DKG KREBSGESELLSCHAFT

Zertifiziertes Uroonkologisches Zentrum für

Prostatakrebs

Harnblasenkrebs

Nierenkrebs

AUO Thüringen e.V.

# Aktuelles aus der Uroonkologie: Nierenzellkarzinom

Thomas Steiner

18.11.2023

Helios

HMU Health and Medical University

# Offenlegung potentieller Interessenkonflikte

1. **Anstellungsverhältnis oder Führungsposition**
   keine

2. **Beratungstätigkeit**
   BMS, Eisai, IPSEN, Novartis, Pfizer, EUSA; MSD

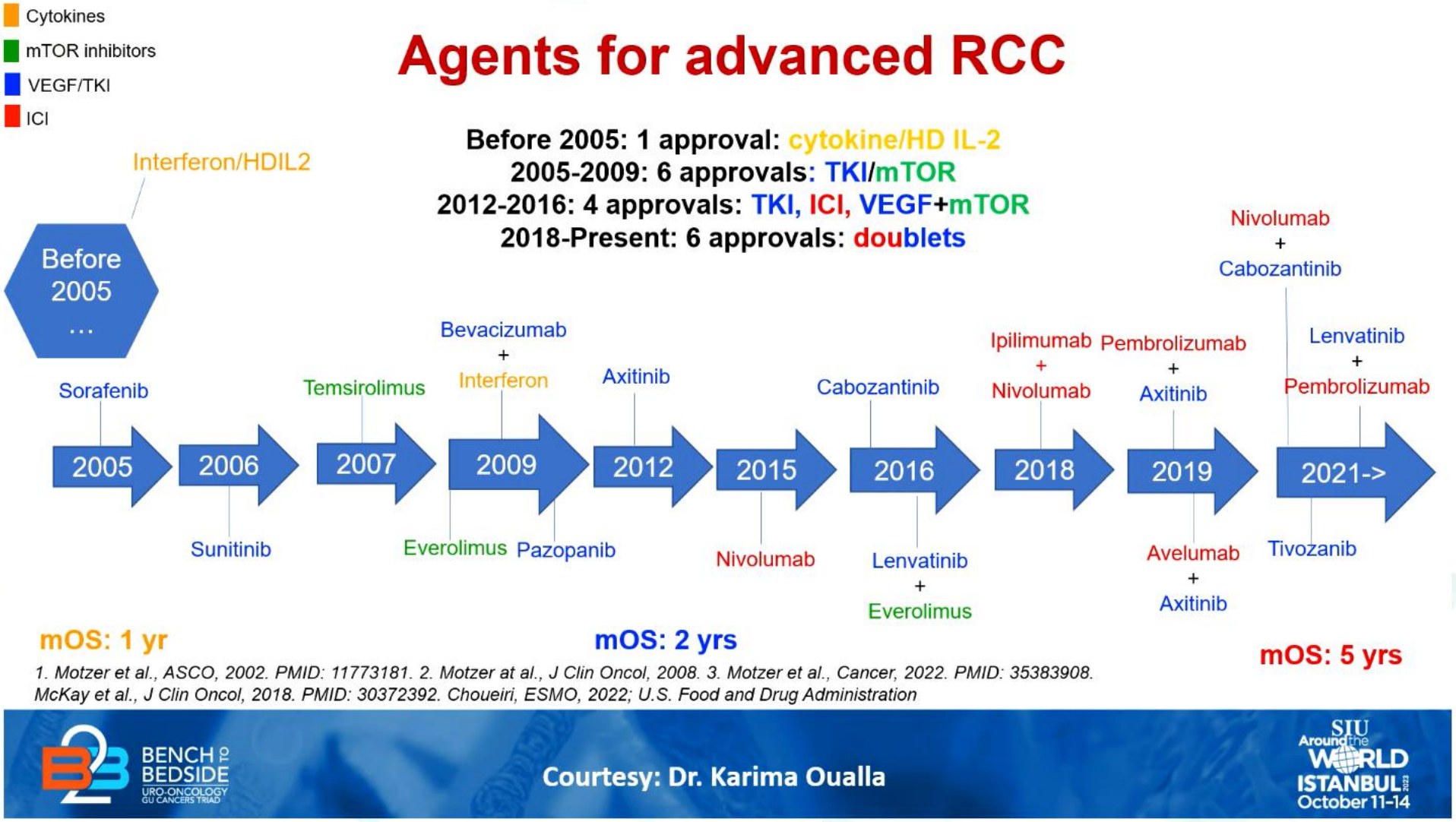
3. **Aktienbesitz**
   keiner

4. **Honorare**
   keine

5. **Finanzierung wissenschaftlicher Untersuchungen**
