



POST-ASH Issue 7, 2015

Final Analysis of Results from the Phase Ib/II Trial of Romidepsin and CHOP in Previously Untreated PTCL

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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

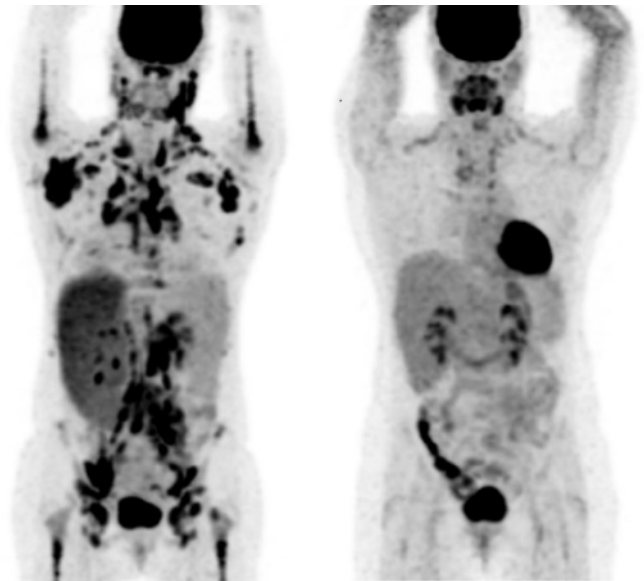
as a fan of the TV show *Portlandia* — where the characters regularly inquire about the detailed life histories of the chicken they are about to eat in a restaurant and the like — it really resonated. More importantly, however, this case relates to a critical issue in contemporary oncology: When is it 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” (R²) 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."



Before and after treatment with lenalidomide/rituximab

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 R² 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 R² 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.

With that said, on this final ASH review we profile new data with R² 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 R²

Whether trials like RELEVANCE will establish equal or greater efficacy of R² 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 R² 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 R2 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 Analysis of Results from the Phase Ib/II Trial of Romidepsin and CHOP in Previously Untreated PTCL

Presentation discussed in this issue

Dupuis J et al. **Final analysis of the RO-CHOP phase Ib/II study: Romidepsin in association with CHOP in patients with peripheral T-cell lymphoma (PTCL).** *Proc ASH 2014*; **Abstract 504**.

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

Romidepsin in Association with CHOP in Patients with Peripheral T-Cell Lymphoma: Final Results of the Phase Ib/II Ro-CHOP Study

Dupuis J et al.

Proc ASH 2014; Abstract 504.

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Background

- Romidepsin is a histone deacetylase inhibitor approved by the Food and Drug Administration for the treatment of cutaneous T-cell lymphoma and peripheral T-cell lymphoma (PTCL) who have received at least 1 prior therapy.
- In recurrent or refractory PTCL, it has been evaluated as a single agent in 2 Phase II studies:
 - Overall response rate: 25%-38% (*Blood* 2011;117(22):5827 and *J Clin Oncol* 2012;30(6):631).
- Toxicity of romidepsin is mainly hematologic and gastrointestinal.
- **Study objective:** To report the final analysis of a Phase Ib/II trial evaluating the safety, tolerability and efficacy of romidepsin in combination with CHOP for patients with previously untreated PTCL.

Dupuis J et al. *Proc ASH* 2014;Abstract 504.

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Phase Ib/II Trial Design

Eligibility (n = 37)

Patients with previously untreated PTCL



Romidepsin + CHOP

Romidepsin (varying doses)
CHOP (up to 8 cycles)

- Based on pharmacokinetic data and previous Phase II studies, the starting dose of romidepsin was 10 mg/m² days 1, 8.
- CHOP: Cyclophosphamide 750 mg/m² day 1, doxorubicin 50 mg/m² day 1, vincristine 1.4 mg/m² day 1, prednisone 40 mg/m² days 1-5.
- The dose-variation scheme followed a traditional "3 + 3" study design.
- Dose-limiting toxicities (DLTs) were assessed during the first 2 cycles.
- DLT was initially defined as nonhematologic toxicity Grade 3/4 or hematological toxicity Grade 3 lasting for >7 days or Grade 4 lasting for >3 days.
- The protocol was subsequently amended to tolerate events lasting for <10 days (Grade 3) or 7 days (Grade 4).

