4th MEETING ON
INNOVATIVE IMMUNOTHERAPIES
FOR LYMPHOID MALIGNANCIES

Società Italiana di Ematologia

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# The Evolving Role of Checkpoint Inhibitors: Hodgkin Lymphoma

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MILANO, STARHOTELS ROSA GRAND
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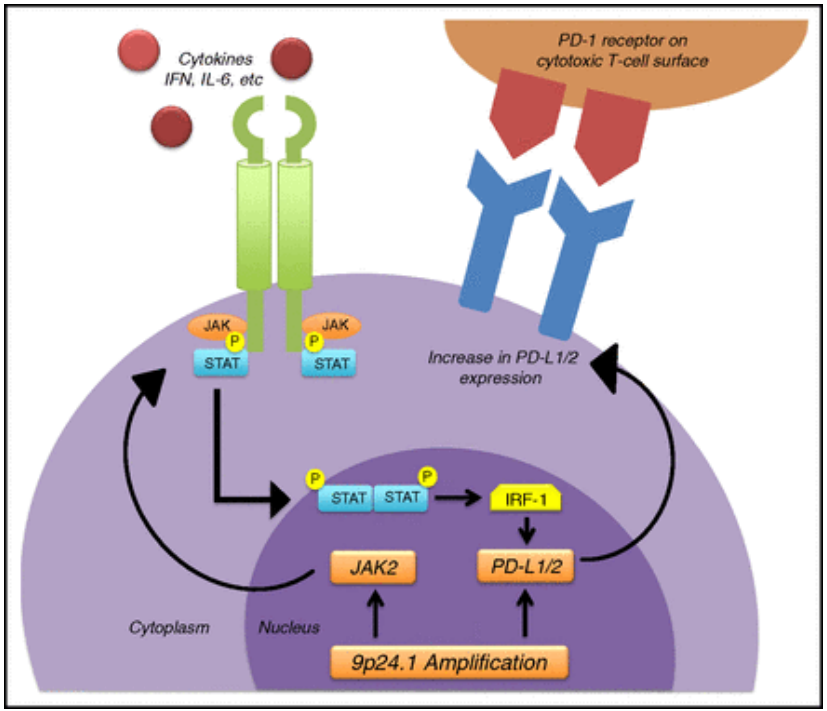
# Disclosures of Alex Herrera

| Company name | Research support | Employee | Consultant | Stockholder | Speakers bureau | Advisory board | Other |
|---|---|---|---|---|---|---|---|
| Bristol Myers Squibb | X | | x | | | | |
| Kite/Gilead | | | x | | | | |
| Incyte | | | x | | | | |
| Genentech | x | | x | | | | |
| Merck | x | | x | | | | |
| AstraZeneca | | | x | | | | |
| Pfizer | x | | x | | | | |
| Lilly | | | x | | | | |
| Genmab | | | x | | | | |
| Abbvie | | | x | | | | |
| Allogene Therapeutics | | | x | | | | |

# PD-1 in Hodgkin Lymphoma

- 9p24.1 alteration directly results in PD-L1/2 expression on RS cells
- 9p24.1 alteration increases JAK2 expression, which can induce PD-L1/2 expression on RS cells
- EBV infection induces PD-L1 expression on RS cells
- Tumor-associated macrophages express PD-L1 in the HL TME



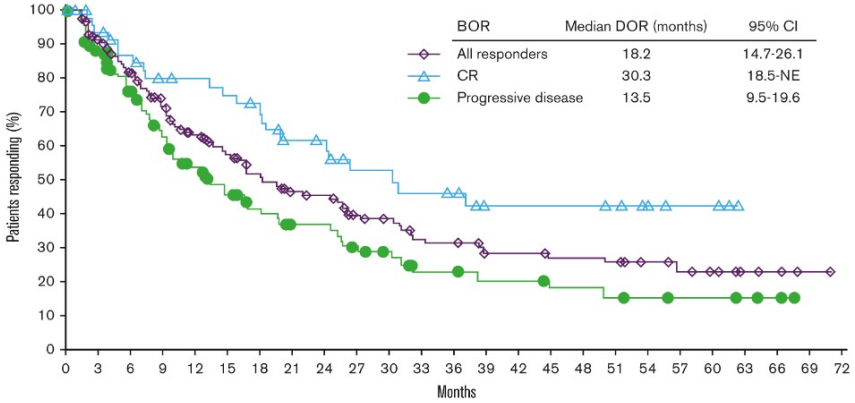

- Cabanillas F and Rivera N. Blood 2017, Green MR et al Blood 2010, Green MR et al. CCR 2012, Carey CD et al. Blood 2017

# Relapsed/Refractory cHL

# PD-1 blockade effective in R/R cHL

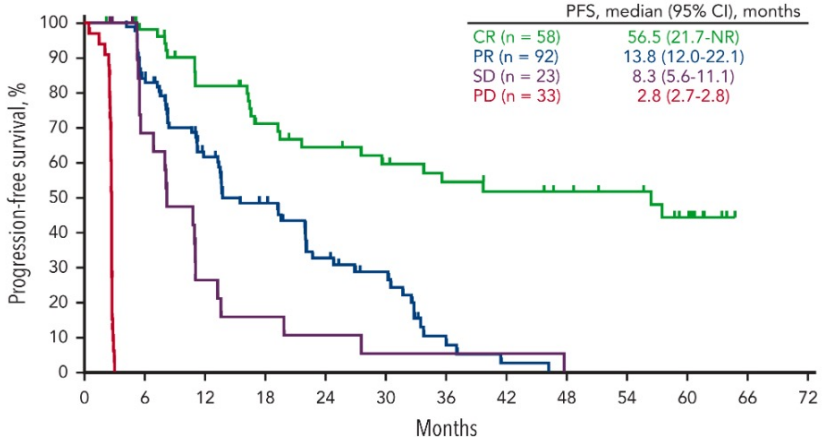
Nivolumab
Late R/R HL, pivotal Ph 2, n = 243

ORR 71%, CR 21%
All: 5y PFS 18%



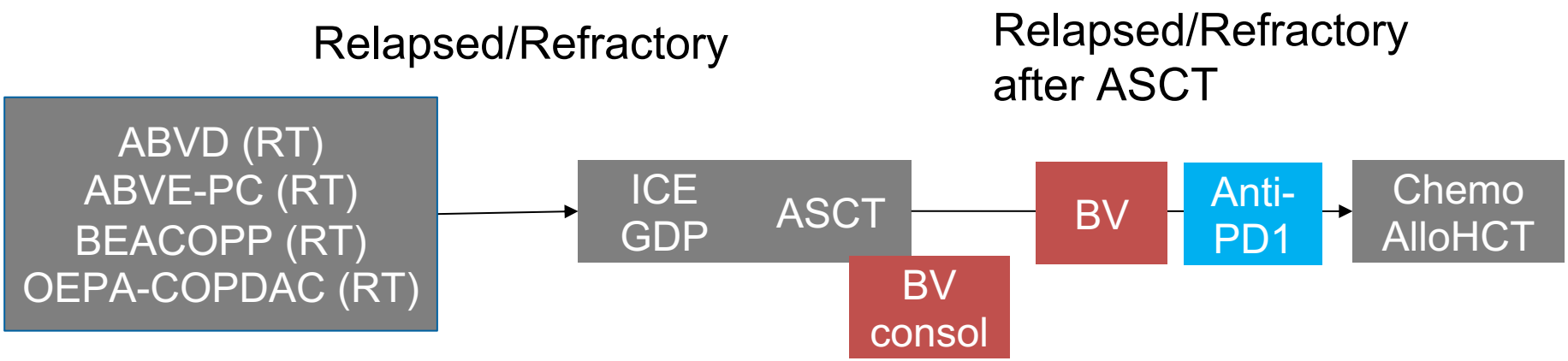

Pembrolizumab
Late R/R HL, pivotal Ph 2, n = 210

ORR 71%, CR 28%
All: 5y PFS 14%
CR: 5y PFS 44%

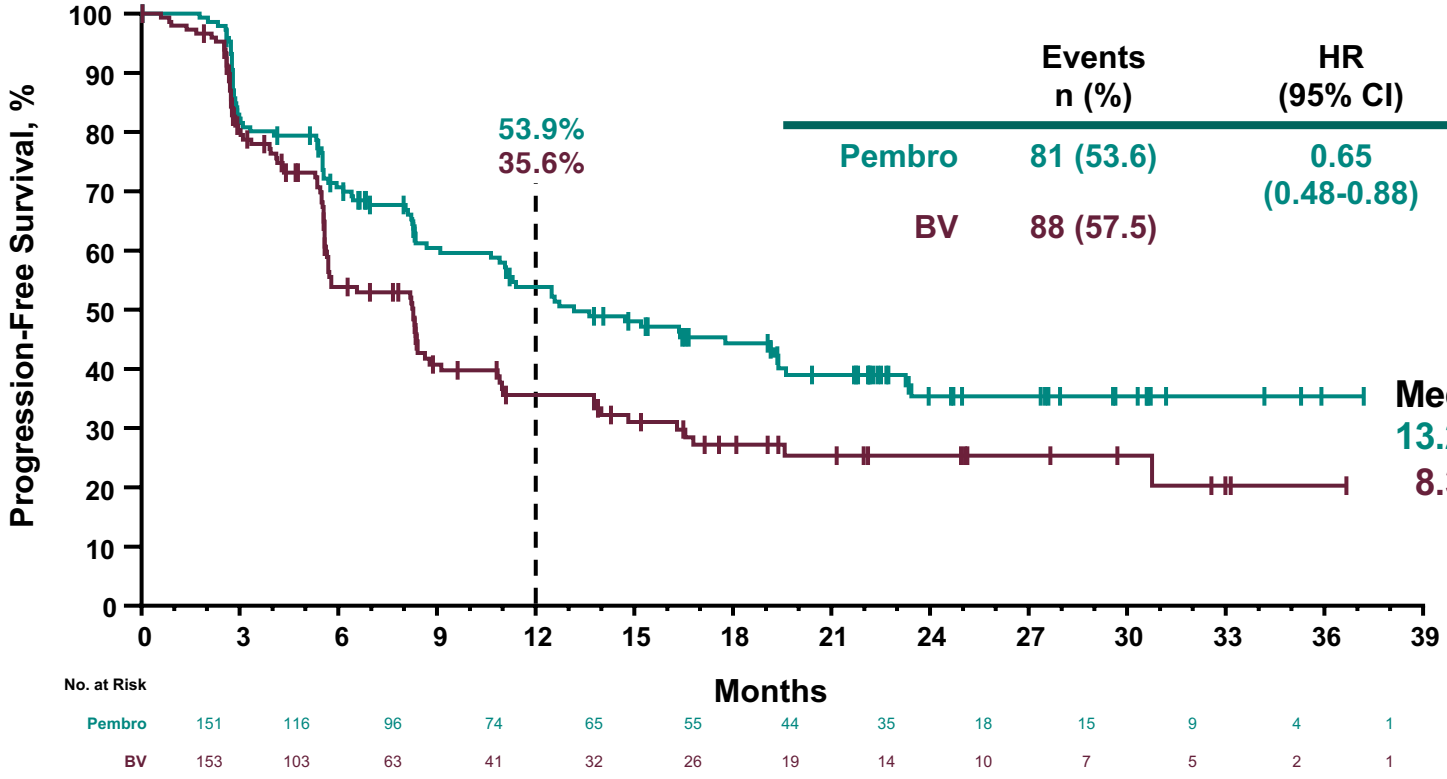



**Ansell SM et al, NEJM 2015, Armand P et al., JCO 2018, Chen R. et al, JCO 2017, Ansell SM et al Blood Adv 2023, Armand P et al, Blood 2023**

# Role of Checkpoint Inhibitiors in Hodgkin Lymphoma: 2016



# KN-204: Pembro prolongs PFS vs BV in R/R cHL



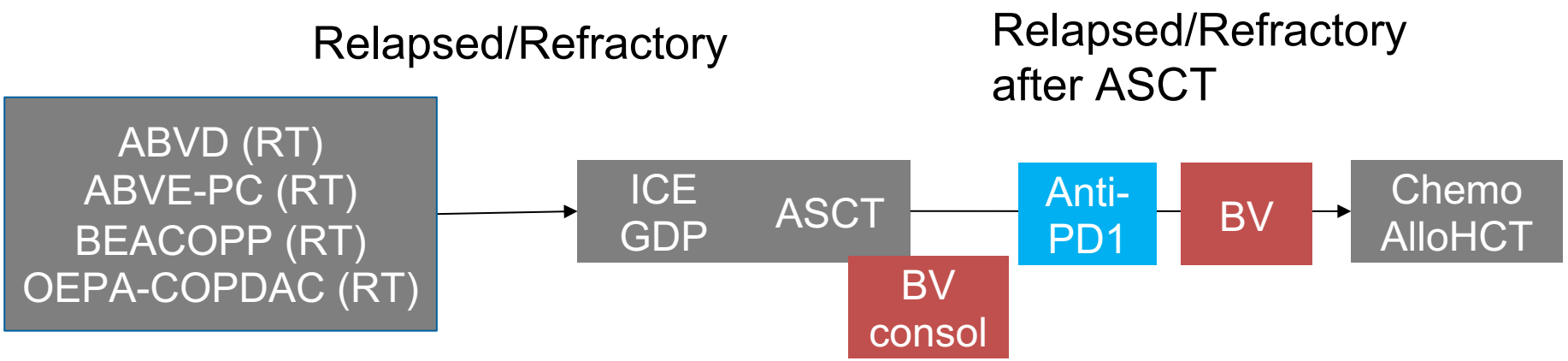

| | Events n (%) | HR (95% CI) | *P* value |
|---|---|---|---|
| Pembro | 81 (53.6) | 0.65 (0.48-0.88) | 0.00271 |
| BV | 88 (57.5) | | |

**Median (95% CI)**
13.2 mo (10.9-19.4)
8.3 mo (5.7-8.8)

Kuruvilla J et al ASCO 2020

Data cutoff: January 16, 2020.