   Studienteilnahmen

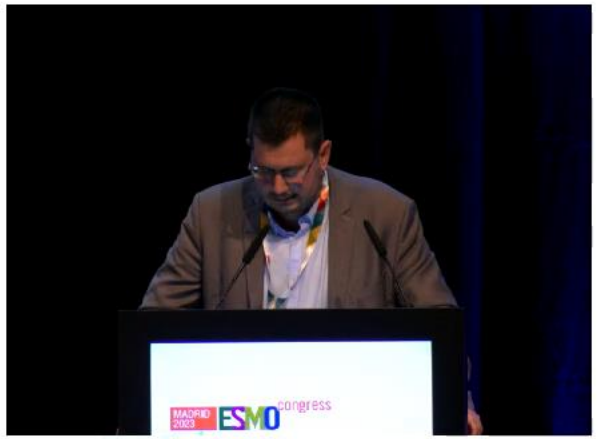
6. **Gutachtertätigkeit**
   keine

7. **Andere finanzielle Beziehungen**
   keine




*1. Motzer et al., ASCO, 2002. PMID: 11773181. 2. Motzer at al., J Clin Oncol, 2008. 3. Motzer et al., Cancer, 2022. PMID: 35383908. McKay et al., J Clin Oncol, 2018. PMID: 30372392. Choueiri, ESMO, 2022; U.S. Food and Drug Administration*



**Petros Grivas**

GU non-prostate


12
1
2
3
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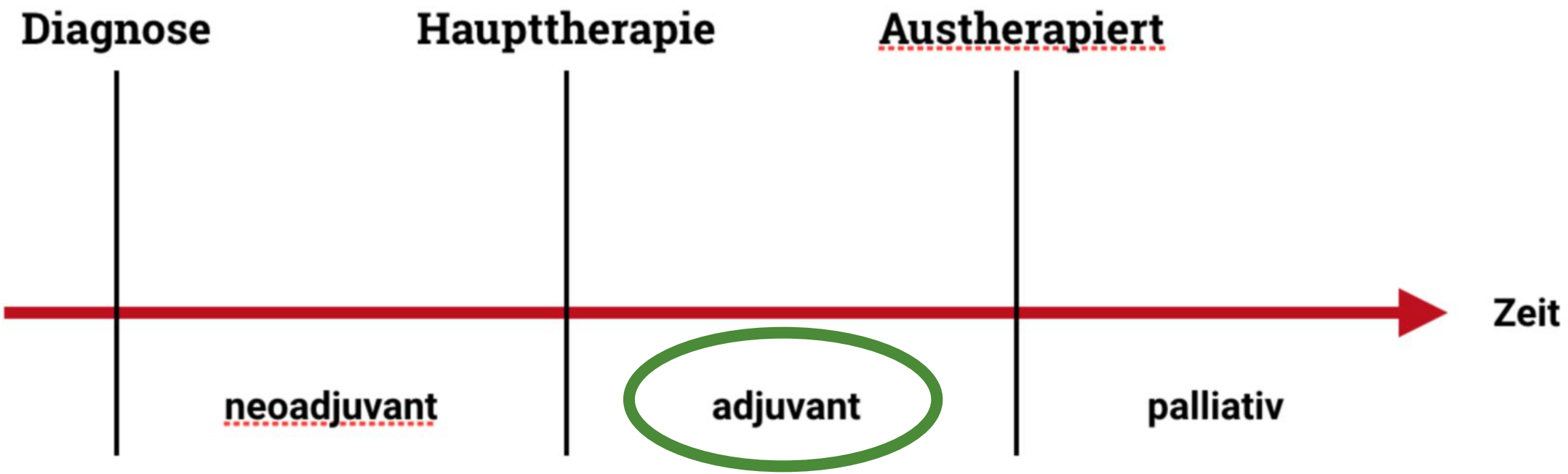
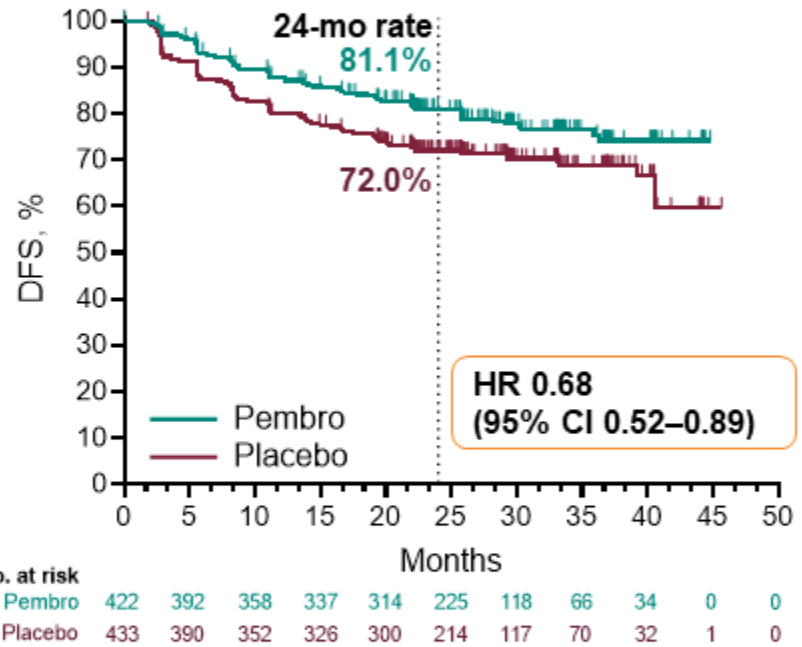
11