Dupuis J et al. *Proc ASH* 2014;Abstract 504.

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3 + 3 Dose-Escalation Scheme

Level	Days	Romidepsin dose	n
-2	D1	8 mg/m ²	3-6
-1	D1, 8	8 mg/m ²	3-6
1	D1, 8	10 mg/m ²	3-6
2	D1, 8	12 mg/m ²	3-6
3	D1, 8	14 mg/m ²	3-6
Expansion cohort	D1, 8	RP2D	25

RP2D = recommended Phase II dose

Dose-Escalation Phase

- Cohort 1 (n = 3): 10 mg/m²
- Cohort 2 (n = 3): 10 mg/m²
- Cohort 3 (n = 3): 8 mg/m²
- Cohort 4 (n = 3): 10 mg/m²
- Cohort 5 (n = 3): 12 mg/m²
- Cohort 6 (n = 3): 12 mg/m²

Dupuis J et al. *Proc ASH* 2014;Abstract 504.

Treatment and Outcomes

- Phase II recommended dose of romidepsin: 12 mg/m²
- Patients who received treatment in the Phase II part of the study: n = 19
- Significant albeit tolerable hematological toxicity was observed in the first 2 cohorts of patients
 - Hence, the definition of DLT was modified during the course of the study.
- Patients who completed 8 planned cycles: 26/37 (70%)

Dupuis J et al. *Proc ASH* 2014;Abstract 504.

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Responses After 8 Cycles

Response	N = 35*
Complete response	51%
Partial response	17%
Progressive disease (PD)	26%

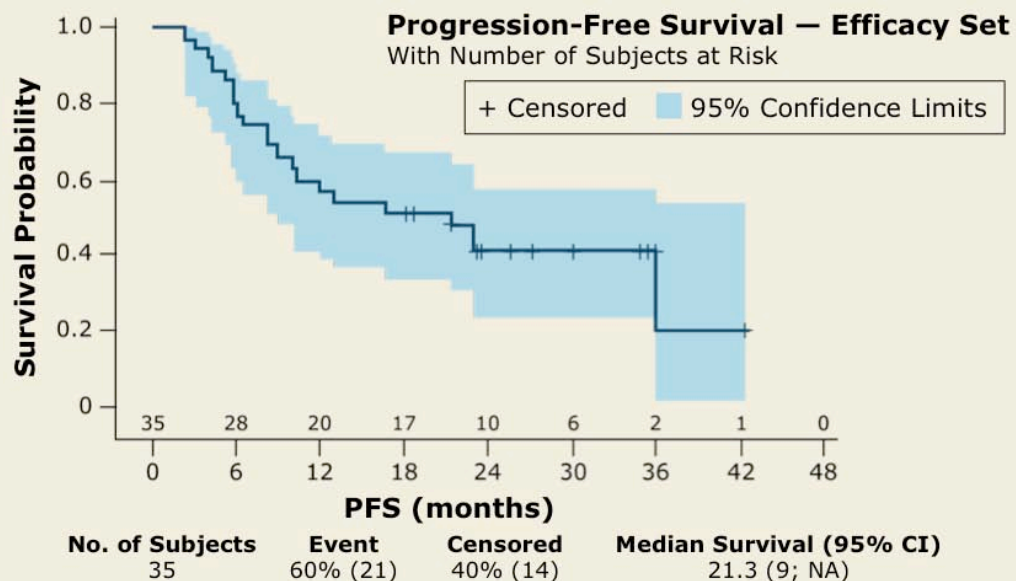
* Evaluable patients

- Two patients experienced early cardiac events (myocardial infarction) and were excluded from the efficacy analysis.