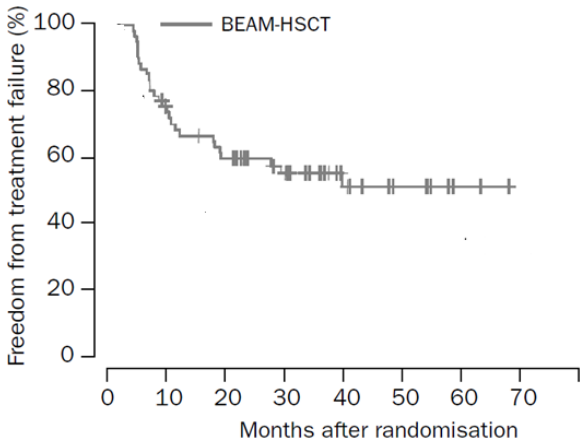
# Role of Checkpoint Inhibitiors in R/R cHL Hodgkin Lymphoma



# Historical Management of R/R cHL

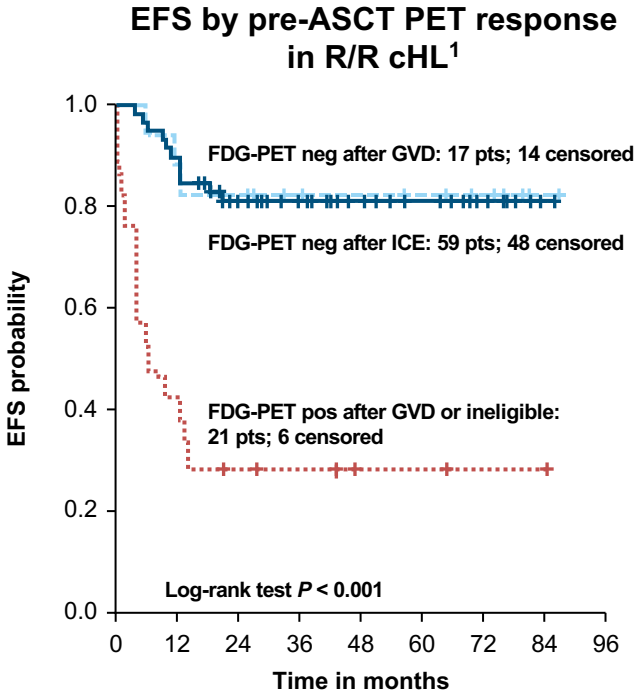
- Standard is salvage chemotherapy followed by autologous stem cell transplant (ASCT) in chemosensitive pts
- Chemotherapy-based salvage yields high ORR/CR rates but is associated with significant toxicity (i.e. hematologic)

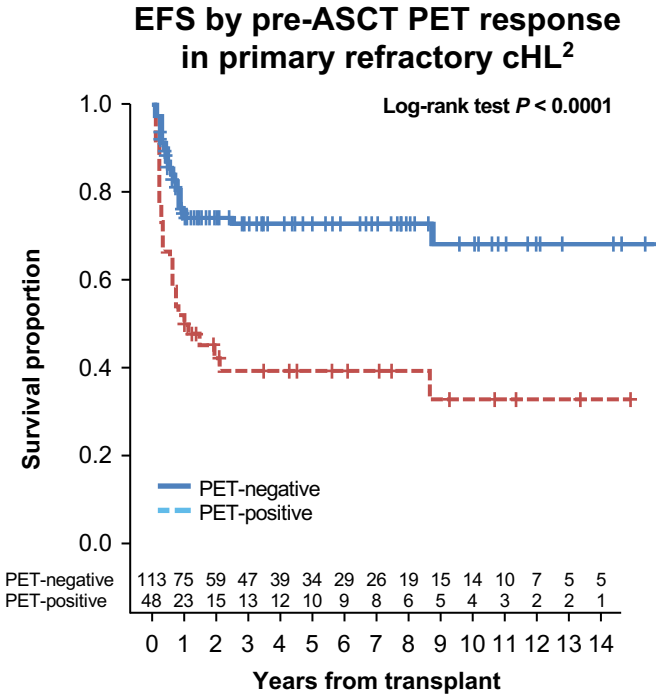
| Salvage regimen | N | ORR (%) | CR (%) CT | CR (%) PET |
|---|---|---|---|---|
| ICE/augICE | 97 | 88% | | 60% |
| DHAP | 102 | 89% | 21% | |
| GVD | 91 | 70% | 19% | |
| GDP | 23 | 70% | 17% | |
| IGEV | 91 | 81% | | 54% |
| BeGEV | 59 | 83% | | 73% |




Moskowitz CH, et al. *Blood* 2012, Bartlett NL, et al. *Ann Oncol* 2007, Baetz T, et al. *Ann Oncol* 2003
Josting A, et al. *Ann of Oncol* 2002, Santoro A, et al. *Haematologica* 2007, Santoro A et al. *J Clin Oncol* 2016

# PET Status After Salvage is Prognostic of ASCT Outcome




ASCT, autologous stem cell transplantation; cHL, classical Hodgkin lymphoma; EFS, event-free survival; FDG, [18F]-fludeoxyglucose; GVD, gemcitabine, vinorelbine, pegylated liposomal doxorubicin; ICE, ifosfamide, carboplatin, etoposide; ITT, intent-to-treat; neg, negative; PET, positron emission tomography; pos, positive; pts, patients; R/R, relapsed/refractory.

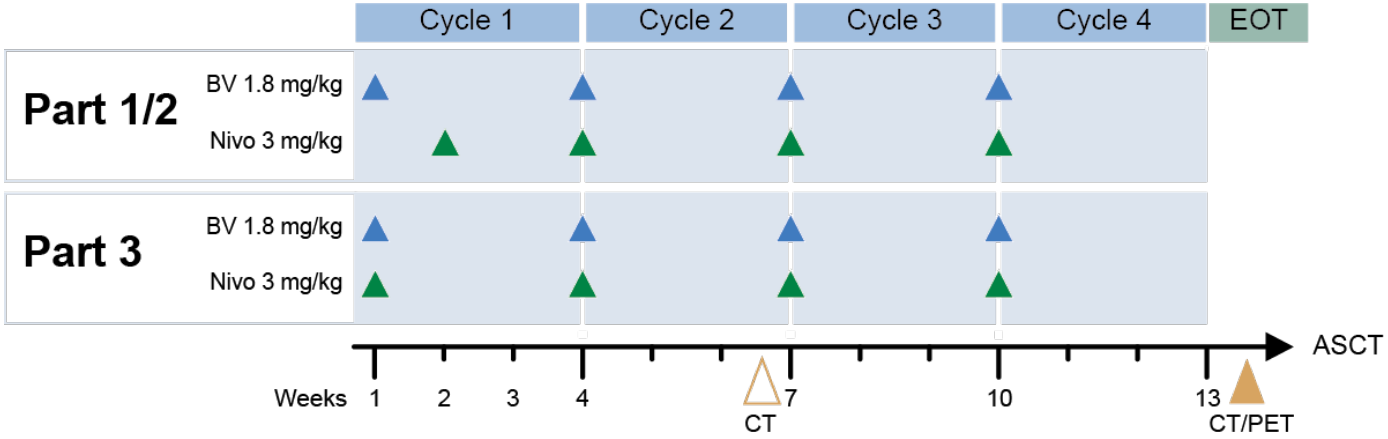
1. Moskowitz CH, et al. *Blood* 2012;119:1665–1670; 2. Shah G, et al. *Br J Haematol* 2016;175:440–447.

# BV-based salvage for transplant-eligible R/R HL

| | Regimen | % PET-neg | PFS | Reference |
|---|---|---|---|---|
| **Sequential** BV and chemo | BV->augICE | 83%<br>27% (BV alone, DS1-2) | 82% @ 3 yrs | Moskowitz AJ, et al. Blood 2017; Lancet Oncol 2015 |
| | BV->ICE and others | 75%<br>43% (BV alone, DS1-3) | 67% @ 2 yrs | Chen R, et al. BBMT 2015<br>Herrera AF, et al. Ann Oncol 2018 |
| **Combined** BV and chemo | BV-bendamustine | 74% | 62.6% @ 2 yrs<br>69.8% (ASCT pts) | LaCasce A, et al. Blood 2018 |
| | BV plus:<br>ICE<br>DHAP<br>ESHAP | <br>69%<br>79%<br>70% | <br>69% @ 1 yr<br>76% @ 2 yrs<br>71% @ 2.5 yrs | Stamatoullas, et al. ASH 2019<br>Hagenbeek, et al. Haematologica 2020<br>Garcia-Sanz, et al. Ann Oncol 2019 |

# BV + Nivolumab as 1st salvage for R/R cHL

- 93 adult patients with relapsed or refractory cHL following 1 line of therapy



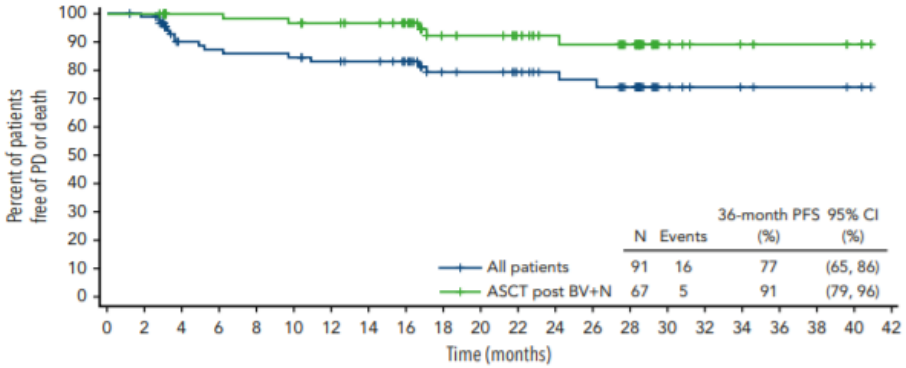

- Exclusion criteria included prior salvage therapy for r/r cHL, BV treatment, immuno-oncology therapy (PD-1, CTLA4, or CD137 pathways), or allogeneic or autologous stem cell transplant (ASCT)

**Herrera AF et al. Blood 2018**
**Advani RH….Herrera AF. Blood 2021**

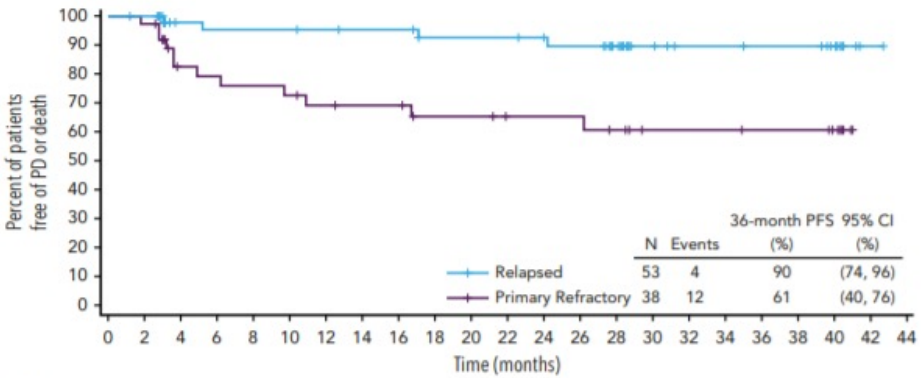
# BV+Nivo as first salvage therapy for R/R HL