Diagnose
Haupttherapie
Austherapiert
Zeit
neoadjuvant
adjuvant
palliativ

KEYNOTE-564 (NCT03142334)

# DFS by Recurrence Risk Subgroups

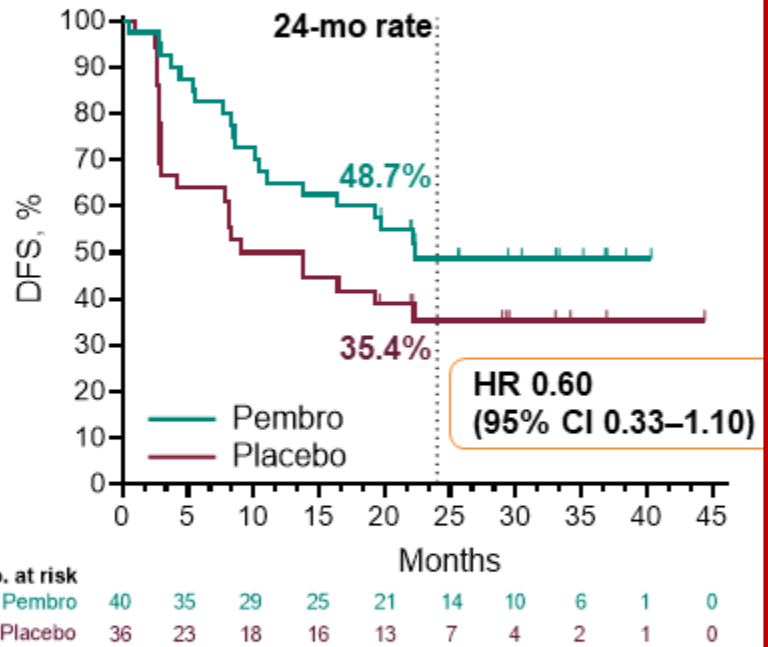
## Intermediate-High Risk




| No. at risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Pembro | 422 | 392 | 358 | 337 | 314 | 225 | 118 | 66 | 34 | 0 | 0 |
| Placebo | 433 | 390 | 352 | 326 | 300 | 214 | 117 | 70 | 32 | 1 | 0 |

| | Pts w/ Event | Median, mo (95% CI) |
|---|---|---|
| **Pembro** | 87 | NR (NR–NR) |
| **Placebo** | 127 | NR (40.5–NR) |

