GITMO

Rete Ematologica Pugliese

SIE
"Società Italiana di Ematologia"

fondazione GIMEMA

# Real World Evidence

## Nuovi target terapeutici in ematologia

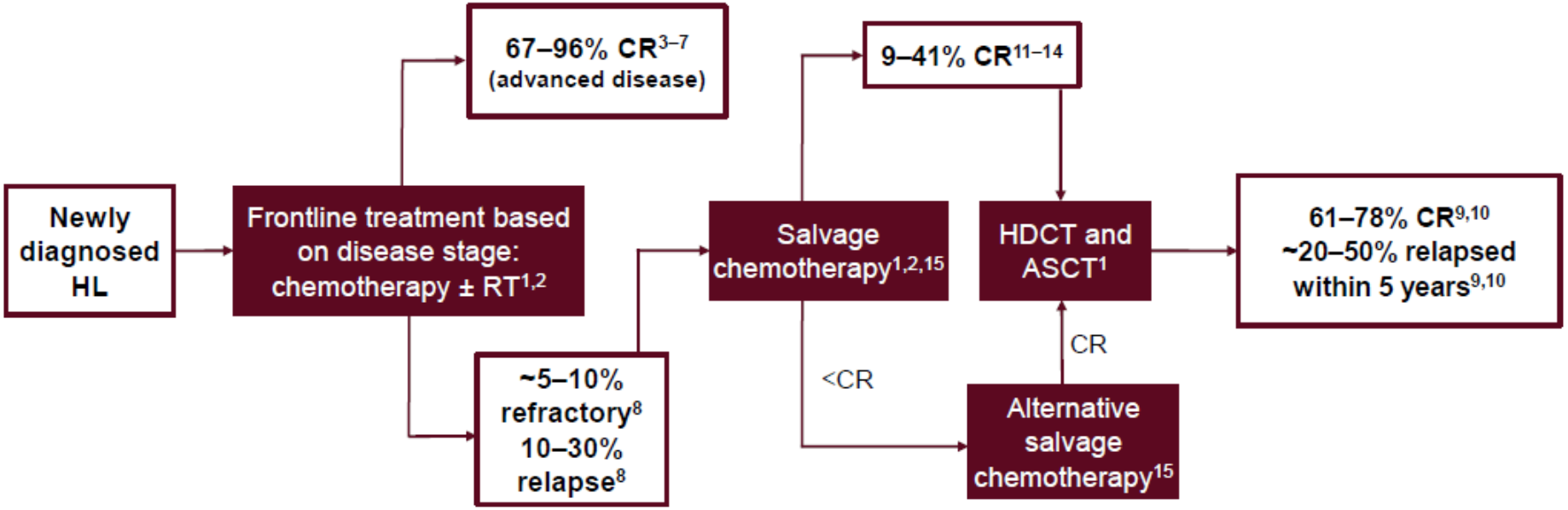
Presidente del Convegno
Nicola Cascavilla

Auditorium "Fra Agostino Daniele"
San Giovanni Rotondo
8 - 9 Novembre 2018

Brentuximab, Nivolumab: L' esperienza Real Word della REP

Dr.ssa Clara De Risi
Az. Osp. Card. G. Panico - Tricase

# Hodgkin lymphoma treatment landscape




ASCT, autologous stem cell transplant; CR, complete response; HDCT, high-dose chemotherapy; RT, radiotherapy

1. Eichenauer DA, et al. Ann Oncol 2018 May 23 [Epub ahead of print]; 2. Ansell SM. Mayo Clin Proc 2015;90:1574–83; 3. Bonadonna G, et al. Cancer 1975;36:252–9; 4. Duggan D, et al. J Clin Oncol 2003;21:607–14; 5. Canellos G, et al. N Engl J Med 1992;19:1478–84; 6. Engert A, et al. J Clin Oncol 2009;27:4548–54; 7. Horning S, et al. J Clin Oncol 2000;18:972–80; 8. Quddus F, Armitage J. Cancer J 2009;15:161–3; 9. Sirohi B, et al. Ann Oncol 2008;19:1312–9; 10. Majhail NS, et al. Biol Blood Marrow Transplant 2006;12:1065–72; 11. Kuruvilla J, et al. Cancer 2006;106:353–60; 12. Moskowitz C, et al. Blood 2001;97:616–23; 13. Josting A, et al. Ann Oncol 2002;13:1628–35; 14. Aparicio J, et al. Ann Oncol 1999;10:593–5; 15. MD Anderson Cancer Center. V5 2018 Available at: https://www.mdanderson.org/documents/for-physicians/algorithms/cancer-treatment/ca-treatment-lymphoma-hodgkins-web-algorithm.pdf. Accessed on 01 Jun 2018.

# MEDICAL NEED IN HL

## OUTCOME

**IMPROVE**
FIRST LINE

**IMPROVE**
SALVAGE
THERAPY

**PREVENT RELAPSE**
CONSOLIDATION THERAPY
MAINTENANCE THERAPY

## REDUCE TOXICITY

RISK-ADAPTED
STRATEGY

RESPONCE-ADAPTED
STRATEGY

KEY ROLE OF NOVEL
AGENTS

# ESPERIENZA REAL-LIFE NELL'AMBITO DELLA REP

**BRENTUXIMAB VEDOTIN**

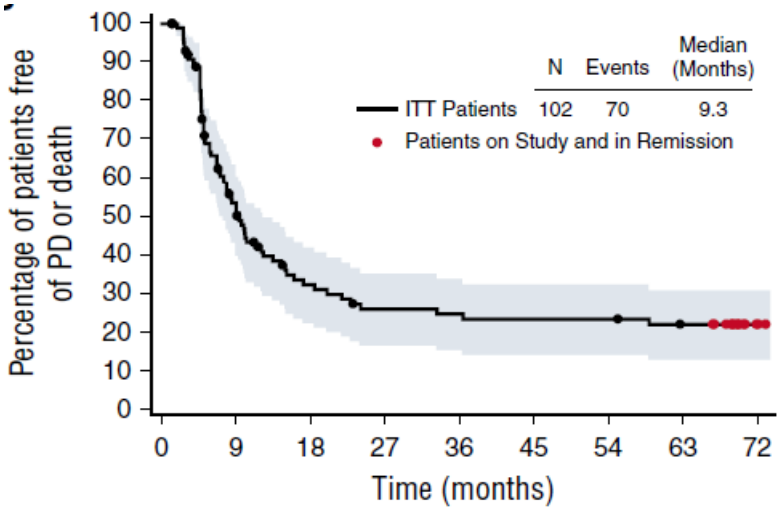
**Single agent for R/R HL after ASCT or following 2 prior lines, not elegible to transplant**

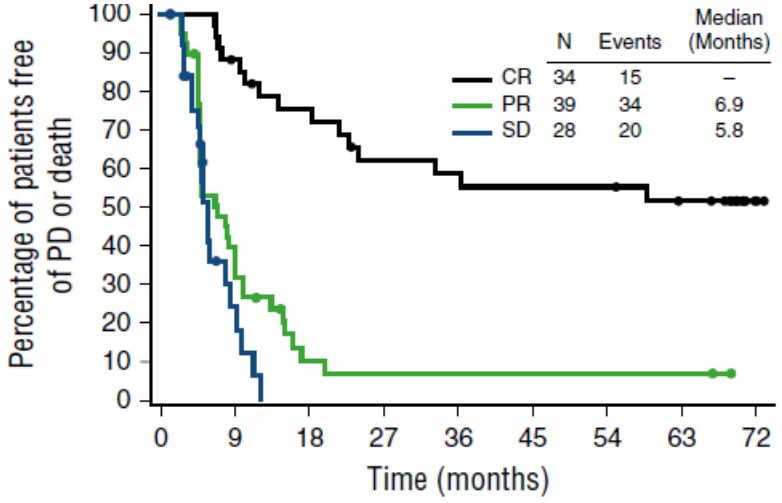
**NIVOLUMAB**

**Single agent for R/R HL after ASCT and BV**

| Regimen | N | Rel | Primary ref | CR-PET neg pre ASCT% | CD34x10 6/Kg | ASCT% | PFS ITT |
|---|---|---|---|---|---|---|---|
| BV (not elegibile to ASCT/multi-agent CHT) Walewsky J et al, 2016 | 60 | 22% | 67% | **12% CR** | ND | 47% | ORR 50 % DOR 6,1 mo in CR |
| BV (R. Chen,2015 A.F.Herrera,2018) | 57 | 22 | 35 | **43%** | 6 | 88% | 67% at 2 yrs |
| BV Sequential ICE (Moscowitz, 2015) | 66 | 33 | 33 | **73%** | 6,2 | 95 | 79% at 3 yrs |
| Benda-BV (LaCasce, 2018) | 54 | 27 | 27 | **74%** | 4 | 74% | 63% at 2 yrs |
| BV-ICE (Stamatoullas, 2017 Cassaday, 2016) | 16 | 5 | 11 | **69%** | 11 | 75% | Too soon |
| BV-ESHAP (Garcia-Sanz, 2015) | 66 | 26 | 40 | **70%** | 5,75 | 92% | Too soon |
| BV-DHAP (Hagenbeek, 2016) | 12 | 10 | 2 | **90%** | 5,3 | 100% | Too soon |