**85% ORR, 67% CR** among all treated patients (n=91)

**3y PFS**
All pts 77% vs **91% BV+N only**




**3y PFS**
Relapse 90% vs **61% 1º refractory**



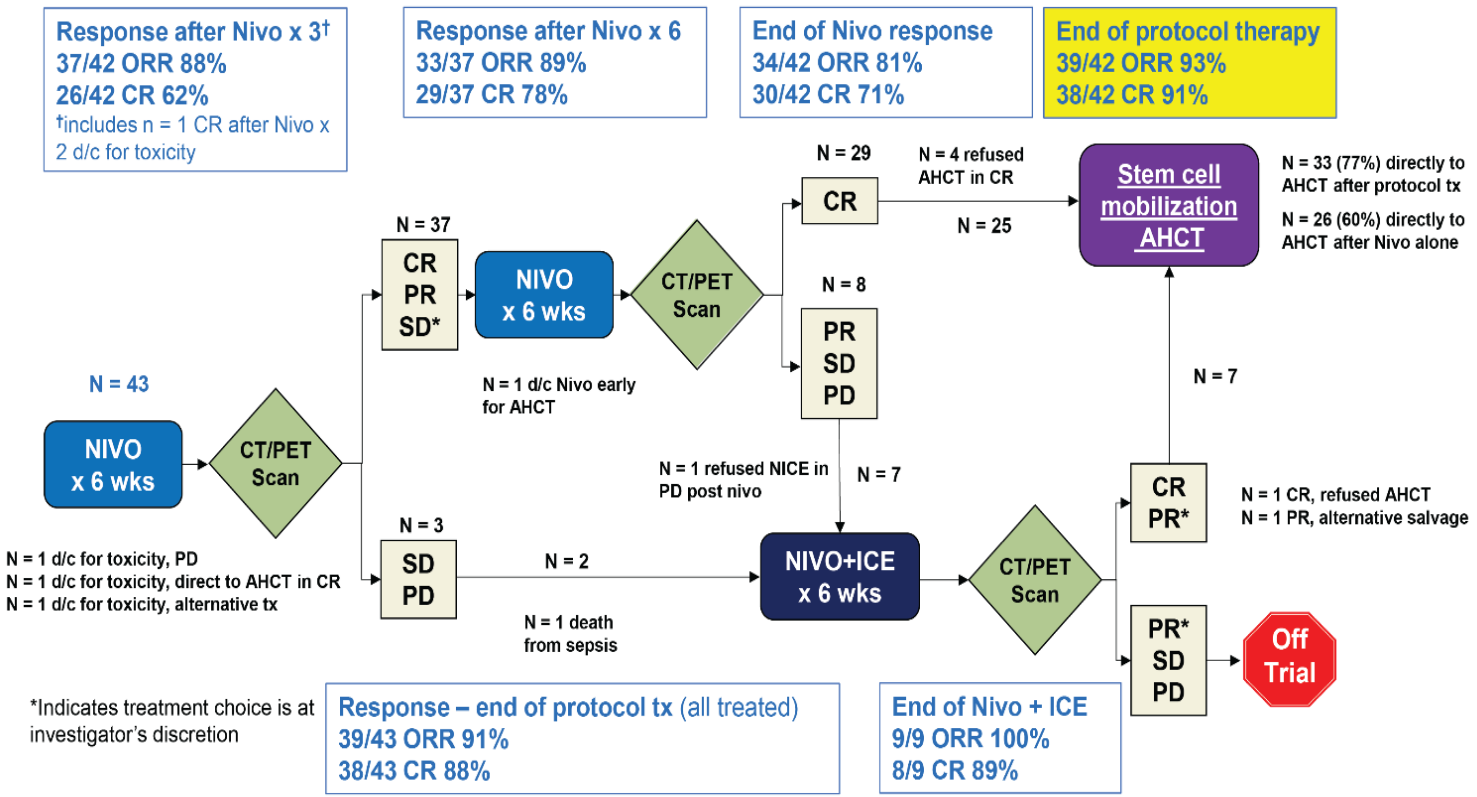

Herrera AF et al. Blood 2018
Advani RH, Herrera AF. Blood 2021

# Studying anti-PD1 salvage independent of BV

- Nivolumab (Nivo) as part of BV+Nivo salvage was a tolerable, fully outpatient regimen with high response rates and excellent post-AHCT PFS
  - Frontline approval of BV → role of BV-based salvage unclear
- Important to study PD-1 blockade in the salvage setting separate from BV
- Goal: evaluate sequential Nivo-first salvage strategy
  - Evaluate Nivo+ICE in pts not in CR with Nivo alone

# Cohort A: PET adapted Nivo/N-ICE

**Figure 1**



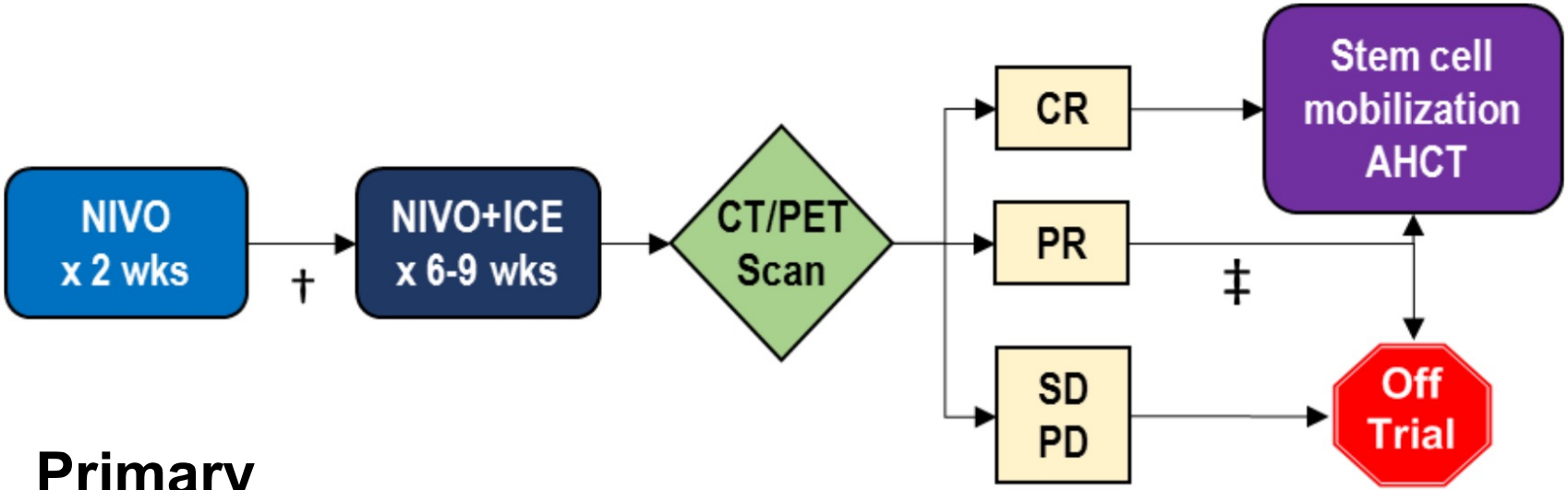

Mei MG,…Herrera AF. *Blood*. 2022

# NICE Cohort B targets highest risk R/R HL patients

- Cohort B additional Inclusion Criteria (most have at least one of the following):
  - Primary refractory disease
  - Relapsed < 1 year after completion of frontline therapy
  - B symptoms at relapse
  - Extranodal disease at relapse
  - Have received brentuximab vedotin as initial therapy

- Initial objective was to further evaluate the safety of Nivo+ICE
  - Only n=9 received Nivo+ICE in Cohort A

# NICE Cohort B Schema



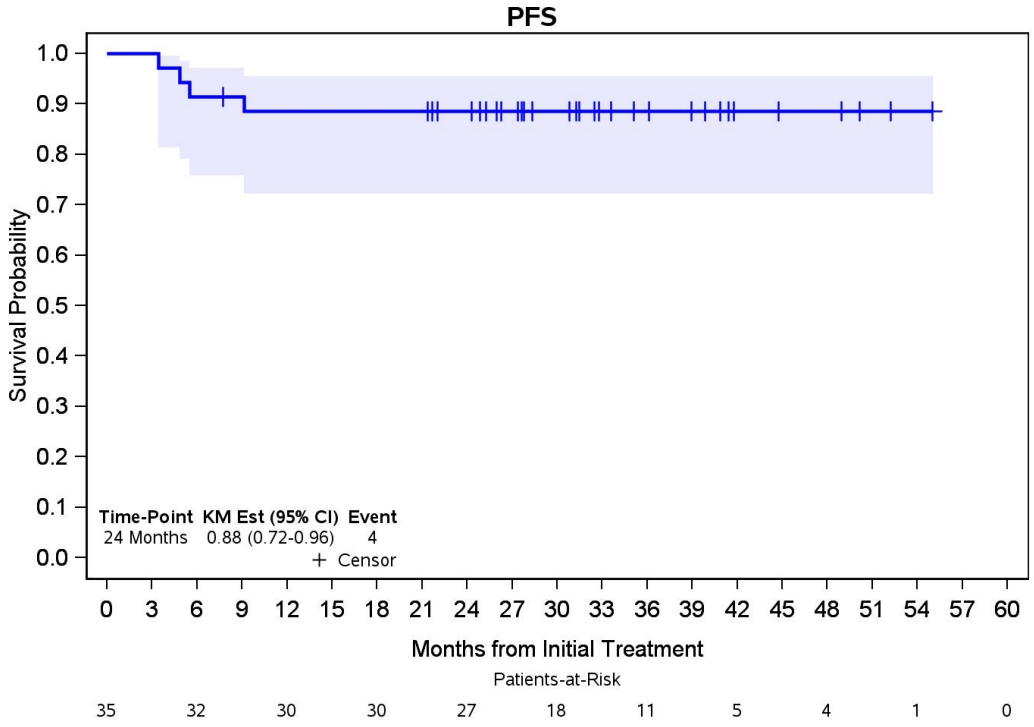

**Primary endpoint: CR**

# Cohort B: Nivo+ICE in High-Risk R/R cHL

**ORR 100%**
CR 89%, PR 11%

2y PFS: 88%
2y OS: 100%
2y Post-HCT PFS: 94%

- No impact of primary refractory vs relapse





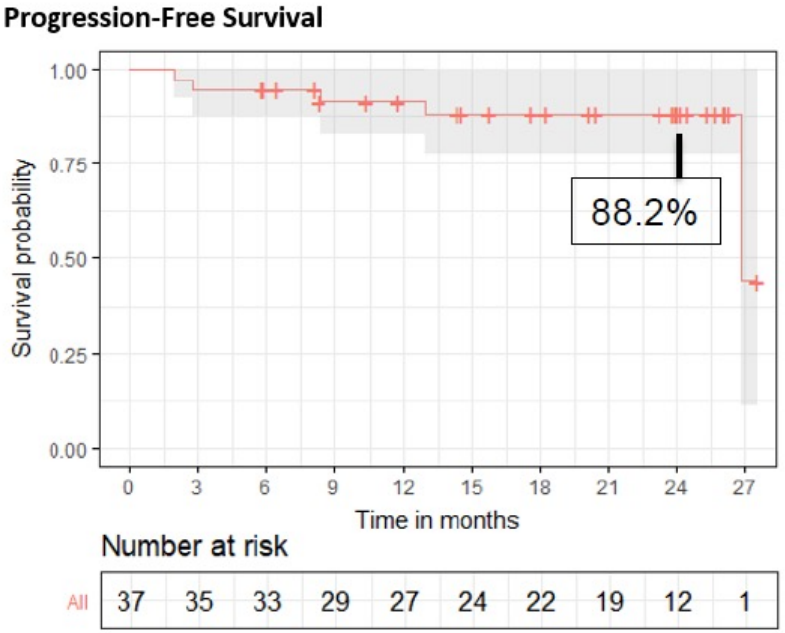

Mei MG…Herrera AF. *Hemasphere 2025*

# Pembro+ICE in R/R cHL

n=37

- **86.5% CR**
- 5/37 received a 3rd cycle of PEM+ICE
- 95% underwent Auto-HCT

| Safety and Tolerability (n = 42) | n | (%) |
|---|---|---|
| Grade 3-4 Hematologic Toxicity | | |
| Thrombocytopenia | 39 | (93) |
| Anemia | 32 | (76) |
| Febrile Neutropenia | 12 | (29) |
| Grade 3-4 Non-hematologic Toxicity | | |
| Hypokalemia | 15 | (36) |
| Hypophosphatemia | 11 | (26) |
| Oral Mucositis | 10 | (24) |
| Attribution to PEM | | |
| PEM-related Autoimmune Events | 1* | |