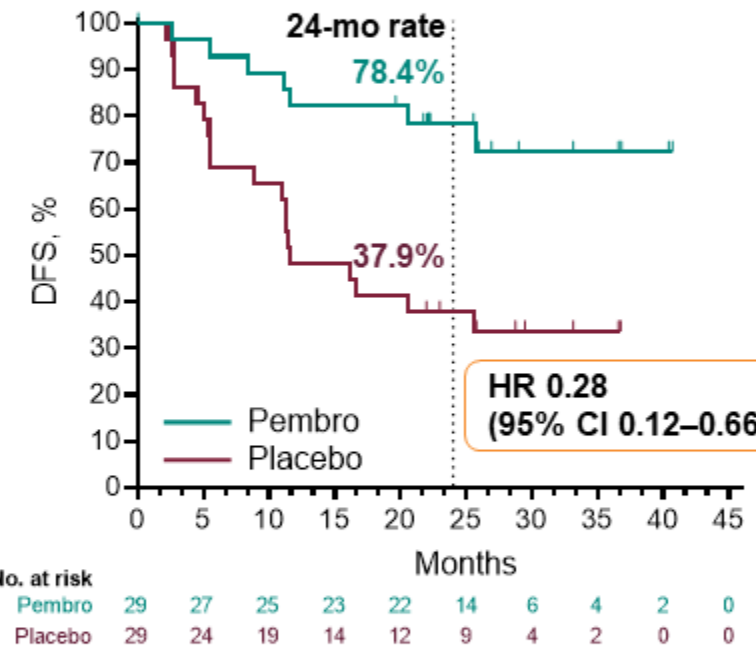
## High Risk




| No. at risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Pembro | 40 | 35 | 29 | 25 | 21 | 14 | 10 | 6 | 1 | 0 | |
| Placebo | 36 | 23 | 18 | 16 | 13 | 7 | 4 | 2 | 1 | 0 | |

| | Pts w/ Event | Median, mo (95% CI) |
|---|---|---|
| **Pembro** | 20 | 22.4 (11.1–NR) |
| **Placebo** | 23 | 11.4 (2.9–NR) |