Dupuis J et al. *Proc ASH 2014*;Abstract 504.

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Progression-Free Survival (PFS)

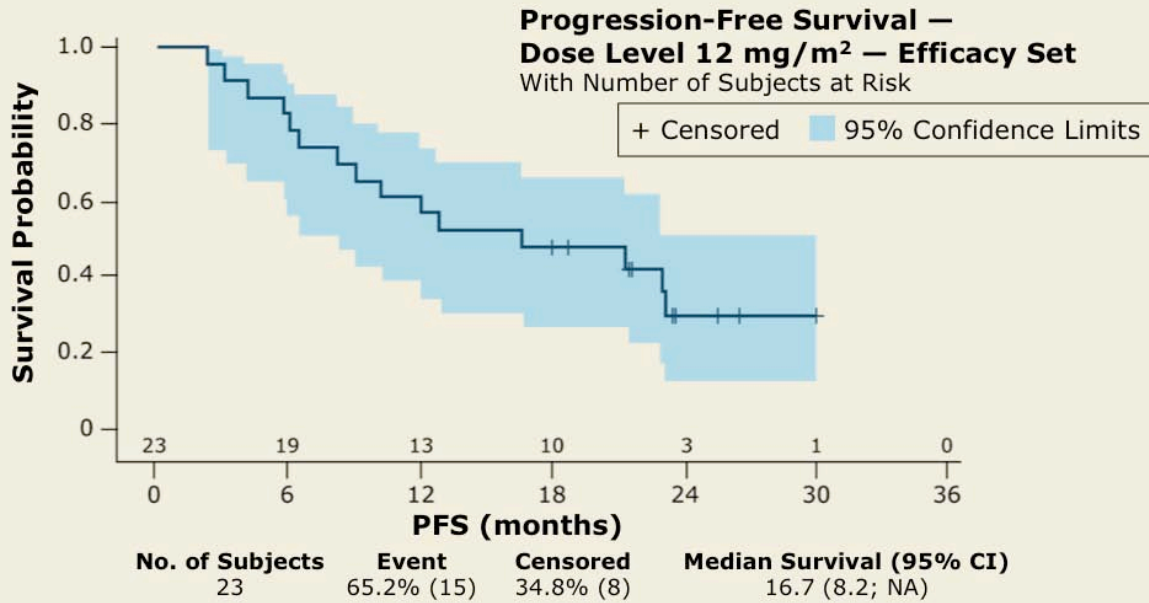


- 1-year estimated PFS = 57%
- Median follow-up = 30 months

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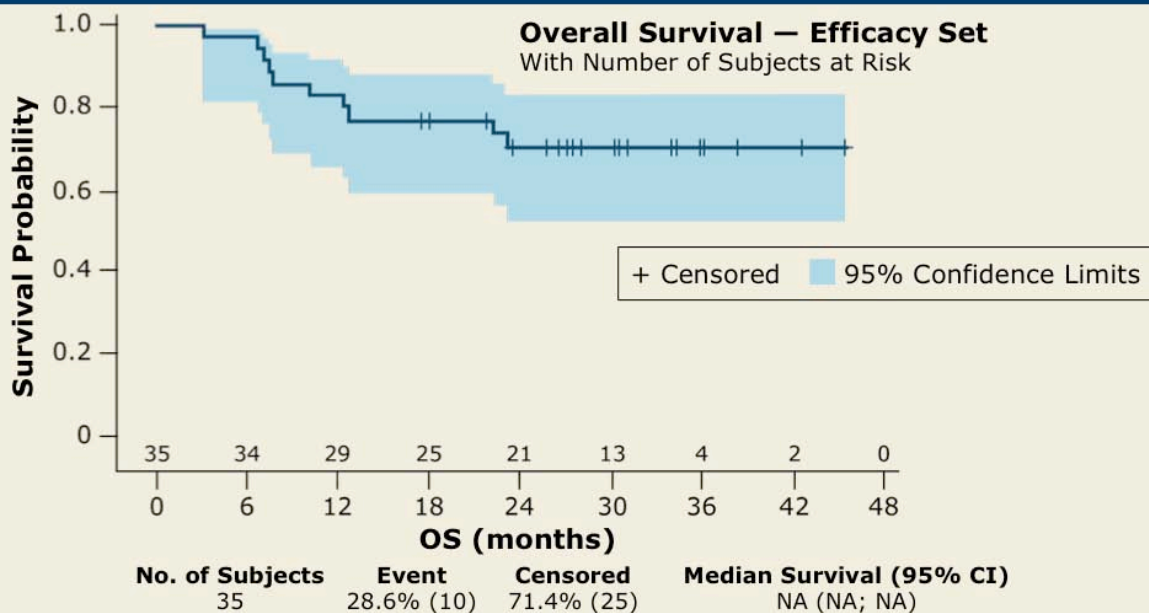
PFS at 12 mg/m² of Romidepsin