# Five-year survival and durability results of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma



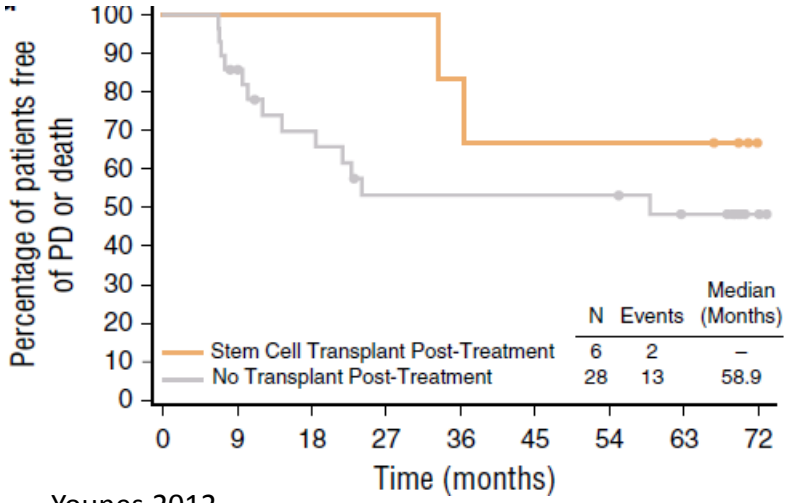




**9% RC without other therapies**

**75% patients had >1 therapies after BV**

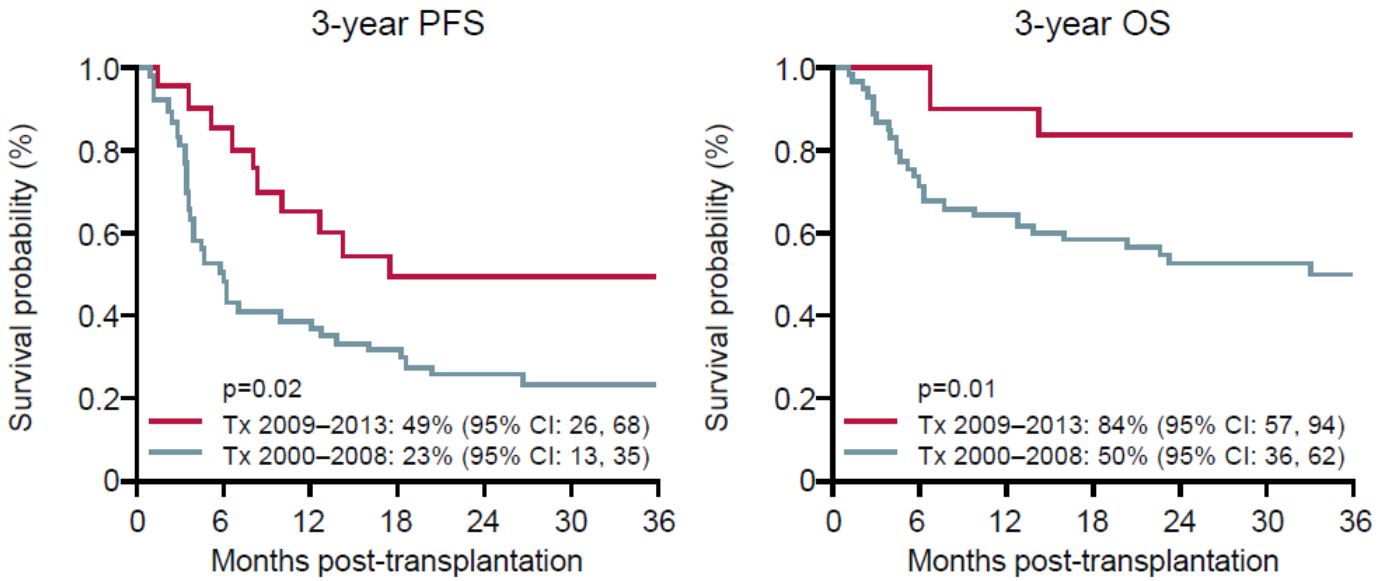
**17% re-treatment with BV: ORR 60% - CR 30% and median DOR 9,2 mo**

**21,5% patients got alloHSCT (41% in RC)**




A. Younes,2012
B. R.Chen, et al Blood 2016

# Improving Outcomes After Allogeneic Hematopoietic Cell Transplantation for Hodgkin Lymphoma in the Brentuximab Vedotin Era




Hegerova et al. Bone Marrow Transplant. 2017 May ; 52(5): 697–703

# Brentuximab vedotin prior to alloSCT in HL: EBMT Lymphoma Working Party[1]

**Multivariate analysis; n=210 patients who received BV as last therapy before alloSCT and n=218 who did not receive BV pre-transplant**

| Variables | Chronic GVHD (95% CI) p | NRM (95% CI) p | CIR (95% CI) p | PFS (95% CI) p | OS (95% CI) p |
|---|---|---|---|---|---|
| Brentuximab vedotin salvage pre-SCT vs no | **0.67 (0.45, 0.99) p=0.0448** | 0.98 (0.55, 1.74) p=0.9372 | 1.03 (0.69, 1.54) p=0.8755 | 1.01 (0.73, 1.4) p=0.9404 | 0.93 (0.62, 1.38) p=0.7204 |

BazarbachiA, et al. Br J Haematol2018;181:86

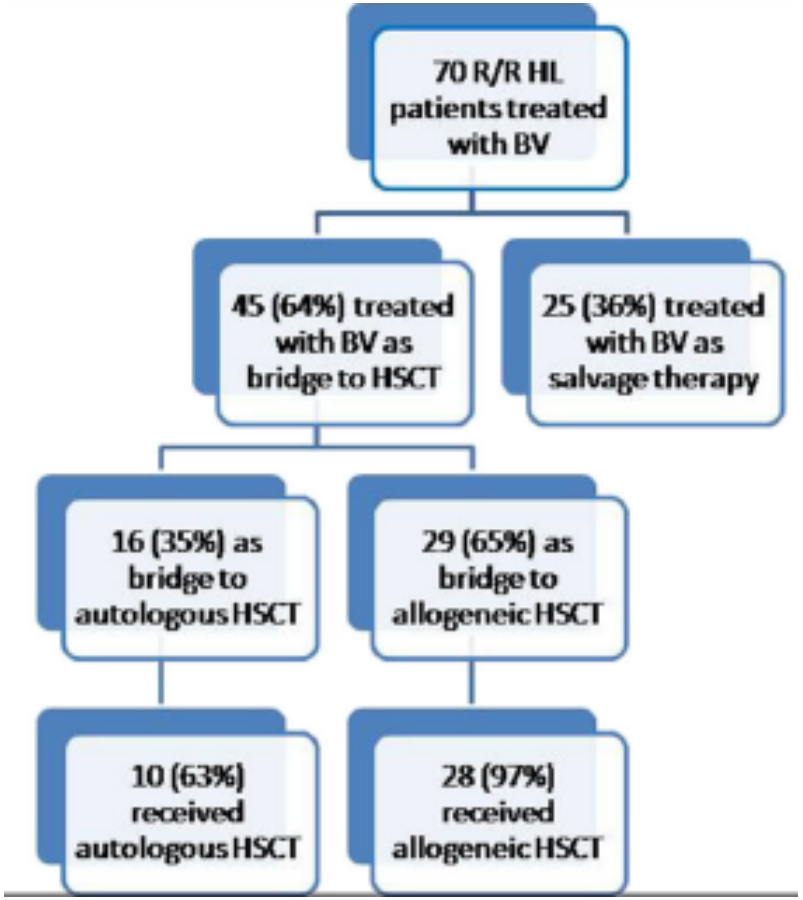
# Brentuximab vedotin as salvage treatment in Hodgkin lymphoma naïve transplant patients or failing ASCT: the real life experience of Rete Ematologica Pugliese (REP)

**MULTICENTRIC RETROSPECTIVE STUDY**

**STUDY PERIOD**
**APRIL 2014- JANUARY 2016**

**ENDPOINTS**

| | |
|---|---|
| **PRIMARY:** | **ORR** |
| **SECONDARY:** | **PFS-OS**<br>**N° pts brought to SCT**<br>**post-SCT ORR**<br>**SAFETY** |




Vincenzo Pavone, Anna Mele et al, Annals of Hematology https://doi.org/10.1007/s00277-018-3379-5