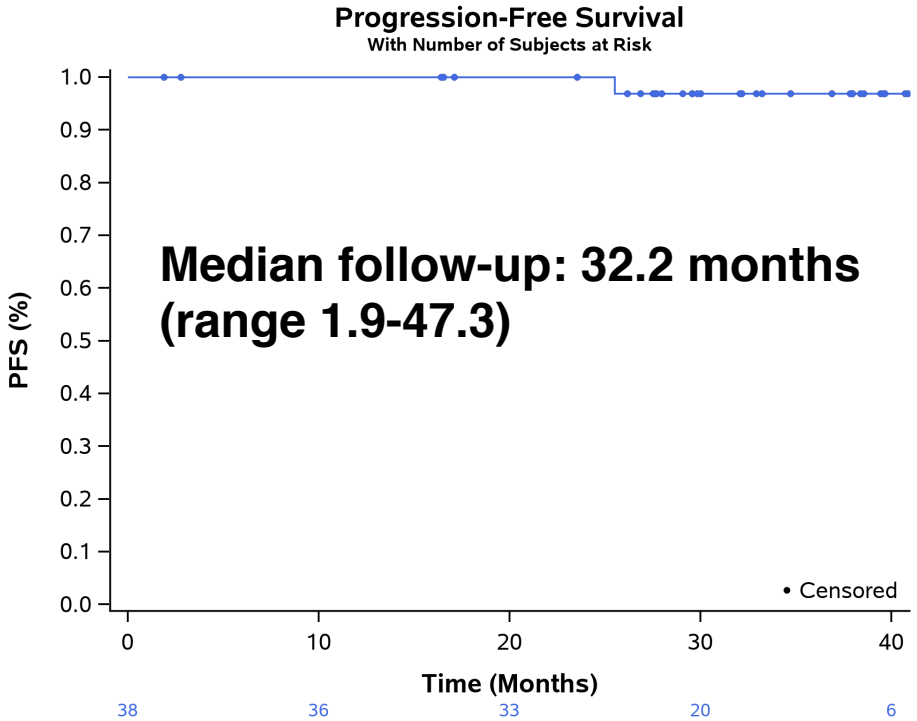



| Grade 5 Toxicities |
|---|
| Cardiac arrest during stem cell collection |
| *ARDS following autoSCT – engraftment syndrome |

Locke BJ et al. *JAMA*

# Pembro+GVD as 1st salvage therapy for R/R HL

- 38 evaluable patients
- ORR: 100%
- CR: 95% (92% after 2 cycles)
- 36 pts proceeded to ASCT
- 1 relapse, 1 death (unrelated)
- 30 month PFS: 96%

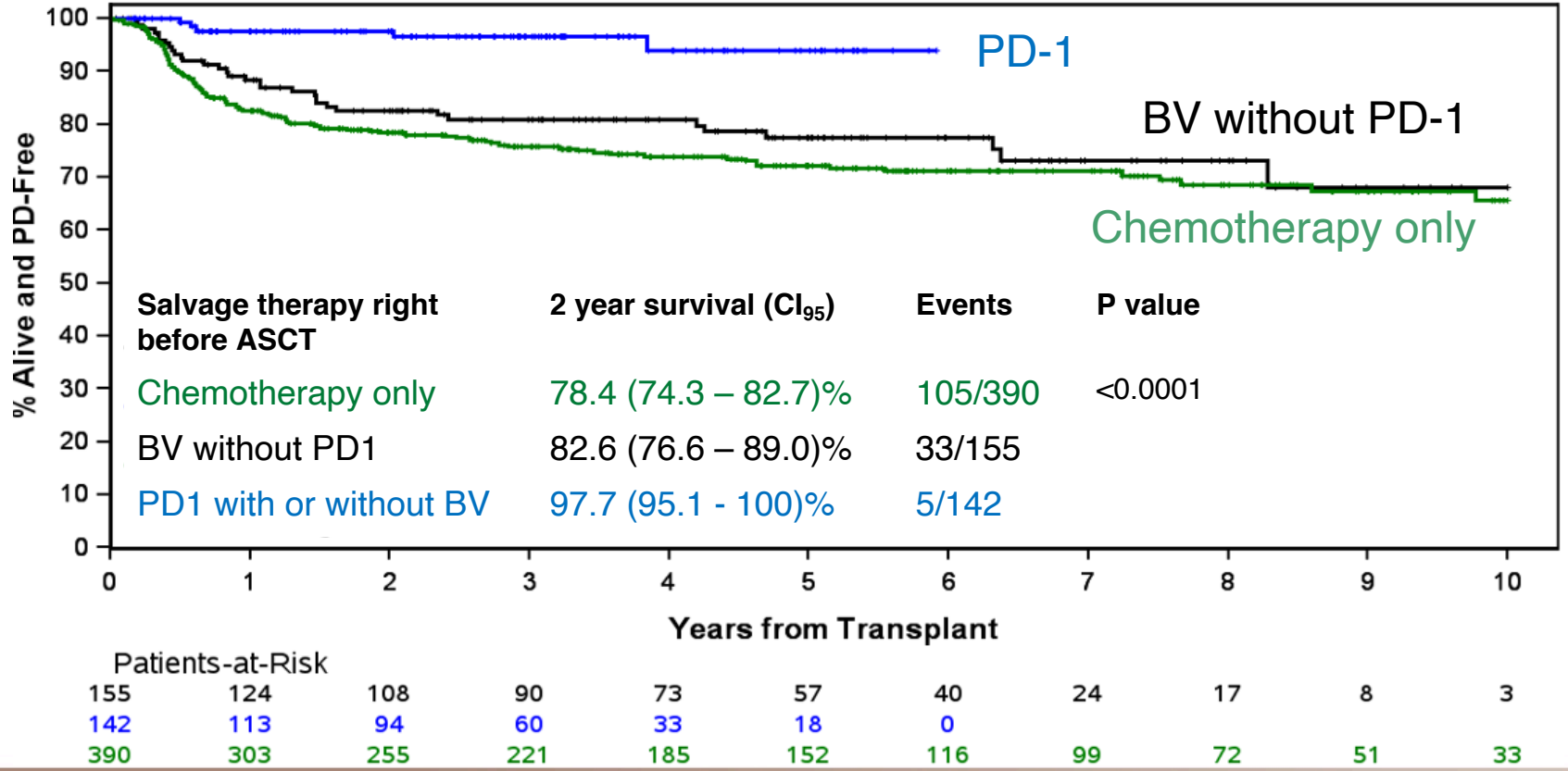



**Moskowitz A et al. *ISHL* 2022** Data cut off: 10/6/2022

# Novel Salvage Regimens for R/R cHL

| | Regimen | % PET-neg | PFS | Reference |
|---|---|---|---|---|
| **Sequential** BV and chemo | BV->augICE | 83%<br>27%(DS1-2) | 82% @ 3 yrs | Moskowitz AJ, et al. Blood 2017; Lancet Oncol 2015 |
| | BV->ICE/chemo | 75%<br>43%(DS1-3) | 67% @ 2 yrs | Chen R, et al. BBMT 2015<br>Herrera AF, et al. Ann Oncol 2018 |
| **BV Combos** | BV-benda | 74% | 62.6% @ 2 yrs<br>69.8% (ASCT) | LaCasce A, et al. Blood 2018 |
| | BV plus: ICE<br>DHAP<br>ESHAP | 74%<br>79%<br>70% | 80% @ 2 yrs<br>76% @ 2 yrs<br>71% @ 2.5 yrs | Lynch R, et al. Lancet Haematology 2021<br>Hagenbeek, et al. Haematologica 2020<br>Garcia-Sanz, et al. Ann Oncol 2019 |
| **BV+Nivo** | BV+Nivo | 67% | 77% @ 3 yrs | Advani RH, et al. Blood 2021, Herrera AF et al. Blood 2018 |
| **Sequential** PD1/chemo | Nivo->NICE | 91% | 72% @ 2 yrs | Mei MG, et al. Blood 2022 |
| **Anti-PD1 + Chemo** | Pem+GVD<br>Pem+ICE<br>Nivo+ICE<br>Tisle+GemOx | 95%<br>86.5%<br>86%<br>97% | 100% @ 13.5m<br>88% @ 2 yrs<br>88% @ 2yr<br>96% @ 1yr | Moskowitz AJ, et al. JCO 2020<br>Bryan LJ, et al. JAMA Oncology 2023<br>Mei MG, et al. Hemasphere 2025<br>Ding K, et al. Haematologica 2023 |

# CPI salvage improves post-ASCT PFS even among CR pts



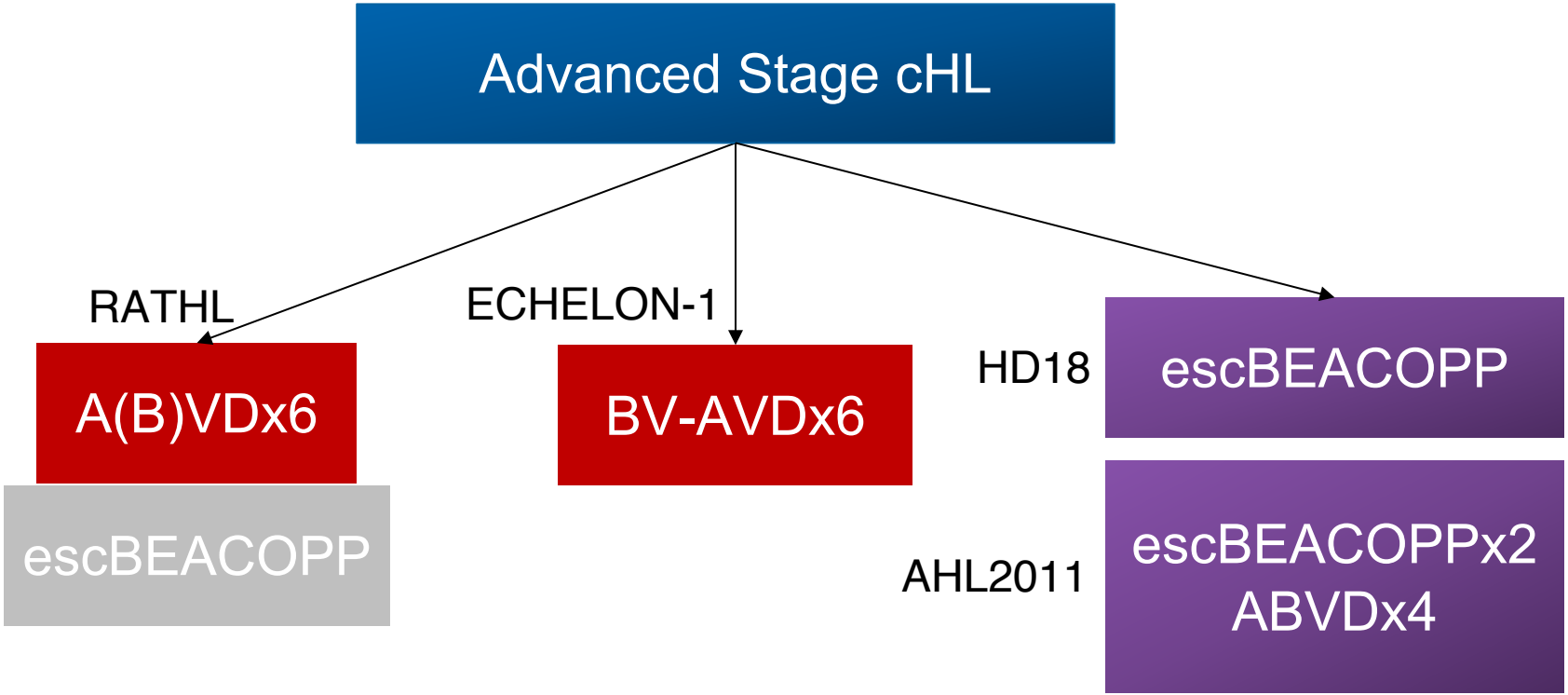

| Salvage therapy right before ASCT | 2 year survival ($CI_{95}$) | Events | P value |
|---|---|---|---|
| Chemotherapy only | 78.4 (74.3 – 82.7)% | 105/390 | <0.0001 |
| BV without PD1 | 82.6 (76.6 – 89.0)% | 33/155 | |
| PD1 with or without BV | 97.7 (95.1 - 100)% | 5/142 | |