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Overall Survival (OS)



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Adverse Events (AEs)

- Patients who experienced at least 1 AE: 100%
- Median number of AEs per patient: 49
- Proportion of AEs that occurred during cycle 1 or 2: 38%
- AEs of Grade 1-2: 84%
- No AE-related deaths were reported
- Some severe toxicities were observed during the expansion phase:
 - Sensory peripheral neuropathy leading to treatment discontinuation (n = 1)
 - Nonfatal acute cardiac toxicity after first cycle (n = 3)
- Severity of thrombocytopenia led to discontinuation of romidepsin in 5 patients
- Reasons for romidepsin discontinuation:
 - PD (n = 5); toxicity (n = 6)

Dupuis J et al. *Proc ASH 2014*;Abstract 504.

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AEs Occurring in $\geq 10\%$ of Patients

Event (n = 37)	All grades	Grade 3-4
Neutropenia	100%	85%
Thrombocytopenia	94%	35%
Anemia	89%	8%
Fatigue	80%	5%
Hypocalcemia	62%	3%
Nausea/vomiting	59.5%	10%
Mucositis	27%	5%
Diarrhea	24%	0%
QT prolongation	24%	0%
Hypophosphatemia	22%	8%
Febrile neutropenia	19%	19%

Dupuis J et al. *Proc ASH 2014*;Abstract 504.

Author Conclusions

- Romidepsin can be combined with CHOP at the price of foreseeable hematological toxicity.
- Some cardiovascular events have been observed, but the relationship with romidepsin is questionable.
- The PFS rates seem promising.
- The ongoing Phase III Ro-CHOP trial is evaluating romidepsin and CHOP versus CHOP alone for patients with previously untreated PTCL (NCT01796002):
 - Estimated enrollment: 420
 - Primary endpoint: PFS

Dupuis J et al. *Proc ASH* 2014;Abstract 504.

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Investigator Commentary: Final Results of the Phase Ib/II Trial of Romidepsin in Combination with CHOP in Previously Untreated PTCL

This is the final analysis of a small Phase Ib/II study of romidepsin and CHOP in patients with previously untreated PTCL. The results are interesting. The 1-year PFS for the overall population was 57%. In the elderly patient population this rate is reasonable and supports the need for a randomized study of romidepsin/CHOP.

The cardiac toxicity associated with this treatment combination does not appear to be negligible. Two early cardiac events (myocardial infarction) occurred, and an additional patient experienced acute cardiac failure. There's no doubt that romidepsin in combination with CHOP also causes more thrombocytopenia than CHOP alone.

In my practice I administer CHOP with etoposide (CHOEP) for younger patients with PTCL before transplantation. We perform autotransplantation at first remission. For patients with CD30-positive PTCL, we administer CHOP/brentuximab vedotin up front.

Interview with Craig Moskowitz, MD, January 6, 2015

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