## M1 NED

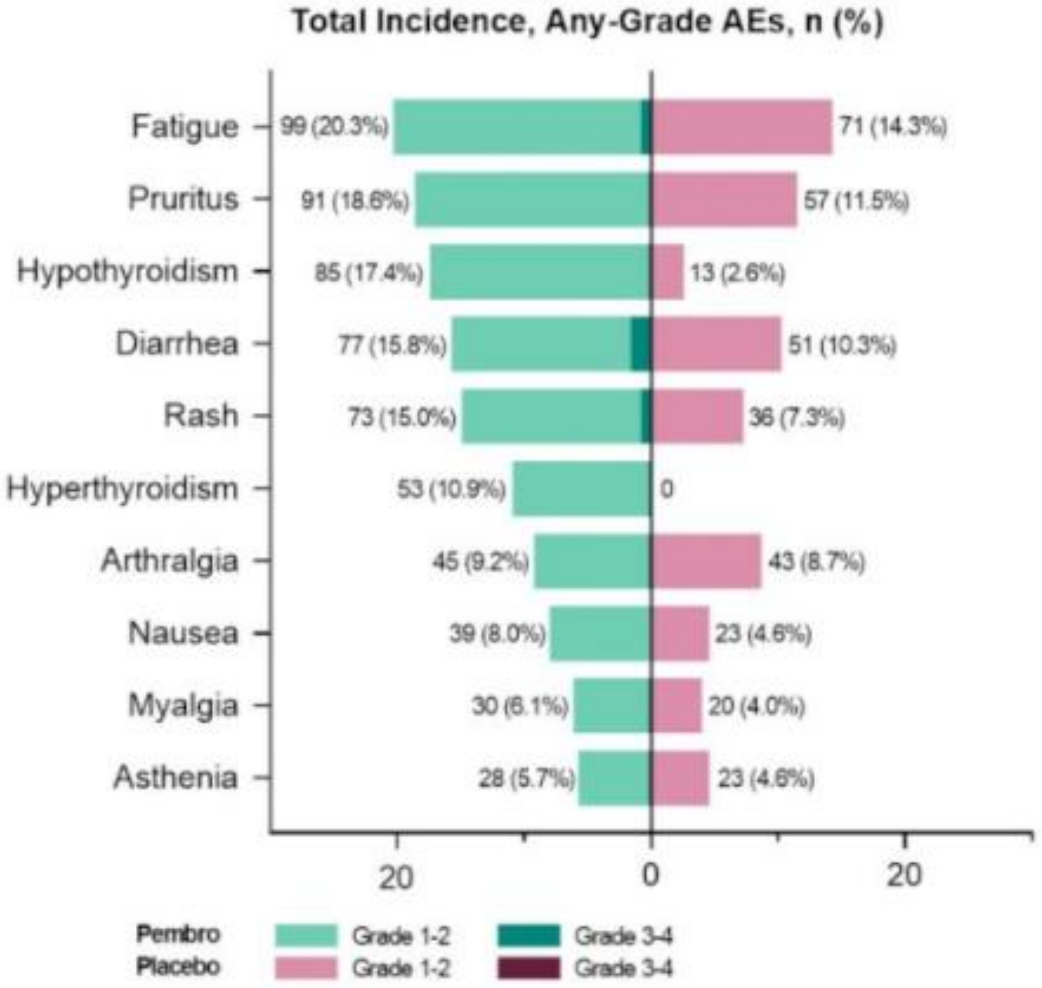


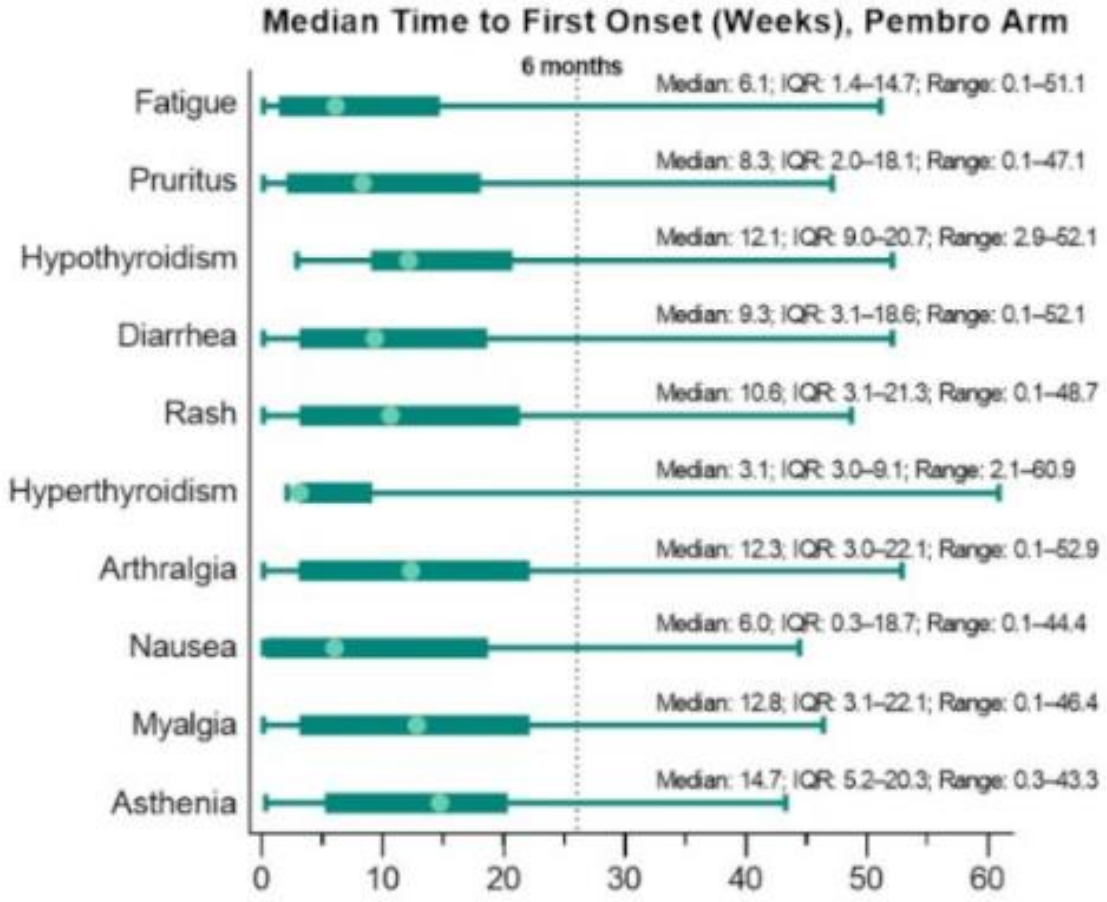

| No. at risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Pembro | 29 | 27 | 25 | 23 | 22 | 14 | 6 | 4 | 2 | 0 | |
| Placebo | 29 | 24 | 19 | 14 | 12 | 9 | 4 | 2 | 0 | 0 | |