# DEMOGRAPHIC CHARACTERISTICS

| | No. of patients (%) ($n = 70$) | Bridge to auto SCT ($n = 16$) | Bridge to allo SCT ($n = 29$) | Salvage therapy ($n = 25$) | $p$ |
|---|---|---|---|---|---|
| Median age, yrs. (range) | 34 (15–84) | 30 (15–65) | 32 (22–54) | 52 (16–84) | |
| > 50 yrs | 19 (28) | 5 (31) | 2 (7) | 12 (50) | 0.001 |
| Disease status at BV | | | | | |
| Refractory | 33 (47) | 6 (37) | 13 (45) | 14 (56) | 0.48 |
| Relapsed | 37 (53) | 10 (63) | 16 (55) | 11 (44) | |
| ECOG performance status | | | | | |
| 0 | 42 (60) | 10 (62) | 20 (69) | 11 (44) | 0.38 |
| 1–2 | 28 (40) | 6 (38) | 9 (31) | 14 (56) | |
| Baseline B symptoms | 39 (57) | 12 (75) | 14 (48) | 13 (56) | 0.22 |
| Extranodal disease at diagnosis | 29 (44) | 7 (47) | 10 (37) | 12 (59) | 0.6 |
| Bulky disease | 22 (33) | 6 (40) | 12 (44) | 4 (16) | 0.09 |
| III–IV stage | 44 (64) | 11 (69) | 16 (55) | 17 (71) | 0.68 |
| Median prior chemotherapy regimens, (range) | 3 (1–6) | 2 (2–3) | 3 (2–5) | 3 (1–6) | 0.001 |
| ≥ 3 | 42 (64) | 4 (27) | 23 (82) | 15 (66) | |
| First remission < 12 months | 41 (68) | 12 (80) | 17 (68) | 12 (60) | 0.45 |
| Median time from diagnosis to BV, months (range) | 17 (3–111) | 14 (5–111) | 20 (4–86) | 19 (3–104) | 0.08 |
| ≥ 17 | 30 (43) | 4 (27) | 17 (61) | 9 (56) | |
| Prior radiation | 16 (23) | 2 (12) | 8 (28) | 6 (26) | 0.48 |
| Prior Auto-SCT | 40 (57) | NA | 28 (97) | 12 (48) | 0.001 |
| Prior Allo-SCT | 6 (9) | NA | NA | 6 (100) | 0.002 |
| Median time from auto to-relapse, months (range) | 5 (1–73) | NA | 5 (1–44) | 5 | 0.71 |
| < 6 months | 21 (52) | | 9 (32) | 1 (8) | |

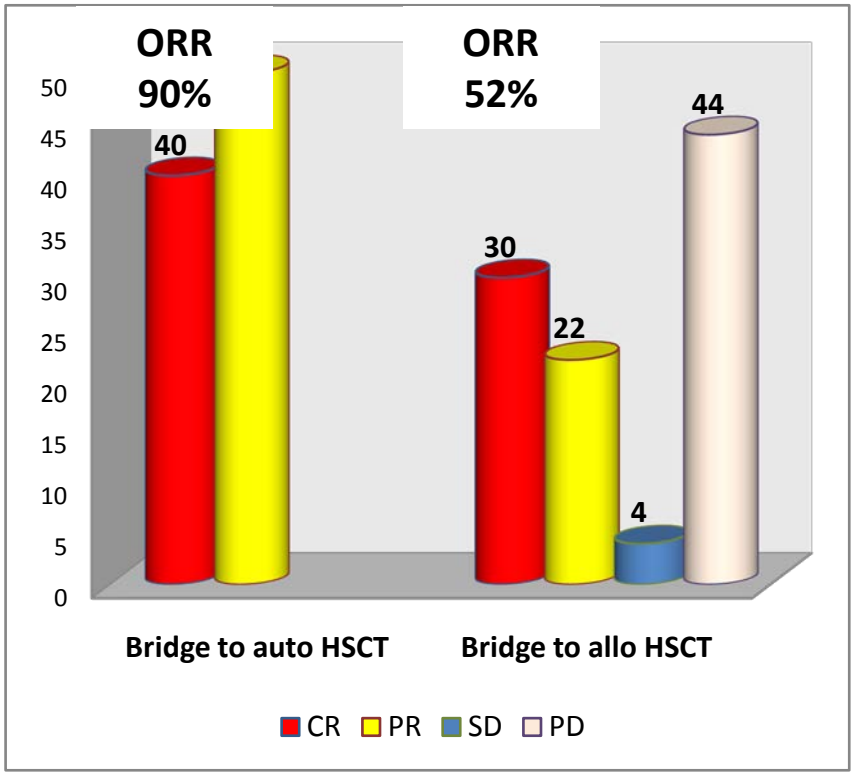
# KEY RESPONSE RESULTS

| | Whole cohort 70 | Bridge to ASCT 16 | Bridge to allo SCT 29 | Salvage Therapy 25 | p |
|---|---|---|---|---|---|
| | No. (%) | No. (%) | | | |
| **Objective Response** | **41 (59%)** | **12 (75%)** | **18 (62%)** | **11 (44%)** | |
| Complete remission | 18 (26%) | 5 (31%) | 7 (24%) | 6 (24%) | |
| Partial remission | 23 (33%) | 7 (44%) | 11 (38%) | 5 (20%) | 0,31 |
| Progressive Disease | 29 (41%) | 4 (25%) | 11 (38%) | 14 (56%) | |

*ASCT: autologous stem cell transplant; AlloSCT: allogeneic stem cell transplant ; No.; number*

# POST TRANSPLANT KEY RESPONSE RESULTS

| | N (%) | |
|---|---|---|
| | Bridge to auto HSCT 16 | Bridge to allo HSCT 29 |
| Transplanted patients | 10/16 (63%) | 28/29 (97%) |
| **ORR** | **10 (90%)** | **14 (52%)** |
| CR | 4 (40%) | 8 (30%) |
| PR | 5 (50%) | 6 (22%) |
| Stable Disease | // | 1 |
| Progressive Disease | // | 12 |
| *Not evaluable* | *1* | *2* |

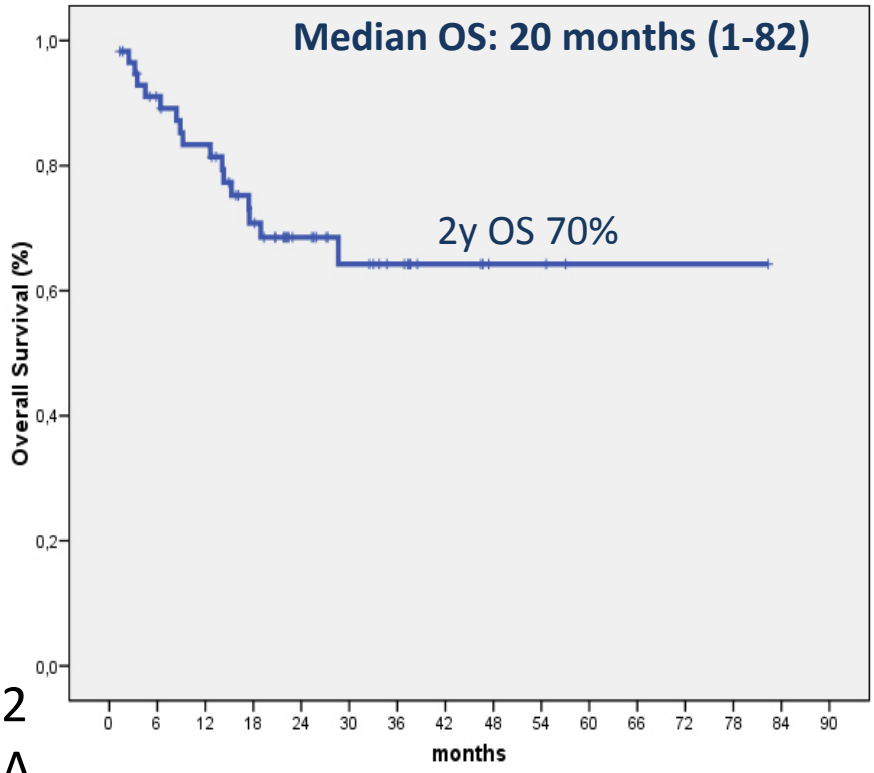


# Univariate and multivariate analysis of whole group

| | Univariate analysis | | | Multivariate analysis |
|---|---|---|---|---|
| | No. of patients (%) | | | |
| | ORR | No ORR | *p* | *p* |
| Median age > 50 yrs | 10 (25) | 9 (32) | 0.9 | |
| Extranodal disease at diagnosis | 17 (42) | 12 (46) | 0.66 | |
| Bulky disease | 17 (42) | 5 (19) | 0.09 | |
| Prior radiation | 8 (20) | 8 (30) | 0.44 | |
| III–IV Stage | 26 (64) | 18 (64) | 0.39 | |
| Naïve -SCT | 17 (42) | 13 (64) | 0.4 | |
| Prior AlloSCT | 2 (5) | 4 (13) | 0.29 | |
| First remission < 12 months | 13 (45) | 19 (76) | 0.03 | |
| N. prior CHT-BV ≥ 3 | 24 (64) | 18 (62) | 0.096 | |
| Time to BV < 17 months | 14 (39) | 15 (65) | 0.05 | |
| Refractory disease | 12 (29) | 21 (72) | 0.005 | 0.005 |