Desai S. et al Blood 2025

# Frontline Therapy
# Advanced Stage cHL

# Standard Management of Advanced Stage cHL

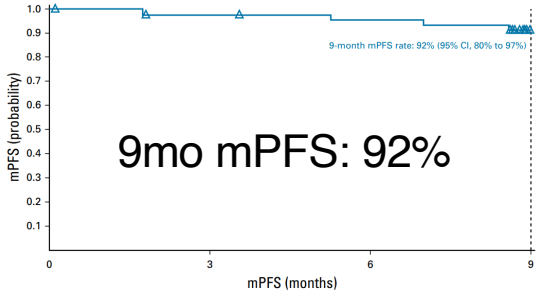



Ansell SM, et al. NEJM 2022, Borchmann P et al. Lancet 2018, Casasnovas O et al. *Lancet Oncol* 2019, Johnson P et al. NEJM 2016

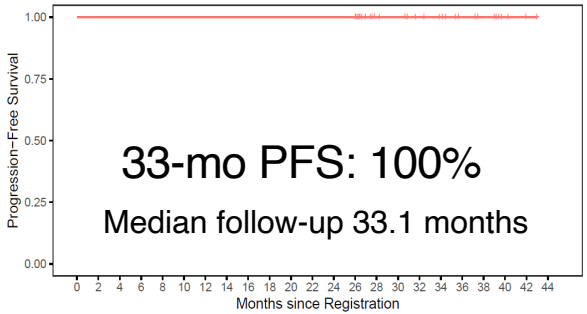
# PD-1 blockade in advanced stage cHL safe and effective

- Studies of frontline PD-1 blockade in cHL have been promising[10,11,12,13]
  - N-AVD well-tolerated
  - Excellent PFS

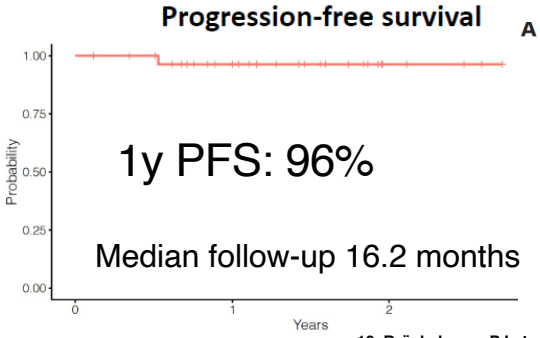
**1L Nivolumab-AVD in advanced stage cHL**



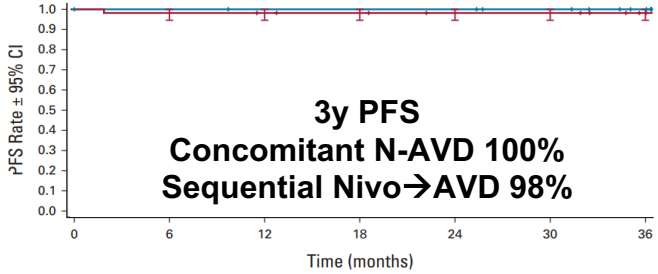

**Sequential Pembro-AVD in cHL**




**Concurrent Pembro-AVD in cHL**

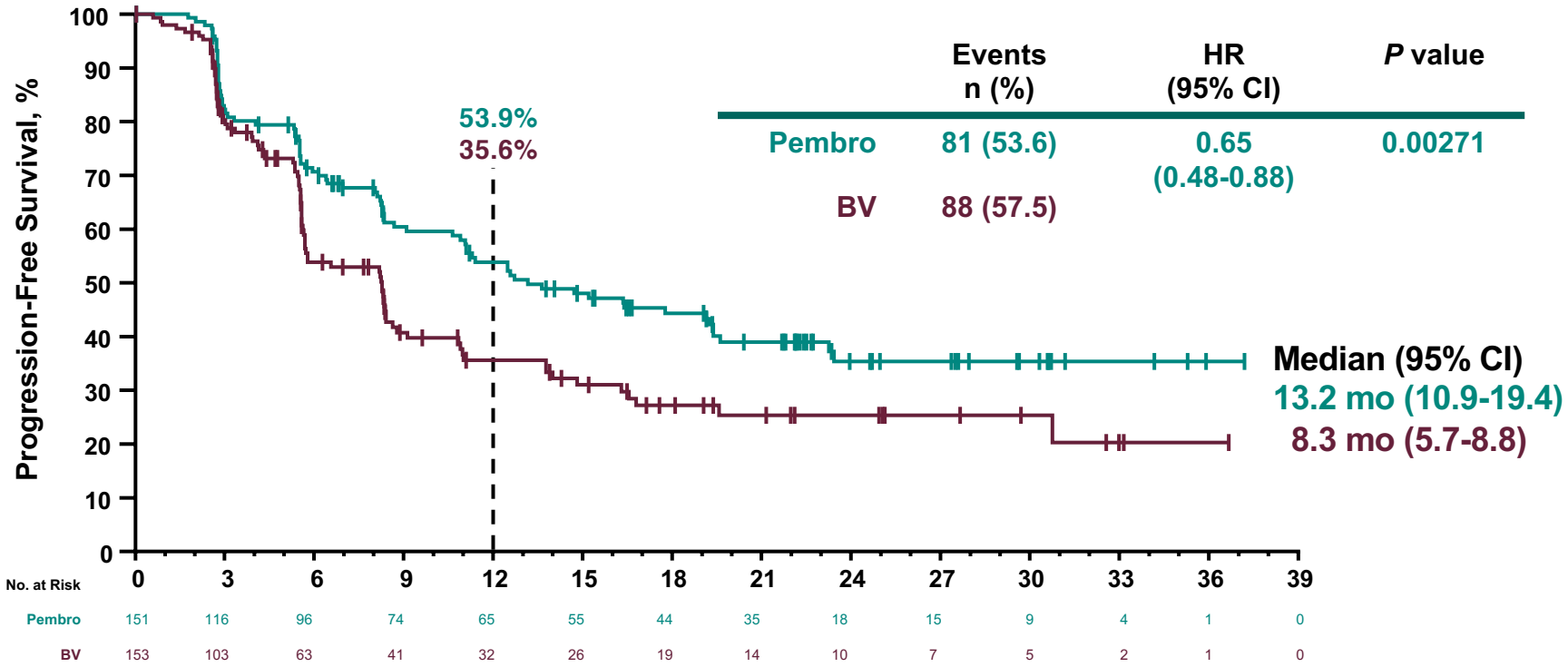



**1L Nivolumab-AVD in early stage cHL**



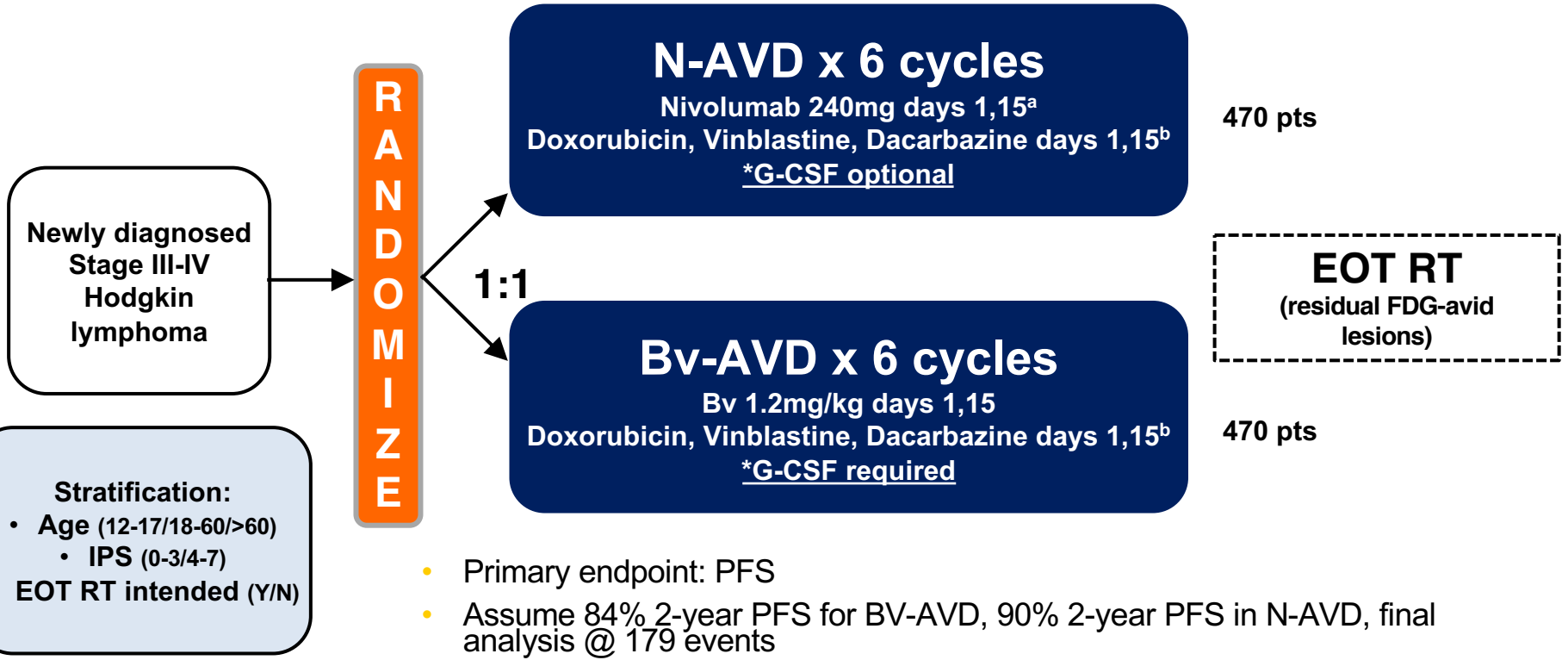

10. Bröckelmann PJ et al JCO. 2023 11. Ramchandren R et al JCO 2019 12. Allen PB, et al Blood. 2021 13. Lynch RC e

# PD-1 superior to BV in R/R HL…




Kuruvilla J et al ASCO 2020, Lancet Oncol 2021

# S1826 evaluates 1L CPI vs BV




- Primary endpoint: PFS
- Assume 84% 2-year PFS for BV-AVD, 90% 2-year PFS in N-AVD, final analysis @ 179 events

Herrera, AF et al. ASCO 2023.

[a] Nivolumab 3mg/kg for ages ≤ 17, max 240mg
[b] Conventional doses of AVD: Stephens DM et al Blood 2019, Ansell SM et al NEJM 2022

# S1826 Baseline Characteristics

| Baseline characteristics | N-AVD n=487 N (%) | Bv-AVD n=483 N (%) |
|---|---|---|
| Age, median (range) | 27 (12-83) | 26 (12-81) |
| 12-17 years | 118 (24%) | 118 (24%) |
| 18-60 years | 321 (66%) | 318 (66%) |
| ≥ 61 years | 48 (10%) | 47 (10%) |
| Female Sex | 216 (44%) | 210 (43%) |
| Race | | |
| White | 372 (76%) | 361 (75%) |
| Black | 58 (12%) | 56 (12%) |
| Asian | 11 (2%) | 17 (4%) |
| Other/Unknown | 46 (9%) | 49 (10%) |
| Hispanic | 66 (14%) | 58 (12%) |

| Baseline characteristics | N-AVD n=487 N (%) | Bv-AVD n=483 N (%) |
|---|---|---|
| Stage | | |
| III | 185 (38%) | 168 (35%) |
| IV | 302 (62%) | 315 (65%) |
| B symptoms present | 288 (59%) | 273 (57%) |
| IPS Score | | |
| 0-3 | 332 (68%) | 328 (68%) |
| 4-7 | 155 (32%) | 155 (32%) |
| Bulky disease > 10cm | 156 (32%) | 127 (26%) |
| HIV+ | 11 (2%) | 5 (1%) |

**Representative study, inclusive of high-risk pts**

Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138.