| | Pts w/ Event | Median, mo (95% CI) |
|---|---|---|
| **Pembro** | 7 | NR (25.7–NR) |
| **Placebo** | 19 | 11.6 (5.6–NR) |

**Intermediate-high risk**: pT2, grade 4 or sarcomatoid, N0, M0; or pT3, any grade, N0, M0;
**High risk**: pT4, any grade, N0, M0; or pT any stage, any grade, N+, M0;
**M1 NED**: No evidence of disease after primary tumor + soft tissue metastases completely resected ≤1 year from nephrectomy.
DFS, disease-free survival; NR, not reached. Data cutoff date: June 14, 2021.

# KEYNOTE-564 - Nebenwirkungen




Choueiri TK ASCO GU 2022

# RCC 1L Combination Studies with significant OS benefit (vs. SUNI) + Triplet information (vs. IPI+NIVO)

| IO/IO and IO/TKI Information selected for approved IMDC groups | **CheckMate-214** IPI + NIVO **[intermediate/poor]** | **KEYNOTE-426** PEM + AXI | **CheckMate-9ER** NIVO + CABO | **CLEAR/KEYNOTE-581** PEM + LEN | **COSMIC-313** IPI + NIVO + CABO **[intermediate/poor]** |
|---|---|---|---|---|---|
| **mFU, month** | **67.7**[1] (first FU 25)[2] | **67.2**[3] (first FU 12.8)[4] | **44.0**[5] (first FU 18.1)[6] | **49.8**[7] (IA3 FU 27)[8] | **20.2**[9] |
| **mOS, month; HR** | 47.0; HR 0.68 (NR; HR 0.63) | 47.2; HR 0.84 (NR; HR 0.53) | 49.5; HR 0.70 (NR, HR 0.60) | 53.7; HR 0.79 (NR, HR 0.47)§ | na. |
| **mPFS, month; HR** **HR**, intermediate (**I**) poor (**P**) | 11.6; HR 0.73 **I/P**: see above **I**: na. **P**: na. | 15.7, HR 0.69 **I/P**: HR 0.68 **I**: na. **P**: na. | 16.6; HR 0.58 **I/P**: 0.55 **I**: 0.61 **P**: 0.38 | 23.9; HR 0.47 **I/P**: HR 0.43 **I**: na. **P**: na. | 16.9; HR 0.74[13] **I/P**: see above **I**: 0.68 **P**: 0.93 |
| **mPFS2, month; HR** favorable (**F**) | na. | 40.1; HR 0.63[11] **F**: 46.0; HR 0.68 | na. | NR; HR 0.50[12] **F**: NR; HR 0.57 | na. |
| **ORR, %** | 42.0 | 60.6 | 55.7 | 71.3 | 43.0 |
| **CR, %** | 9.6 (9.4) | 11.6 (5.8) | 12.4 (8.0) | 18.3 (16.1) | 3.0 |
| **PD, %** | 19.3* | 11.6 | 6.2 | 5.4 | 8.0 |
| **mDOR, month** | NR | 23.6 | 23.1 | 26.7 | NR |
| ITT IMDC Risk Groups **Fav \| Inter \| Poor**,% | 23 \| 61 \| 17 | 32 \| 55 \| 13 | 23 \| 58 \| 19 | 31 \| 59 \| 9 | 0 \| 75 \| 25 |

**CAVE: cross study comparisons are not valid**

Information is based on most recent data update/longest median follow-up data (see mFU row); [Effective June 2023]; **na**.: not available

**§** CLEAR IA2 Analysis (mFU 17.4 mo), Motzer et al. NEJM Feb 2021 Supplement**; ϕ** Enrollment into the NIVO+IPI+CABO arm was discontinued as of a December 2017 protocol amendment. Enrolled patients remained on arm B per protocol and were not required to change/discontinue therapy.