*Yrs* years, *No* number, *SCT* stem cell transplant, *AlloSCT* allogeneic stem cell transplant, *BV* brentuximab vedotin, *CHT* chemotherapy

# KAPLAN-MEIER PLOTS: WHOLE GROUP

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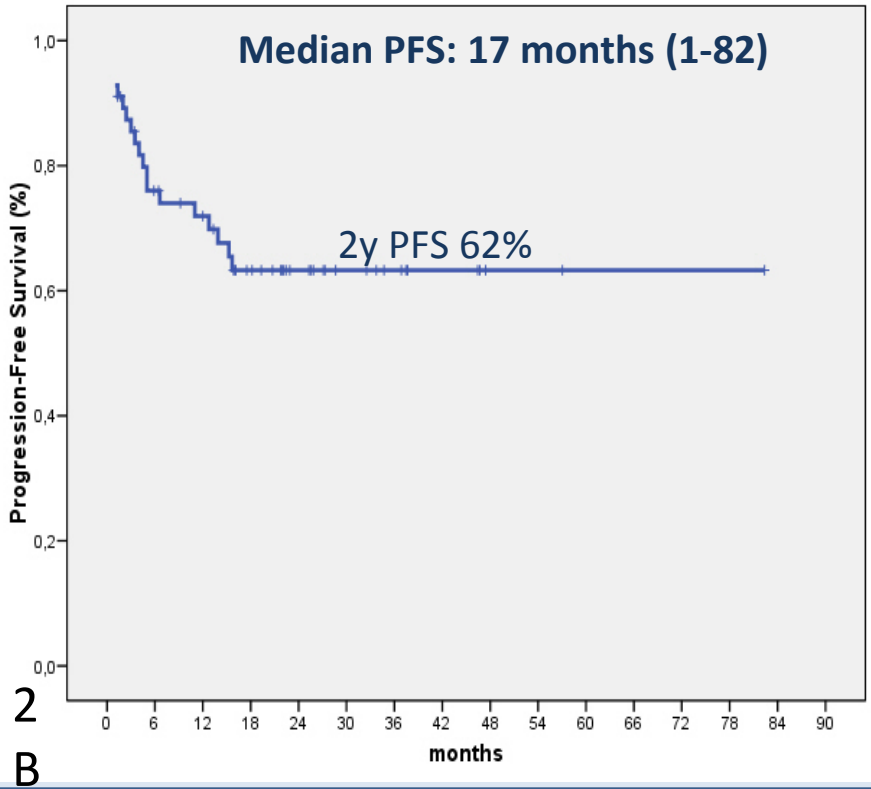
A

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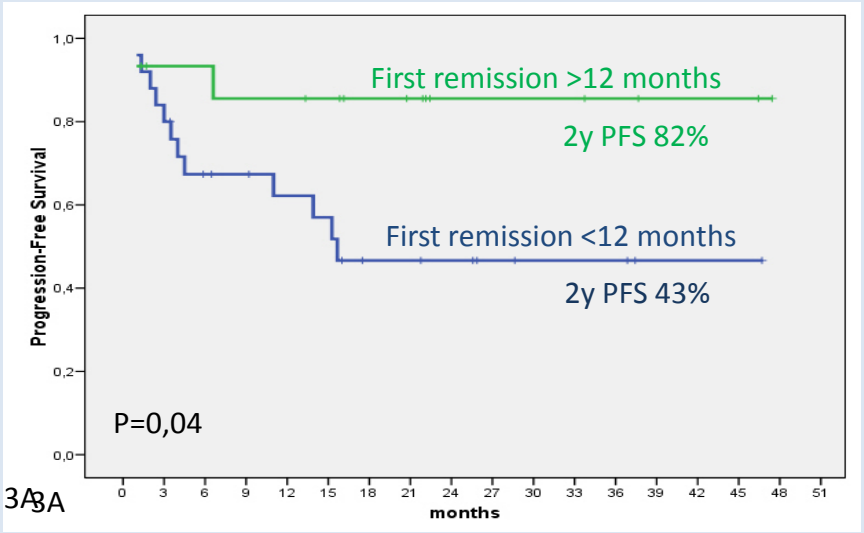
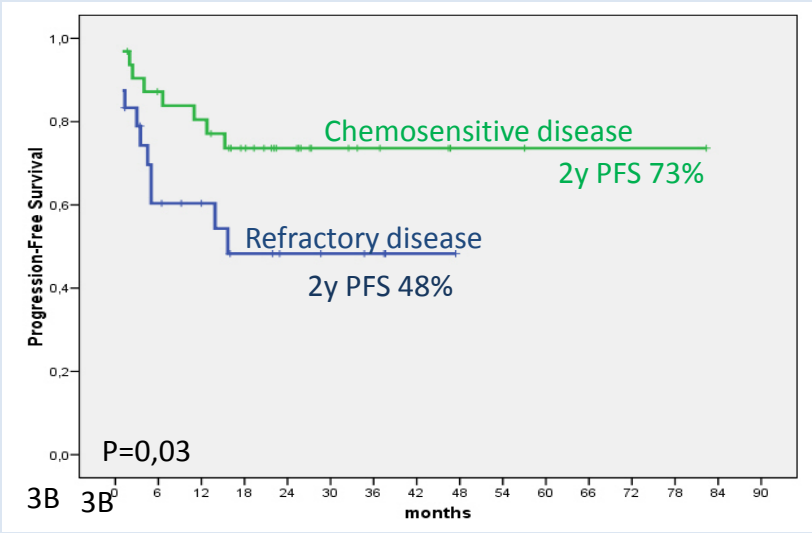
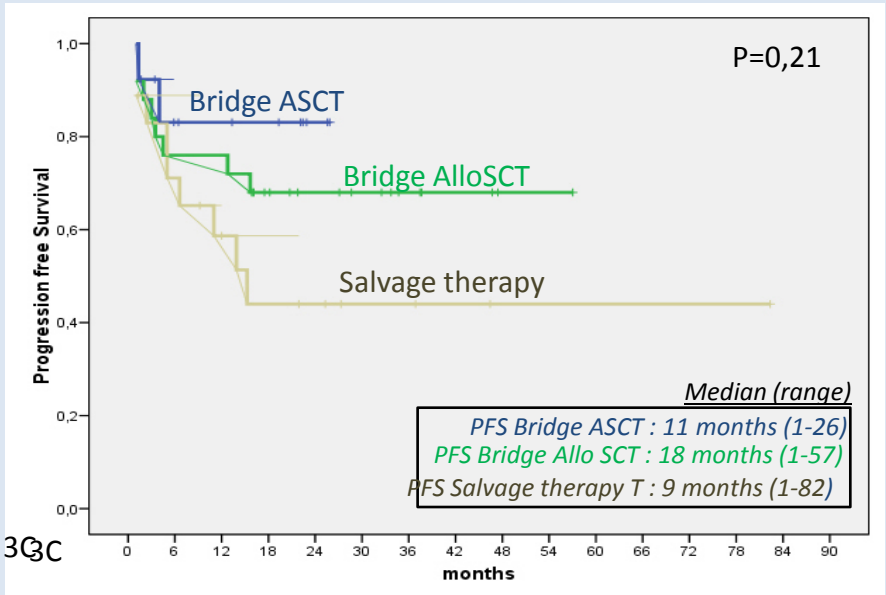
B

# KAPLAN-MEIER PLOTS 2




**PFS according to (3°A) time to relapse, (3B) to refractory disease and (3C) to timing of Brentuimab Vedotin (BV)**

# SAFETY

Rete Ematologica Pugliese

**Table 6** Drug-related adverse events in the different groups of patients

| | Bridge to allo SCT ($n=29$) | | Bridge to ASCT ($n=16$) | | Salvage therapy ($n=25$) | | $p$ |
|---|---|---|---|---|---|---|---|
| | No. of patients (%) | | | | | | |
| | Any grade events | Any grade 3–4 events | Any grade events | Any grade 3–4 events | Any grade events | Any grade 3–4 events | |
| Median BV cycles, range | 6 (2–8) | | 4 (1–6) | | 8 (2–16) | | 0.32 |
| Peripheral sensory/motor neuropathy | 11 (18) | 2 (3) | 5 (7) | | 14 (20) | 3 (5) | 0.19 |
| Pyrexia | 3 (5) | 2 (3) | 1 (2) | NA | 2 (3) | NA | 0.23 |
| Neutropenia | 11 (18) | 3 (5) | 5 (7) | 2 (3) | 4 (6) | 3 (5) | 0.38 |
| Anemia | 4 (6) | 2 (3) | 1 (2) | NA | 3 (5) | 1 (2) | |
| Trombocytopenia | 3 (5) | 2 (3) | NA | | 2 (3) | 1 (2) | |
| Delayed administration | 1 (2) | | 1 (2) | | 1 (2) | | 0.81 |
| Dose reduction BV | 2 (3) | | NA | | 2 (3) | | 0.16 |

