%
Nausea	28%	0%
Alopecia	22%	0%
Neutropenia	19%	13%
Anorexia	19%	0%
Skin eruption	13%	9%
Dyspepsia	13%	0%
Diarrhea	9%	0%

- Medium time to any PN = 13 weeks
- Median time to improvement/resolution of PN = 49 weeks

Kim YH et al. *Proc ASH* 2014;Abstract 804.

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## Author Conclusions

- BV showed significant clinical activity in patients with refractory or advanced MF/SS, most of whom had transformed or folliculotropic MF.
- Not all BV-associated PN is reversible.
- Clinical responses were observed in all CD30 groups, but reliability or depth of response correlates with CD30<sub>max</sub> expression.
- No significant correlation was observed between pretreatment tissue microenvironment factors and clinical response.
- The abundance of tumor-associated macrophages with significant coexpression of CD30 may contribute to an additional mode of action for BV.
- Further studies of biomarkers and effects on the microenvironment are warranted and may help optimize management strategies with BV.

Kim YH et al. *Proc ASH* 2014;Abstract 804.

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## **Investigator Commentary: Final Analysis of a Phase II Study of BV in MF/SS**

One of the interesting aspects of this study is the availability of multiple biopsy samples, which allowed the quantification of CD30 expression levels. In tumors with at least 5% CD30 expression, there was no correlation with response to BV. The overall response rate for all patients was 70%, and some of these patients have been receiving therapy for up to 1 year.

A debate is ongoing on whether BV has activity in tumors that are CD30-negative. In this study, there was no evidence of response to BV in CD30-negative MF/SS. In my institution, we would never be able to get approval to study the efficacy of BV in a CD30-negative patient population due to issues with the testing assays.

There is absolutely no doubt in my mind that BV will become a standard treatment for patients with CD30-positive cutaneous lymphomas based on the results of this study.

***Interview with Craig Moskowitz, MD, January 6, 2015***

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