# N-AVD better tolerated than BV-AVD

| | Received G-CSF | Gr ≥ 3 neutropenia | Febrile neutropenia | Gr ≥ 3 infections, infestations | Sepsis | Bone pain |
|---|---|---|---|---|---|---|
| N-AVD (n = 482) | 56% | 48% | 6% | 5% | 2% | 8% |
| BV-AVD (n = 476) | 97% | 26% | 7% | 7% | 3% | 20% |

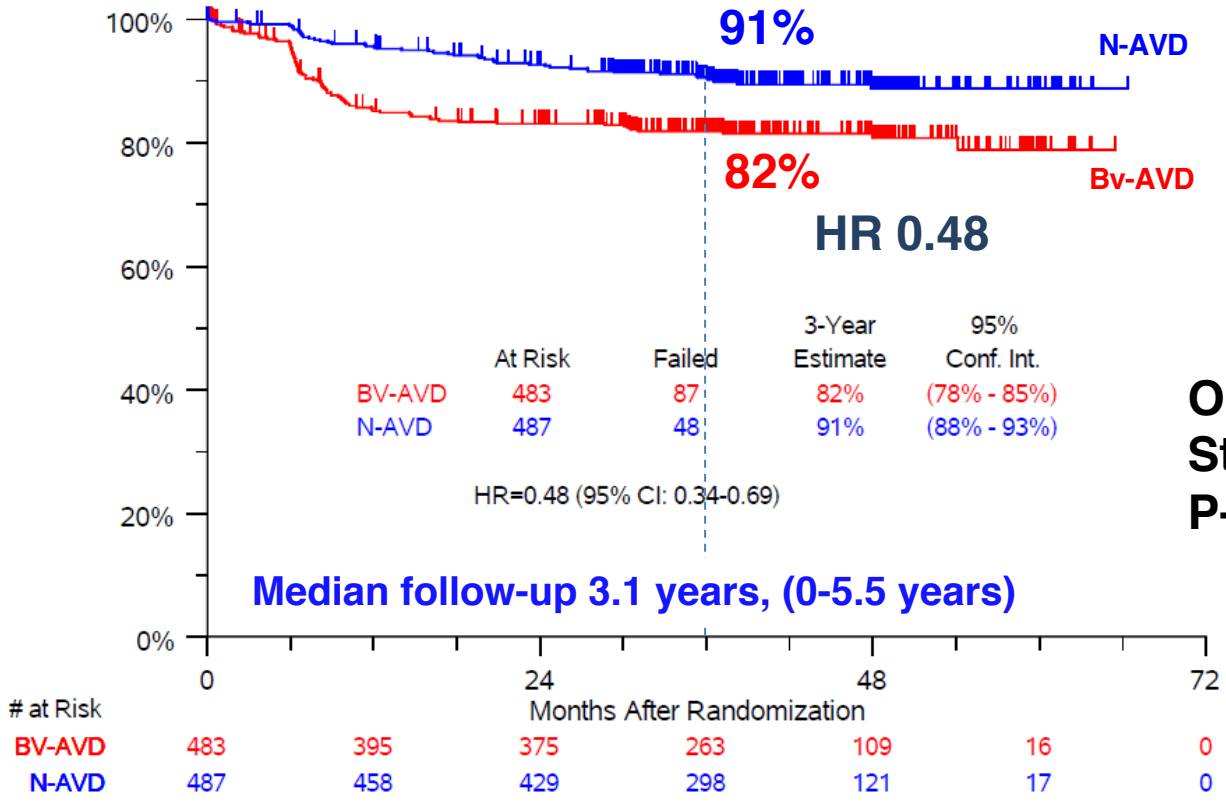
| | Peripheral sensory Neuropathy All Gr/Gr 2+ | Peripheral motor neuropathy All Gr/Gr 2+ | Thyroid dysfunction | ALT increased | Pneumonitis | Colitis |
|---|---|---|---|---|---|---|
| N-AVD (n = 482) | 29%/9% | 4%/1% | 10% | 33% | 2% | 1% |
| BV-AVD (n = 476) | 56%/32% | 7%/5% | 1% | 42% | 3% | 1% |

Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138.

# Treatment Discontinuation and Deaths

| Disposition | N-AVD (n=487) N (%) | Bv-AVD (n=483) N (%) |
|---|---|---|
| Completed treatment | 450 (92.4%) | 425 (88%) |
| **Discontinued all treatment early** | **37 (7.6%)** | **58 (12%)** |
| Adverse event | 20 (4.1%) | 20 (4.1%) |
| Refusal unrelated to AE | 9 | 13 |
| **Progression/relapse** | **0 (0%)** | **9 (1.9%)** |
| **Death on treatment** | **3 (0.6%)** | **8 (1.7%)** |
| Other – not protocol specified | 5 | 8 |
| **Any discontinuation Bv or Nivolumab** | **46 (9.4%)** | **107 (22.2%)** |
| **Dose reduction** | **NA** | **129 (26.7%)** |
| **Received radiotherapy** | **3 (0.6%)** | **4 (0.8%)** |

# N-AVD improves PFS compared to Bv-AVD



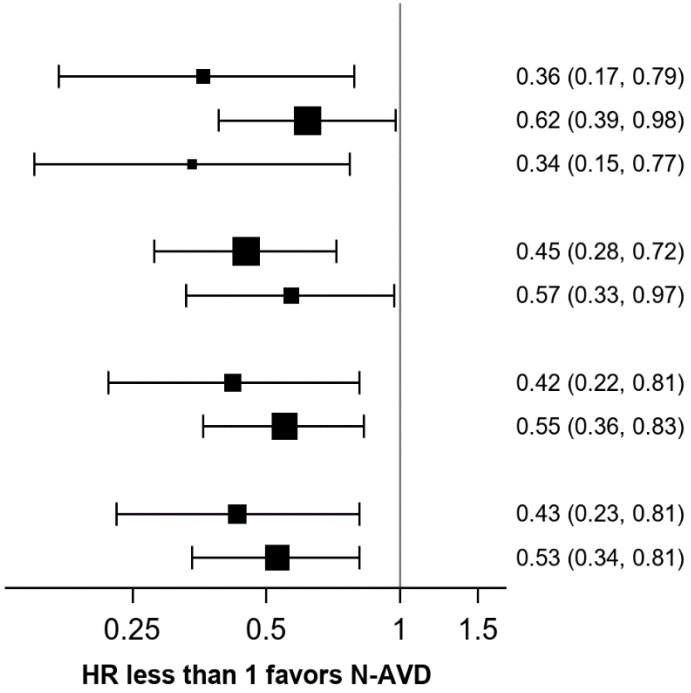

**3-year PFS**
**N-AVD 91%**
**Bv-AVD 82%**

**One-sided**
**Stratified Log-rank**
**P-value < .0001**

Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025

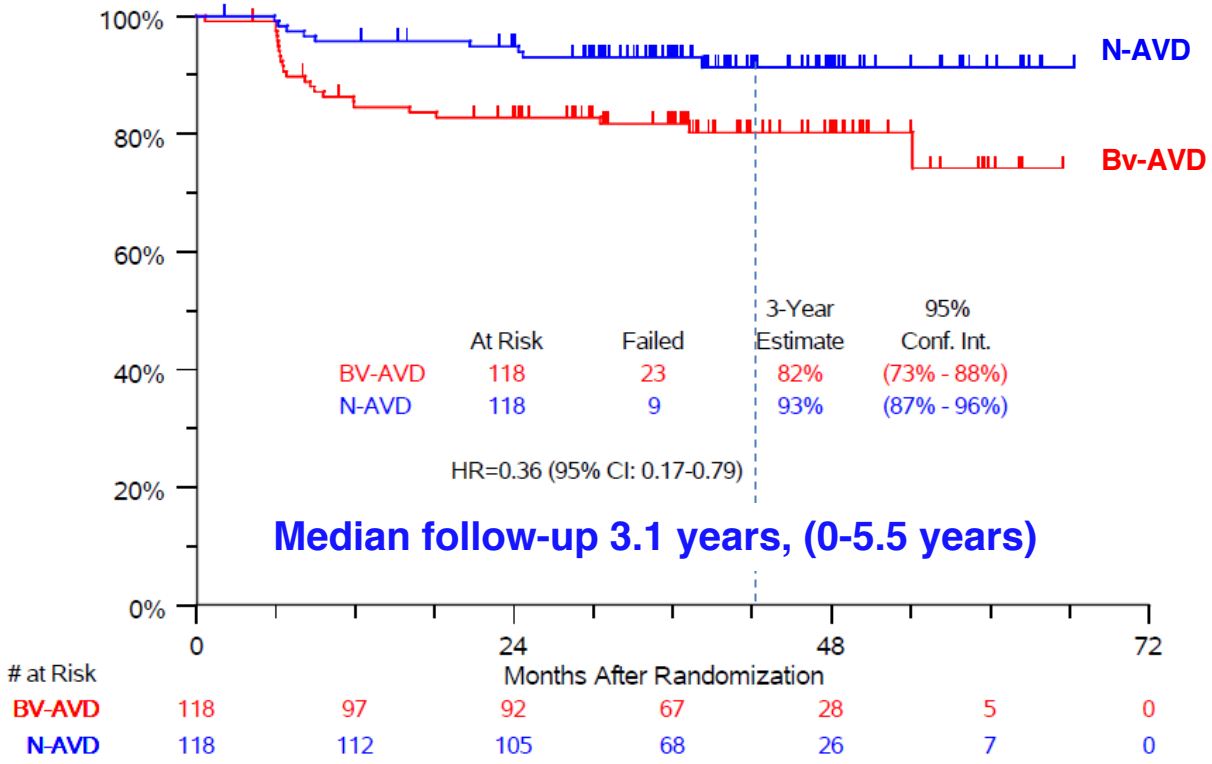
# PFS benefit consistent across subgroups

| Subgroup | N + AVD Events/N (%) | BV + AVD Events/N (%) | Hazard Ratio for Disease Progression or Death (95% CI) |
|---|---|---|---|
| **Age** | | | |
| 12 - 17 y | 9/118 ( 7.6) | 23/118 (19.5) | 0.36 (0.17, 0.79) |
| 18 - 60 y | 31/321 ( 9.7) | 46/318 (14.5) | 0.62 (0.39, 0.98) |
| > 60 y | 8/48 (16.7) | 18/47 (38.3) | 0.34 (0.15, 0.77) |
| **IPS** | | | |
| 0 - 3 | 26/331 ( 7.9) | 53/328 (16.2) | 0.45 (0.28, 0.72) |
| 4 - 7 | 22/156 (14.1) | 34/155 (21.9) | 0.57 (0.33, 0.97) |
| **Stage** | | | |
| III | 13/184 ( 7.1) | 26/168 (15.5) | 0.42 (0.22, 0.81) |
| IV | 35/303 (11.6) | 61/315 (19.4) | 0.55 (0.36, 0.83) |
| **Symptoms** | | | |
| A | 14/199 ( 7.0) | 32/210 (15.2) | 0.43 (0.23, 0.81) |
| B | 34/288 (11.8) | 55/273 (20.1) | 0.53 (0.34, 0.81) |




Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025

# N-AVD prolongs PFS in adolescents

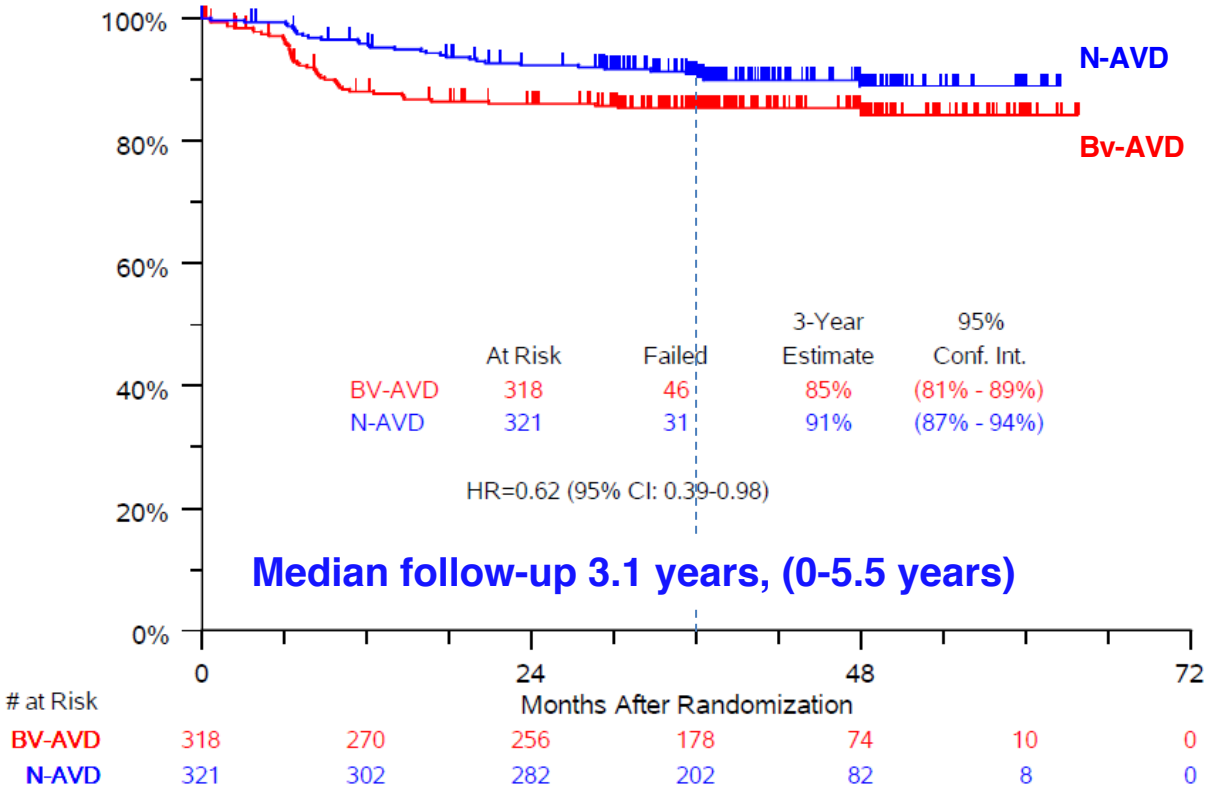



**3-year PFS**
**N-AVD 93%**
**Bv-AVD 82%**

One-sided Stratified Log-rank P-value = .004

**Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025**

# N-AVD prolongs PFS in 18-60 year-old adults

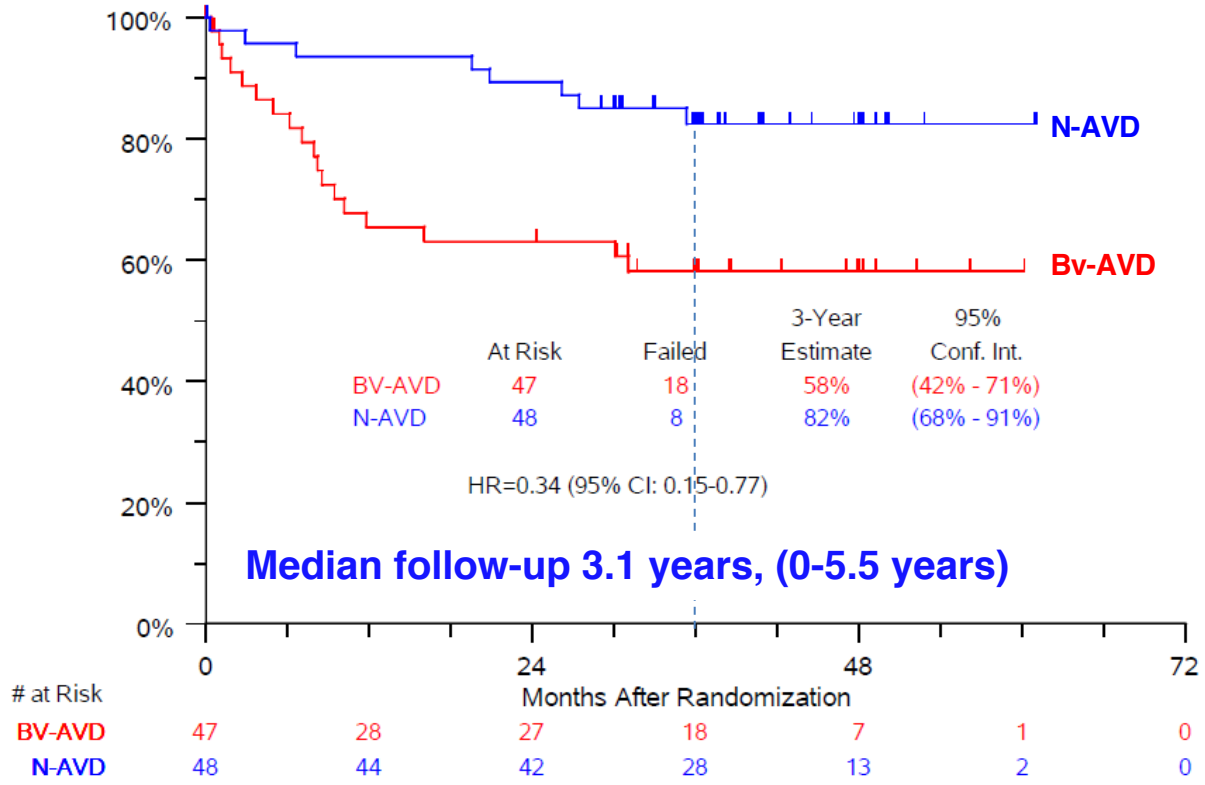



**3-year PFS**
**N-AVD 91%**
**Bv-AVD 85%**

One-sided Stratified Log-rank P-value = .015

**Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025**

# N-AVD prolongs PFS in older adults

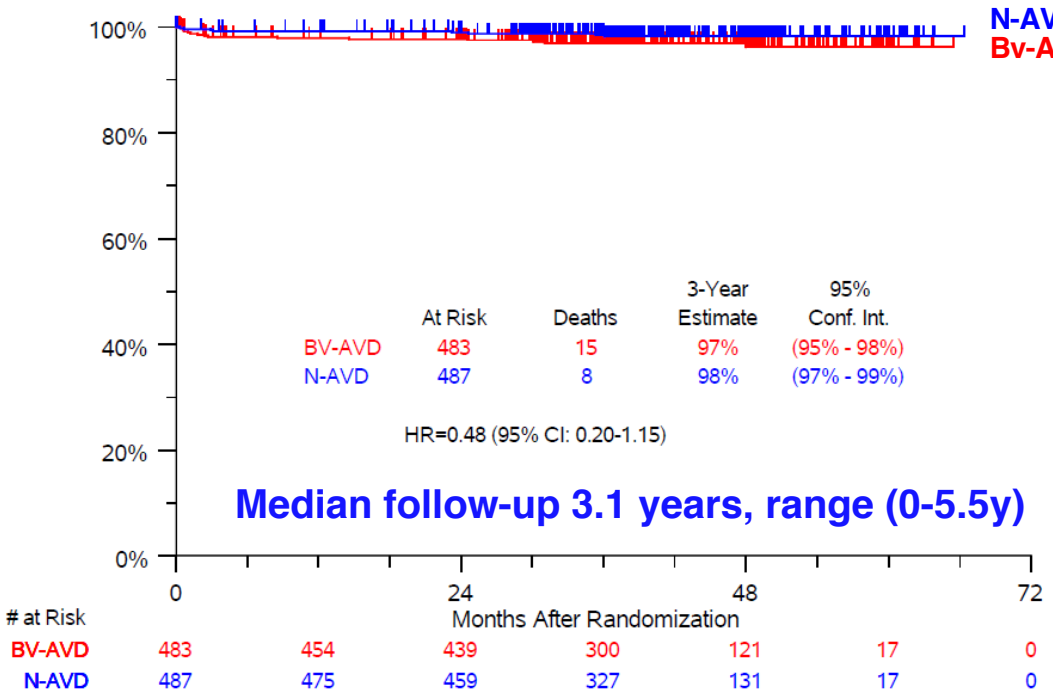



**3-year PFS**
**N-AVD 82%**
**Bv-AVD 58%**

One-sided Stratified Log-rank P-value = .003

**Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025**

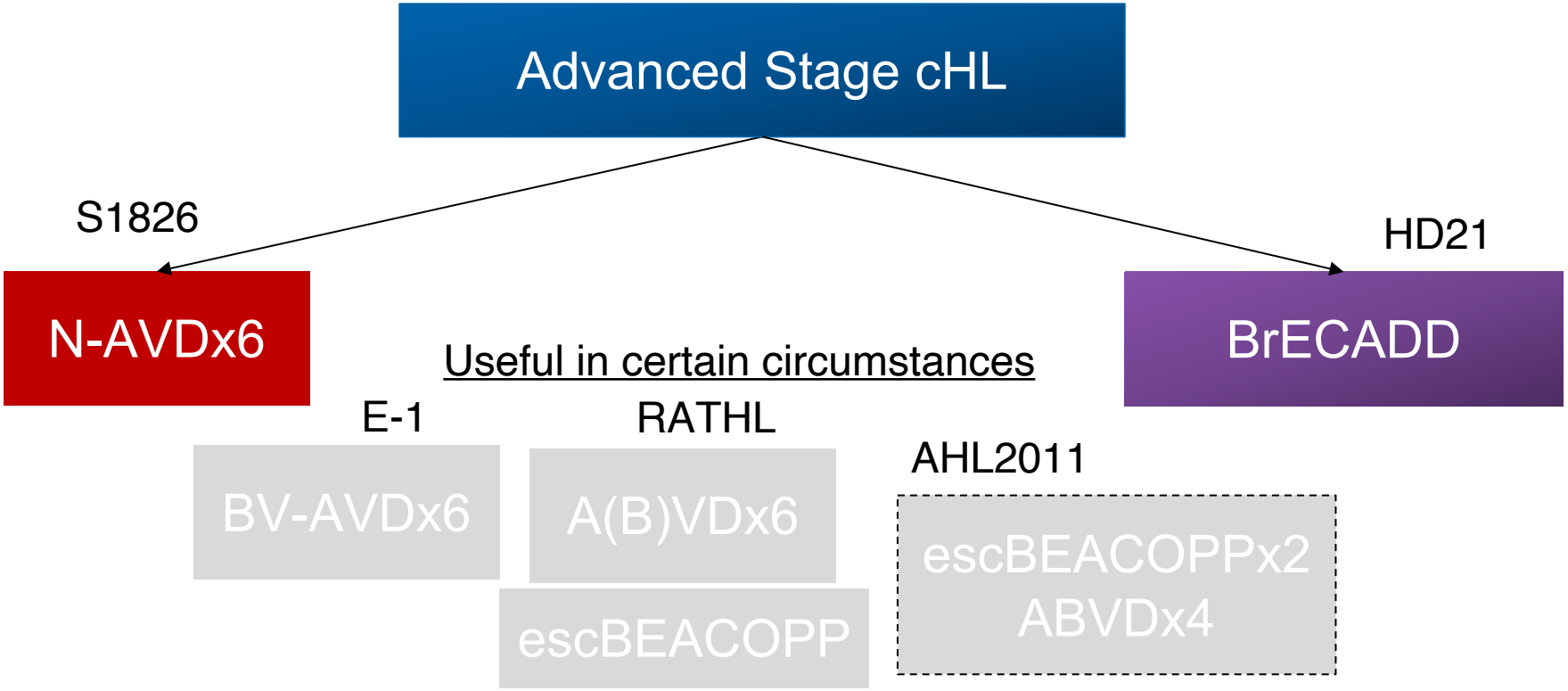
# Overall Survival




| Cause of Death | N-AVD N=487 | BV-AVD N=483 |
|---|---|---|
| Infection/Sepsis | 5 | 6 |
| Lymphoma | **1** | **2** |
| Medical issues other than cancer | 2 | 4 |
| New primary cancer | 0 | 1 |
| Unknown | 0 | 2 |
| Total | **8** | **15** |

Herrera, AF et al. N Eng J Med. 2024 Oct 17;391(15):1379-138. Herrera AF et al. ASH 2025

# Current Management of Advanced Stage cHL




Herrera AF, et al. ASCO 2022. Borchmann P, et al. ICML 2022. Ansell SM, et al. NEJM 2022, Borchmann P et al. Lancet 2018, Casasnovas O et al. *Lancet Oncol* 2019, Johnson P et al. NEJM 2016

# BrECADD vs N-AVD hematologic toxicity

| Toxicity | Frequency (%) |
|---|---|
| Gr ≥ 3 anemia | 30% (vs 6%) |
| PRBC transfusion | 24% |
| Gr ≥ 3 thrombocytopenia | 55% (vs 2%) |
| Platelet transfusion | 17% |
| Gr ≥ 3 leukopenia | 87% (vs 47%) |
| Febrile neutropenia | 28% (vs 5%) |
| Gr ≥ 3 infection | 20% (vs 5%) |

- Use of consolidative radiation: BrECADD 14% vs S1826 < 1%

# Pros/Cons of N-AVD vs BrECADD

## Nivo-AVD

- Tolerability
  - Pros: less heme/infectious/GI tox; older pts can tolerate
  - Cons: Immune tox, more anthracycline
- Efficacy
  - No direct comparison, no clear difference
- Duration
  - 24 wks, longer than BrECADD, esp PET2 neg
- Logistics
  - Familiarity globally with PD1 blockade
  - Q2 week dosing


## BrECADD

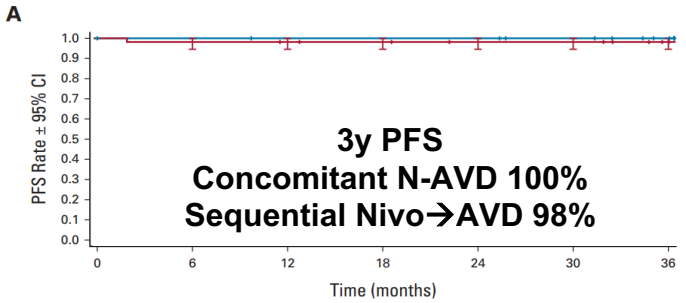
- Tolerability
  - Pros: no immune tox, less anthracycline
  - Cons: more heme/infectious/GI tox, toxic in older pts
- Efficacy
  - No direct comparison, no clear difference
- Duration
  - 12-18 wks, shorter than N-AVD, esp PET2 neg
- Logistics
  - Daily dosing x 3-4 days
  - Transfusions, ~30% febrile neutropenia