# BV CONCLUSIONS

Rete Ematologica Pugliese

REP Real Word Experience is comparable with literature data

BV is very effective and safe salvage therapy in R/R HL

Very effective as bridge to transplant producing substantial level of CR

Key agent to improve post-transplant outcome

BEST RESULTS if Bridge to ASCT

# LITERATURE DATA

| Agent | Trial / phase | Author | N / N ASCT | ORR % | CR% | Median duration Response |
|---|---|---|---|---|---|---|
| MONOTHERAPY | | | | | | |
| Nivolumab | Checkmate 039/I | Ansell, NEJM 2015 | 23 / 18 | **87%** | **17%** | NR; 6mPFS 86% |
| Nivolumab | Checkmate 205/II | Younes, Lancet Oncol 2016 | 80 (ASCT/BV) | **68%** | **9%** | 17 mo; PFS 15 mo |
| COMBINATION THERAPY | | | | | | |
| Nivolumab + BV | I/II (first relapse) | Herrera, Blood 2018 | Ongoing (55) | **82%** | **61%** | 6mPFS 91% 44% 1-2 IRR |

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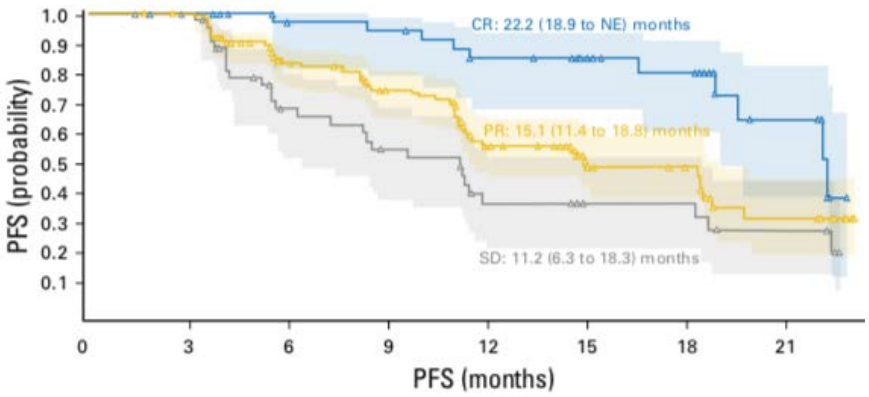
JOURNAL OF CLINICAL ONCOLOGY

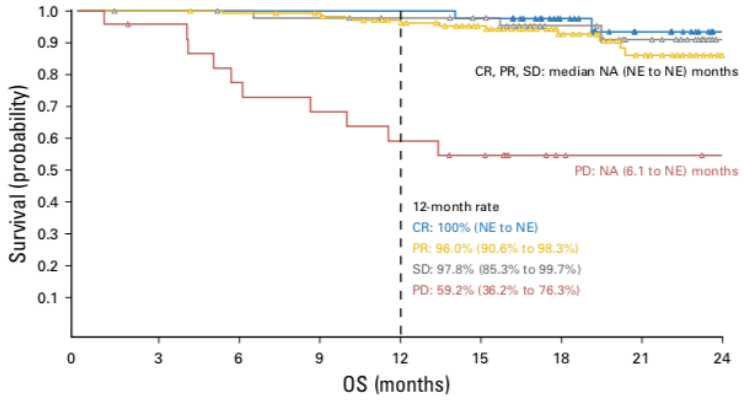
ORIGINAL REPORT

# Nivolumab for Relapsed/Refractory Classic Hodgkin Lymphoma After Failure of Autologous Hematopoietic Cell Transplantation: Extended Follow-Up of the Multicohort Single-Arm Phase II CheckMate 205 Trial

*Philippe Armand, Andreas Engert, Anas Younes, Michelle Fanale, Armando Santoro, Pier Luigi Zinzani, John M. Timmerman, Graham P. Collins, Radhakrishnan Ramchandren, Jonathon B. Cohen, Jan Paul De Boer, John Kuruvilla, Kerry J. Savage, Marek Trneny, Margaret A. Shipp, Kazunobu Kato, Anne Sumbul, Benedetto Farsaci, and Stephen M. Ansell*

| Response | Protocol-Specified Analysis by Cohort: BV Naïve: Cohort A (n = 63) | BV After Auto-HCT: Cohort B (n = 80) | BV Before and/or After Auto-HCT: Cohort C (n = 100) | All patients (N = 243) |
|---|---|---|---|---|
| ORR, % (95% CI) | 65 (52-77) | 68 (56-78) | 73 (63-81) | 69 (63-75) |
| Best overall response | | | | |
| Complete remission | 18 (29) | 10 (13) | 12 (12) | 40 (16) |
| Partial remission | 23 (37) | 44 (55) | 61 (61) | 128 (53) |
| Stable disease | 15 (24) | 17 (21) | 15 (15) | 47 (19) |
| Progressive disease | 7 (11) | 6 (8) | 10 (10) | 23 (9) |
| Unable to determine | 0 | 3 (4) | 2 (2) | 5 (2) |



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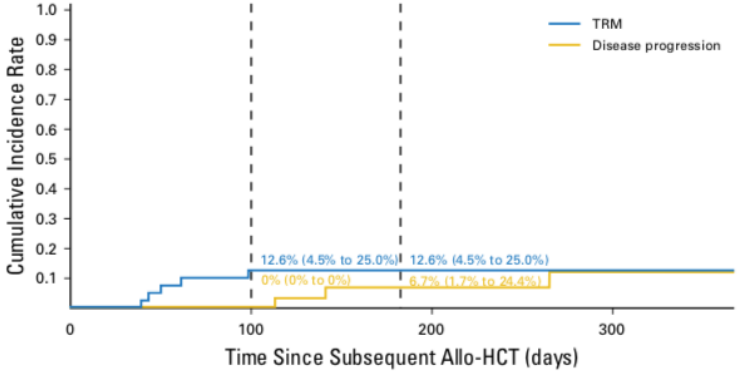
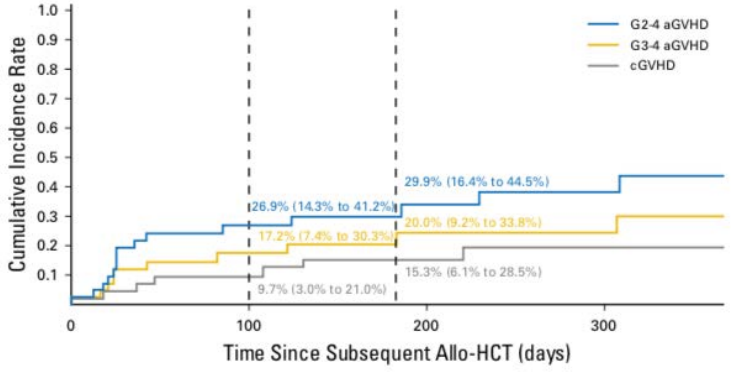
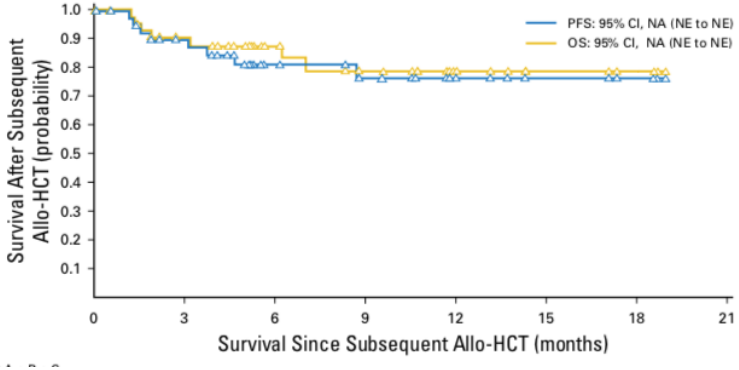


Original article

REAL LIFE

# Nivolumab for relapsed or refractory Hodgkin lymphoma: real-life experience

Table 1: Patient demographics and disease and response characteristics (*n*=82)

| | |
|---|---|
| Median age, years | 30 (18-75) |
| Male/Female | 48 / 34 |
| ECOG status ≤1 | 73 (89%) |
| B symptoms present | 40 (49%) |
| Stage 3-4 disease ¥ | 55 (81%) |
| Median lines of previous therapy | 5 (2-11) |
| 5 or more lines | 47 (57%) |
| Previous stem cell transplantation | 57 (70%) |
| Autologous | 55 (67%)¶ |
| Allogeneic | 16 (30%)µ |
| Previous brentuximab vedotin (BV) treatment | 63 (77%) |
| Refractory to BV ± | 40 (66%) |
| Median follow-up under nivolumab (months) | 7 (1-22) |
| Median cycles of nivolumab | 12 (1-40) |
| Early response (≤12 weeks of treatment) | |
| CR | 16 (21%) |
| PR | 32 (43%) |
| SD | 8 (11%) |
| PD | 19 (25%) |
| Late response (≥16 weeks of treatment) | |
| CR | 16 (26%) |
| PR | 21 (34%) |
| SD | 2 (3%) |
| PD | 23 (37%) |

Supplemental Table S1: Response evaluation by the investigators vs. by central revision

| | Investigator assessed | Central Revision |
|---|---|---|
| Early response (≤12 weeks of treatment) | Of 75 patients, 54 were centrally revised (71%); *p*=0.000 | |
| CR | 11 (20%) | 12 (22%) |
| PR | 28 (52%) | 25 (46%) |
| SD | 4 (7%) | 4 (7%) |
| PD | 11 (21%) | 11 (21%) |
| IR | | 2 (4%) |
| Late response (≥16 weeks of treatment) | Of 64 patients, 31 were centrally revised (48%); *p*=0.000 | |
| CR | 7 (23%) | 6 (19%) |
| PR | 13 (42%) | 14 (45%) |
| SD | 1 (3%) | 1 (3%) |
| PD | 10 (32%) | 10 (32%) |

**6 mo PFS 77,3%**
**6 mo OS 91,2%**

**Bridge to ASCT 9 pts**
**Bridge to Allo-SCT 11 pts (2 dead/4 GvHD>2)**

H. Beköz et al, Oxford University Press 2017

REAL LIFE



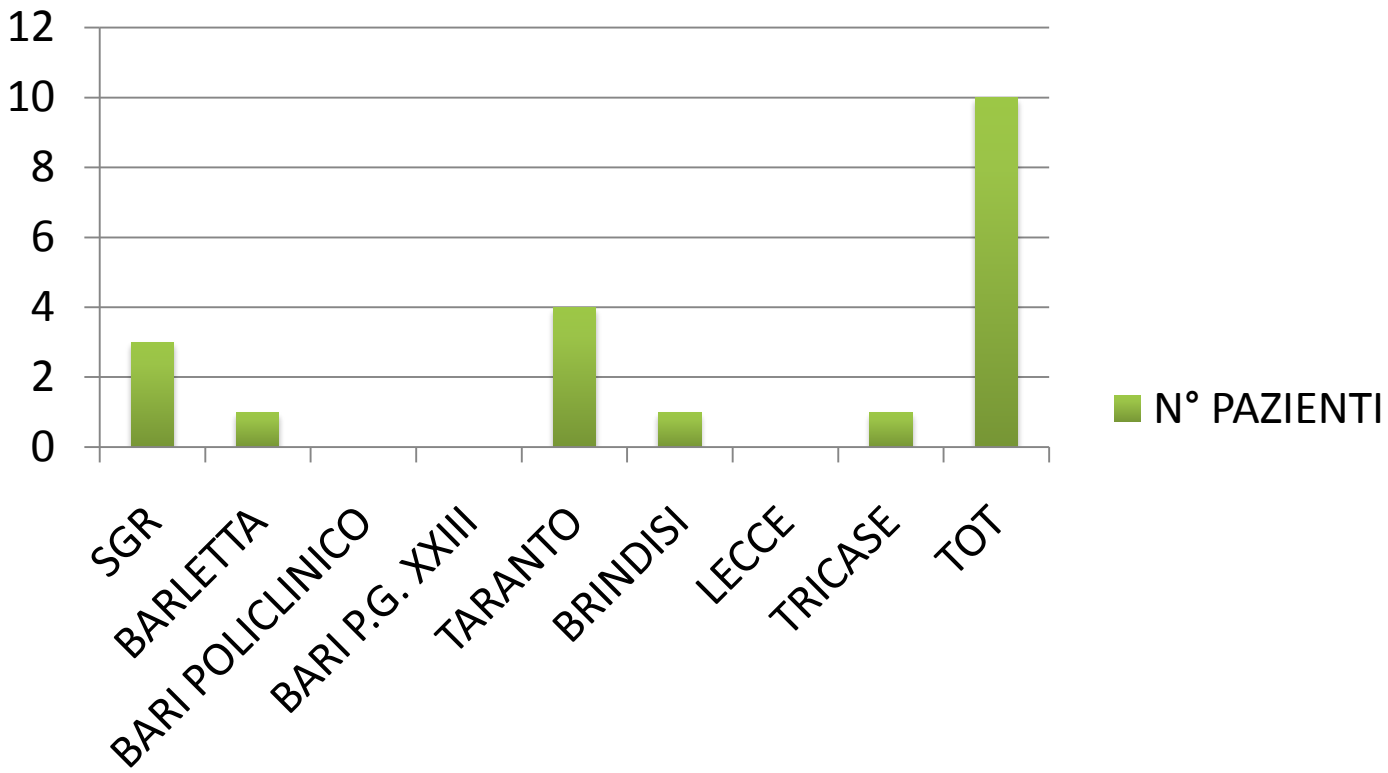
# Nivolumab induces impressive responses in relapsed/refractory classic Hodgkin lymphoma: Single institutional experience

| Patients' number | Age (year) | Stage | Number of prior lines | Response after four cycles | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|
| 1 | 15 | IVB | 6 | PD | 6 | After 9: NR |
| 2 | 20 | IVB | 7 | CmR | After 10: NR | After 10: NR |
| 3 | 33 | IVB | 3 | CmR | After 19: NR | After 19: NR |
| 4 | 30 | IVB | 9 | CmR | 32 | 32 |
| 5 | 25 | IVA | 8 | CmR | 9 | 11 |
| 6 | 26 | IIIA | 8 | CmR | After 16: NR | After 17: NR |
| 7 | 24 | IVB | 9 | PR | After 12: NR | After 13: NR |
| 9 | 18 | IIB | 3 | SD | 5 | 5 |
| 8 | 31 | IIIB | 3 | CmR | After 8: NR | After 8: NR |
| 10 | 40 | IVA | 4 | CmR | After 8: NR | After 8: NR |

**Table 2.** Comparison of our results with results of CHECKMATE 039 and cohort B of CHECKMATE 205.

| Study | Number of patients | Prior brentuximab vedotin | Prior transplantation | Median number of prior lines | Response rate | Complete remission rate |
|---|---|---|---|---|---|---|
| Our study | 10 | 50% | 30% | 6.5 | 80% | 70% |
| CHECKMATE 039 | 23 | 78% | 78% | 87% had ≥3 | 87% | 17% |
| CHECKMATE 205 cohort B | 80 | 100% | 100% | 4 | 66% | 9% |