# Early Stage cHL

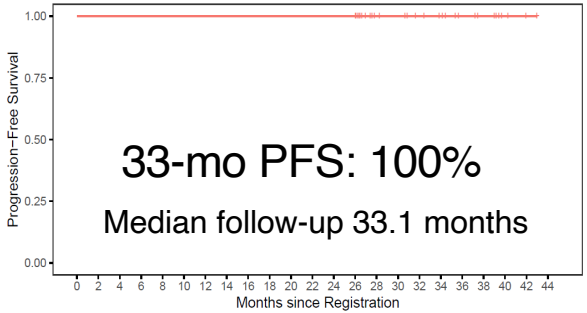
# PD-1 blockade in early stage cHL safe and effective

- Studies of frontline PD-1 blockade in cHL have been promising[10,11,12,13]
  - Well-tolerated
  - Excellent PFS

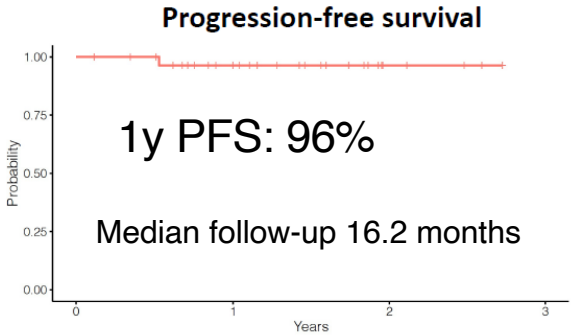
**1L Nivolumab-AVD + RT in early stage cHL**




**Sequential Pembro-AVD in cHL**

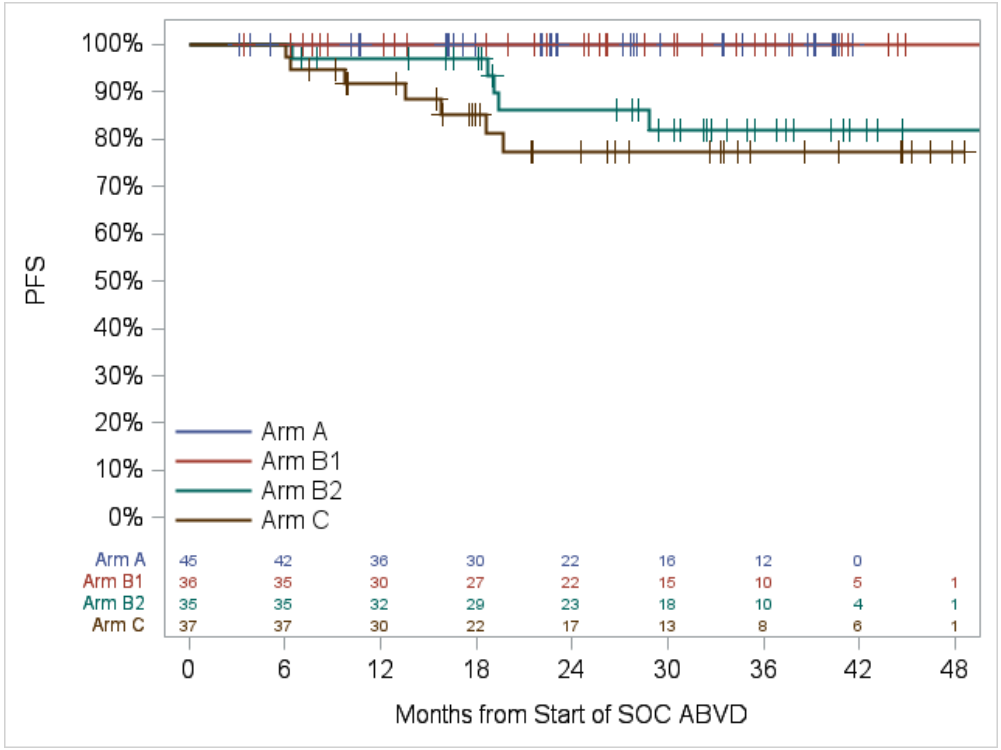


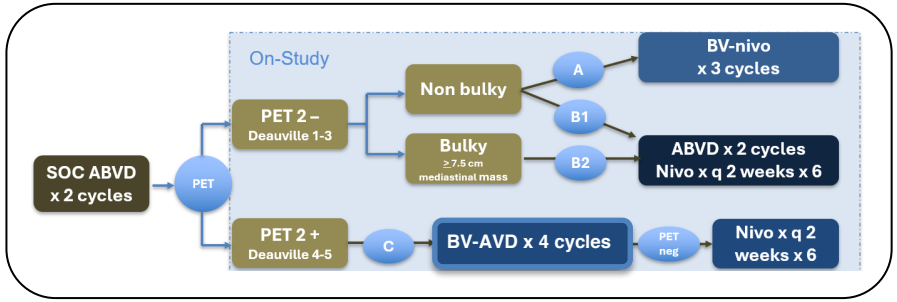

**Concurrent Pembro-AVD in cHL**




10. Bröckelmann PJ et al JCO. 2023 11. Ramchandren R et al JCO 2019 12. Allen PB, et al Blood. 2021 13. Lynch RC et al Blood 2023

# PET-adapted Nivo (and BV) in early stage cHL



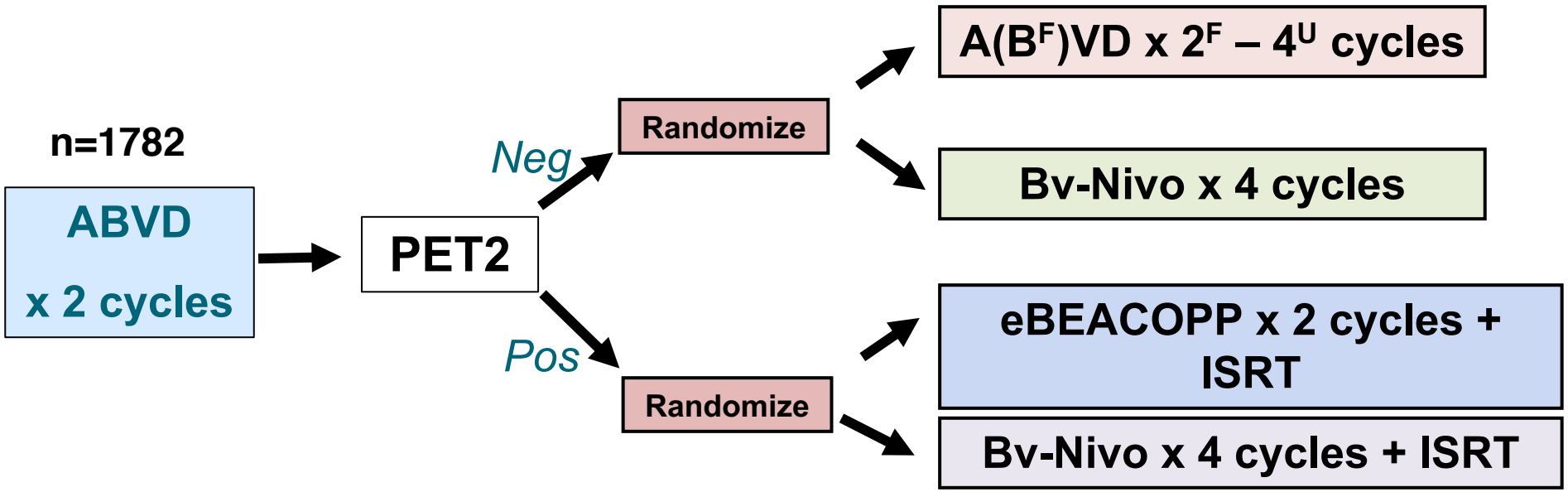

| PFS (95% CI) | # of PD/Rel | 18-month | 24-month |
|---|---|---|---|
| **Arm A (n=45)** | 0 | 100% | **100%** |
| **Arm B1 (n=36)** | 0 | 100% | **100%** |
| **Arm B2 (n=35)** | 5 | 97% (81-100%) | **86% (67-95%)** |
| **Arm C (n=37)** | 7 | 85% (68-94%) | **77% (57-89%)** |

No deaths reported thus far.
Median follow-up is 27.7 months (range 3.2-51.0).



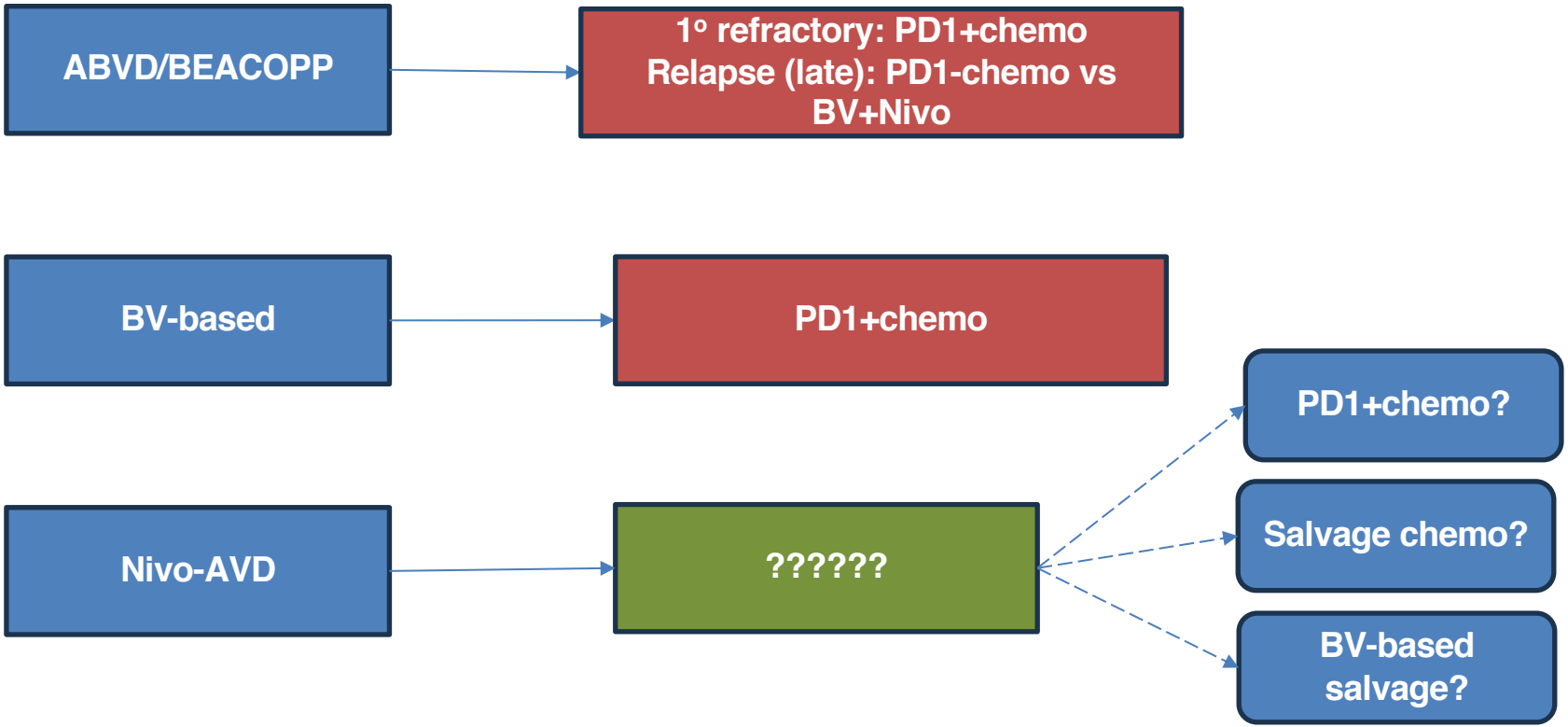
**LaCasce A…Herrera AF. ASH Oral Presentation 2024.**

# AHOD2131: PET-adapted BV-Nivo in early stage cHL




[a] 1 cycle = 28 days
[b] PET2 positive defined as Deauville 4 or 5

# Next Questions: What's Next After Frontline Therapy



# Evolving Role of CPI in Hodgkin Lymphoma

- Moving PD-1 blockade into earlier lines of cHL treatment has been promising and established a new paradigm of immunotherapy-based treatment of cHL
  - CPI-based salvage associated with best outcomes in R/R cHL
- N-AVD is a new standard therapy for advanced stage cHL
  - N-AVD improved PFS compared to Bv-AVD in advanced stage cHL
  - Nivo-AVD better tolerated than BV-AVD
- Future questions
  - Nivo-AVD vs BrECADD?
  - How to salvage frontline anti-PD-1 relapses?

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- David Bond

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- Sanjal Desai

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