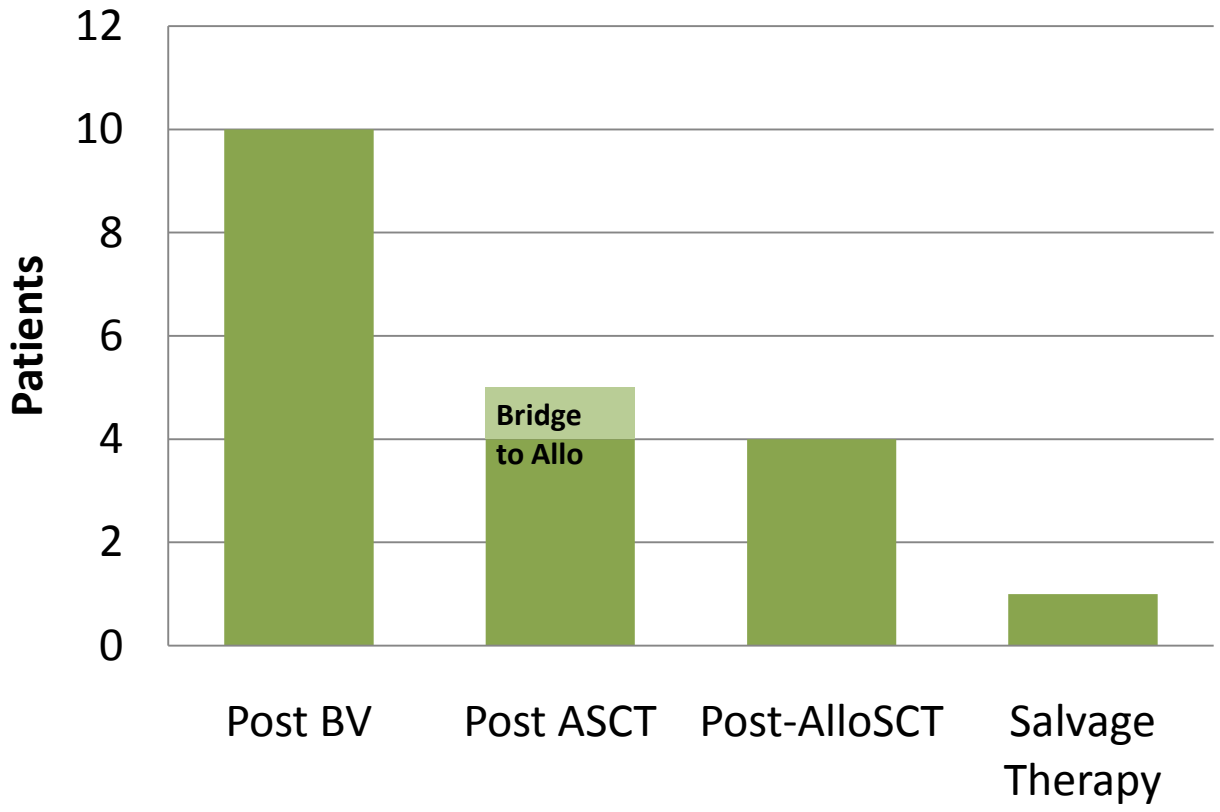
# NIVOLUMAB
# REP'S REAL LIFE EXPERIENCE



# NIVOLUMAB
# DEMOGRAPHIC CHARACTERISTICS

| | |
|---|---|
| Age median (range) | 33 (19-67) |
| Sex M | 5 (50%) |
| Stage IV | 3 (30%) |
| Bulky | 5 (50%) |
| B Sint. | 7 (70%) |
| PET2+ | 6 (86%) |
| Relapse<6 mo | 7 (70%) |
| Chemorefractory disease | 8 (80%) |
| PET+ pre ASCT | 8/9 (89%) |
| Previous Allo-SCT | 4 (40%) |
| Previous ASCT | 9(90%) |
| BV Refractory | 6(60%) |
| Median prior chemotherapy regimens | 5 (2-8) |

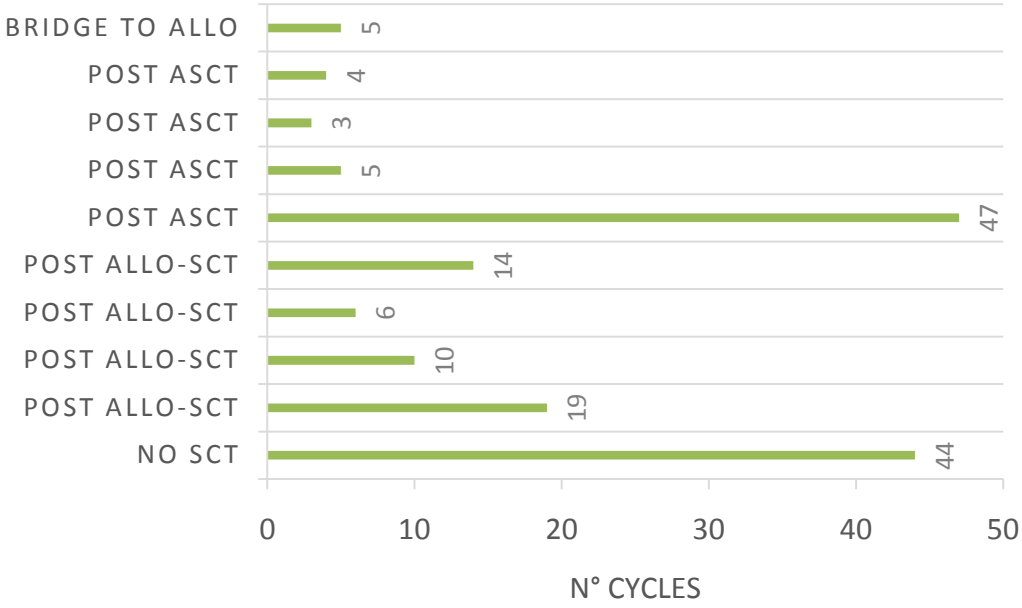
# NIVOLUMAB
# FIELD OF USE



# NIVOLUMAB THERAPY
# TIMING AND DURATION

| | Mediana mo (range) |
|---|---|
| Time from DG to Nivolumab | 80 (8,3-152) |
| Time from BV to Nivolumab | 33,5(1-63) |
| Time from ASCT to Nivolumab | 86 (3-131) |
| Time from Allo-SCT to Nivolumab | 41 (8,5-87) |
| Duration of Nivolumab therapy | 4 (1,5-23,5) |

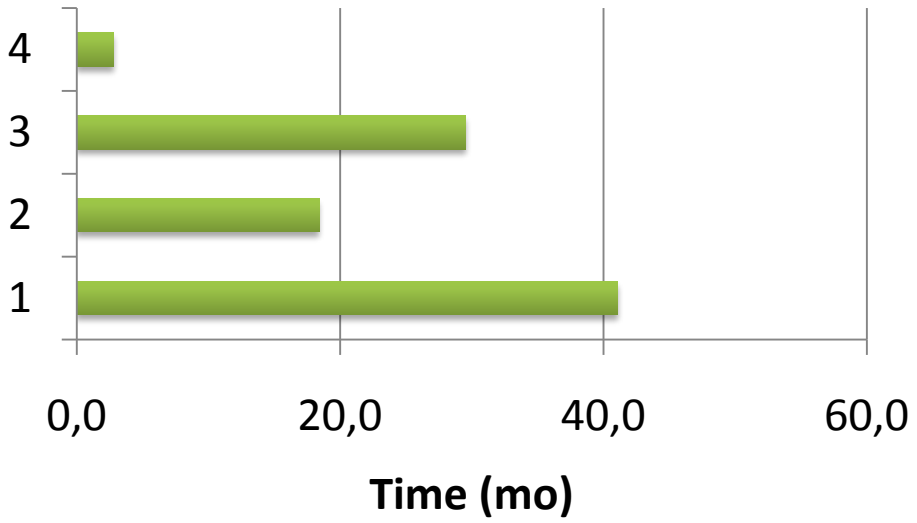
| | | Mediana (range) |
|---|---|---|
| N° Cycles | | 8 (3-47) |
| Ongoing Therapy | | 6 |
| WD TX | 4 | |
| Tox | | 1 (epat. G3) |
| PD | | 2 |
| SCT | | 1 |



# NIVOLUMAB
# KEY POINTS IN POST ASCT SETTING

| | Median mo (range) |
|---|---|
| Time from ASCT to Nivolumab | 24 (2,8-41) |
| N° Cycles | 4 (3-47) |
| | N° (%) |
| BV Refractory | 2 **(50%)** |
| Responce to Prior Therapy | |
| RC | 0 |
| PR | 1 (25%) |
| PD/NR | **2 (75%)** |
| **Response to Nivo** | |
| **PD/SD** | **2 (50%)** |
| **NV** | **2 (50%)** |
| WD | 1 (25%) |
| N 1 (Exitus) | PD |

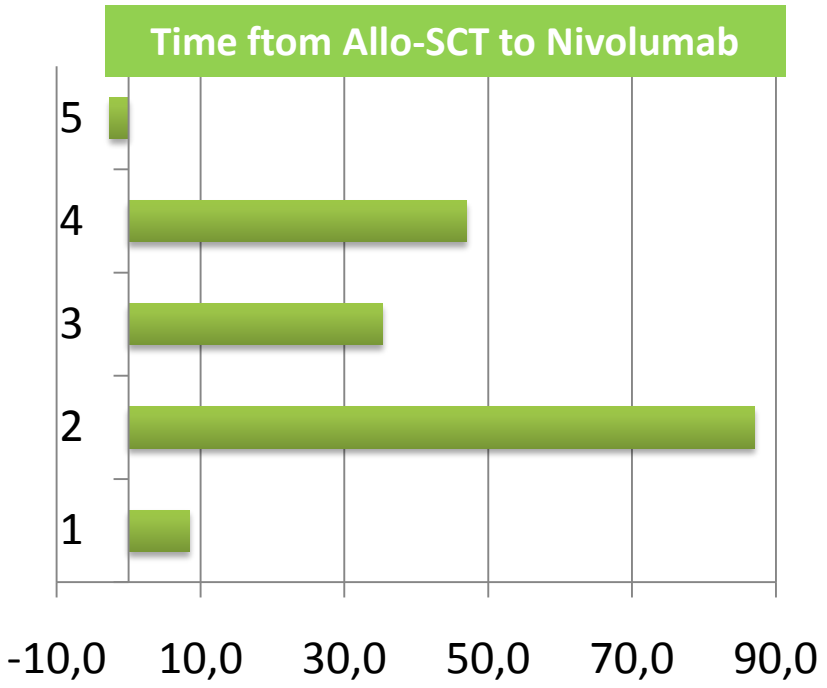
## Time from ASCT to Nivolumab



# NIVOLUMAB
# KEY POINTS NEL SETTING POST Allo-TMO

| | Median mo (range) |
|---|---|
| Time from Allo-SCT to Nivolumab | 35,3 (-2,7-87) |
| N° Cycles | 10 (5-19) |

| | N° (%) |
|---|---|
| BV Refractory | **(40%)2** |
| Responce to prior therapy | |
| RC | 1 (20%) |
| RP | 2 (40%) |
| PD/NR | 2 (40%) |
| **Responce to Nivo** | |
| **RC** | **1 (20%)** |
| **RP** | **2 (40%)** |
| **PD/SD** | **2 (40%)** |
| **WD (SCT/TOX/PD)** | **3 (60%)** |

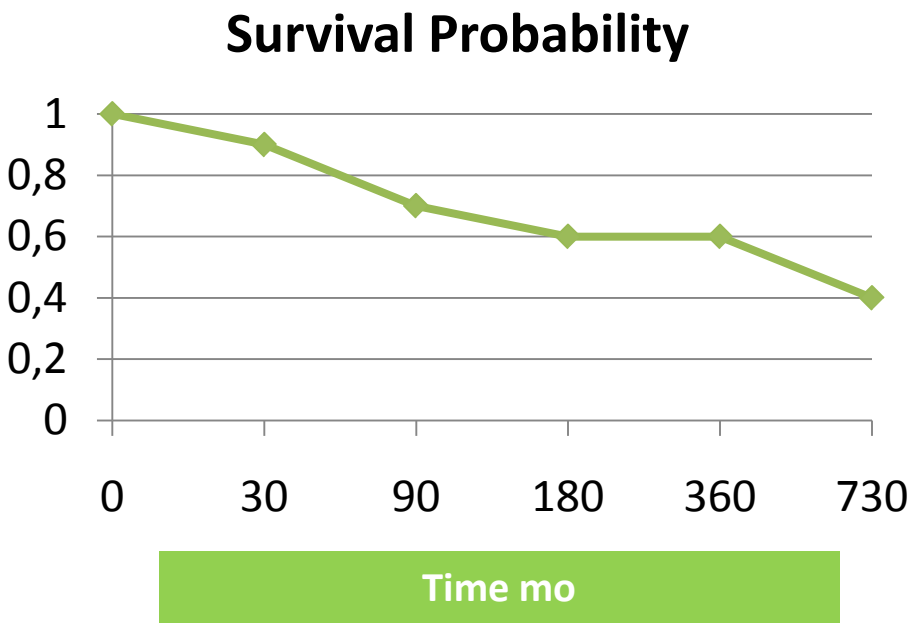



| | aGvHD>2 | cGvHD>2 |
|---|---|---|
| N1 | 0 | Cute G2 |
| N2 | missing | missing |
| N3 | 0 | 0 |
| N4 | 0 | 0 |
| N5 | Epatica G3 | Epatica G3 |

# NIVOLUMAB
# OUTCOME AND SAFETY

| | % | Mediana mo(range) |
|---|---|---|
| Responce | | |
| RC | 1 | |
| RP | 2 | |
| SD | 2 | |
| PD | 3 | |
| NA | 2 | |
| ORR | 37,5% | |
| CR | 12,5% | |
| F-UP | | 7,8 (1-27,7) |

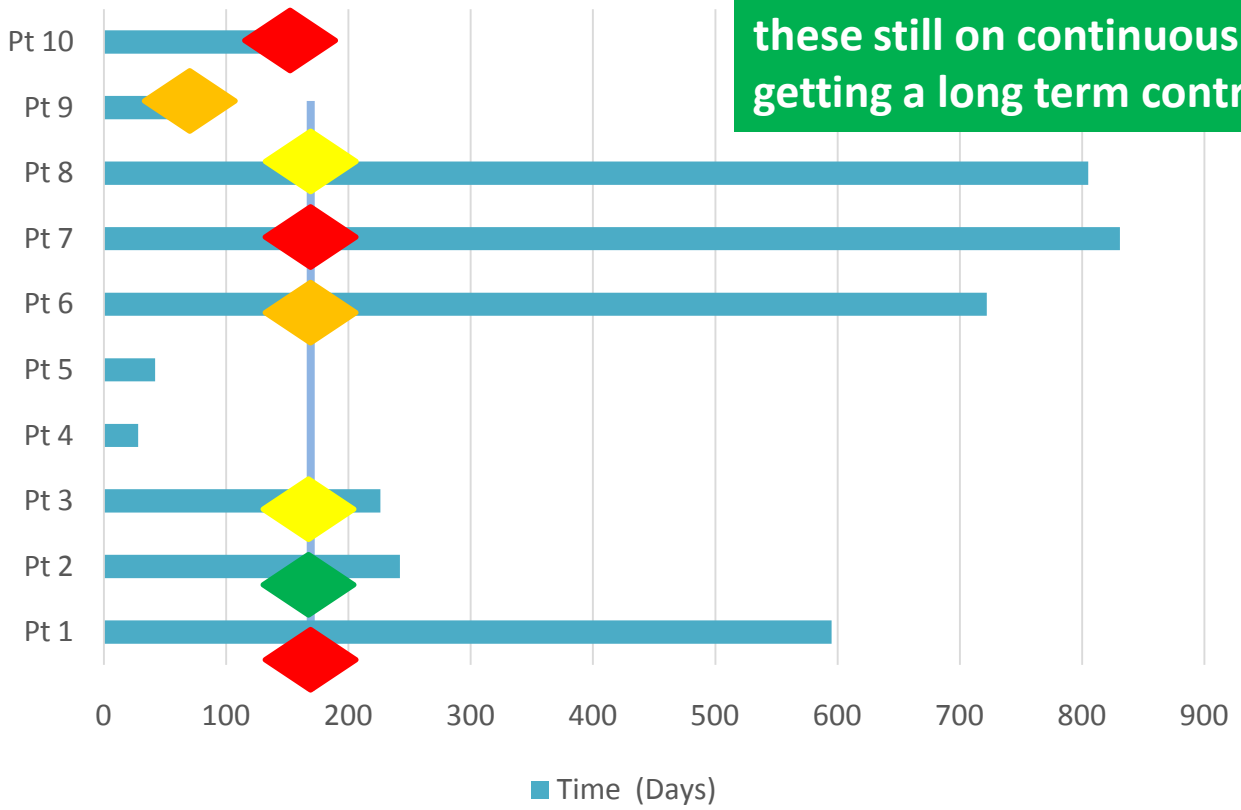
| | |
|---|---|
| Toxicity G3-4 | 10% |
| Exitus | 10% |



# NIVOLUMAB OUTCOME

**62,5% Progressive/non Responders**

**At a median time of 18 mo 60% of these still on continuous treatment getting a long term control of disease**




**PD** **RP**

**SD** **RC**

# NIVOLUMAB CONCLUSION

Rete Ematologica Pugliese

REP Real Word Experience is comparable with literature data

In our experience Nivolumab is effective and safe (also in post allogeneic SCT setting)

Predictive Biomarkers ?

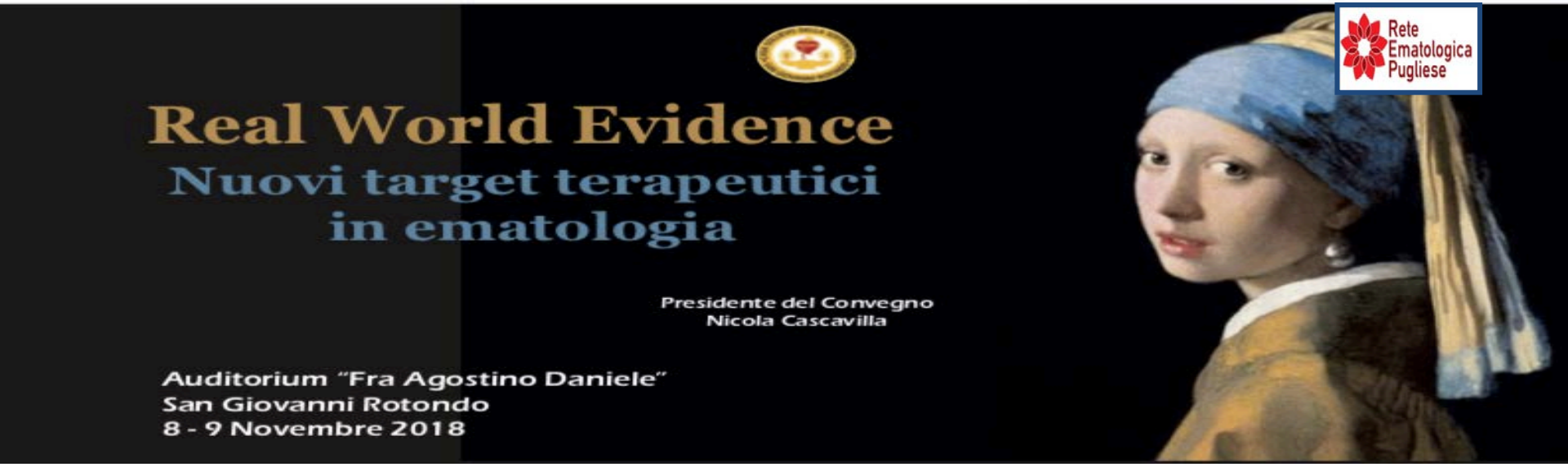
Long control of disease even in pts with sub optimal response ?

INTERMEDIATE RESPONSE: HOW DEAL IT ?

**Could they be targets for the REP?**

REP SHARING
- Salvage Therapy Strategy
- Experiences

REP Multidisciplinary CPI-TASKFORCE
to periodically review clinical cases and response assesment

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