**1**. Motzer et al. Cancer 2022; * Albiges et al. ESMO Open Nov 2020; **2**. Motzer et al. NEJM Mar 2018; **3**. Rini et al. ASCO 2023 Abs. LBA4501; **4**. Rini et al. NEJM Feb 2019; **5**. Burotto et al. ASCO GU 2023 Abs.603; **6**. Choueiri et al. NEJM Mar 2021; **7**. Motzer et al. ASCO 2023 Abs.4502; **8**. Motzer et al. NEJM Feb 2021; **9**. Choueiri et al. ESMO 2022, Abs.LBA8; **10**. Escudier et al. IKCS: EUROPE 2022 **11**. Powles et al. ASCO 2022 ; **12**. Voss et al. ASCO 2022; **13.** Powels ASCO GU 2023

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| **mOS, month; HR** | 47.0; HR 0.68 (NR; HR 0.63) | 47.2; HR 0.84 (NR; HR 0.53) | 49.5; HR 0.70 (NR, HR 0.60) | 53.7; HR 0.79 (NR, HR 0.47)§ | na. |
| **mPFS, month; HR**<br>**HR**, intermediate (**I**) poor (**P**) | [illegible]<br>**I/P**: see above<br>**I**: na.<br>**P**: na. | 15.7, HR 0.69<br>**I/P**: HR 0.68<br>**I**: na.<br>**P**: na. | 16.6; HR 0.58<br>**I/P**: 0.55<br>**I**: 0.61<br>**P**: 0.38 | 23.9; HR 0.47<br>**I/P**: HR 0.43<br>**I**: na.<br>**P**: na. | 16.9; HR 0.74[13]<br>**I/P**: see above<br>**I**: 0.68<br>**P**: 0.93 |
| **mPFS2, month; HR**<br>favorable (**F**) | na. | 40.1; HR 0.63[11]<br>**F**: 46.0; HR 0.68 | na. | NR; HR 0.50[12]<br>**F**: NR; HR 0.57 | na. |
| **ORR, %** | 42.0 | 60.6 | 55.7 | 71.3 | 43.0 |
| **CR, %** | 9.6 (9.4) | 11.6 (5.8) | 12.4 (8.0) | 18.3 (16.1) | 3.0 |
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| ITT IMDC Risk Groups **Fav**\|**Inter**\|**Poor**,% | 23\|61\|17 | 32\|55\|13 | 23\|58\|19 | 31\|59\|9 | 0\|75\|25 |

**CAVE: cross study comparisons are not valid**

Information is based on most recent data update/longest median follow-up data (see mFU row); [Effective June 2023]; **na**.: not available

**§** CLEAR IA2 Analysis (mFU 17.4 mo), Motzer et al. NEJM Feb 2021 Supplement**; ϕ** Enrollment into the NIVO+IPI+CABO arm was discontinued as of a December 2017 protocol amendment. Enrolled patients remained on arm B per protocol and were not required to change/discontinue therapy.

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| **mPFS2, month; HR** favorable (**F**) | na. | 40.1; HR 0.63[11] **F**: 46.0; HR 0.68 | na. | NR; HR 0.50[12] **F**: NR; HR 0.57 | na. |
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| **CR, %** | 9.6 (9.4) | 11.6 (5.8) | 12.4 (8.0) | 18.3 (16.1) | 3.0 |
| **PD, %** | 19.3* | 11.6 | 6.2 | [illegible] | 8.0 |
| **mDOR, month** | NR | 23.6 | 23.1 | 26.7 | NR |
| ITT IMDC Risk Groups **Fav \| Inter \| Poor**,% | 23 \| 61 \| 17 | 32 \| 55 \| 13 | 23 \| 58 \| 19 | 31 \| 59 \| 9 | 0 \| 75 \| 25 |

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**§** CLEAR IA2 Analysis (mFU 17.4 mo), Motzer et al. NEJM Feb 2021 Supplement**; ϕ** Enrollment into the NIVO+IPI+CABO arm was discontinued as of a December 2017 protocol amendment. Enrolled patients remained on arm B per protocol and were not required to change/discontinue therapy.

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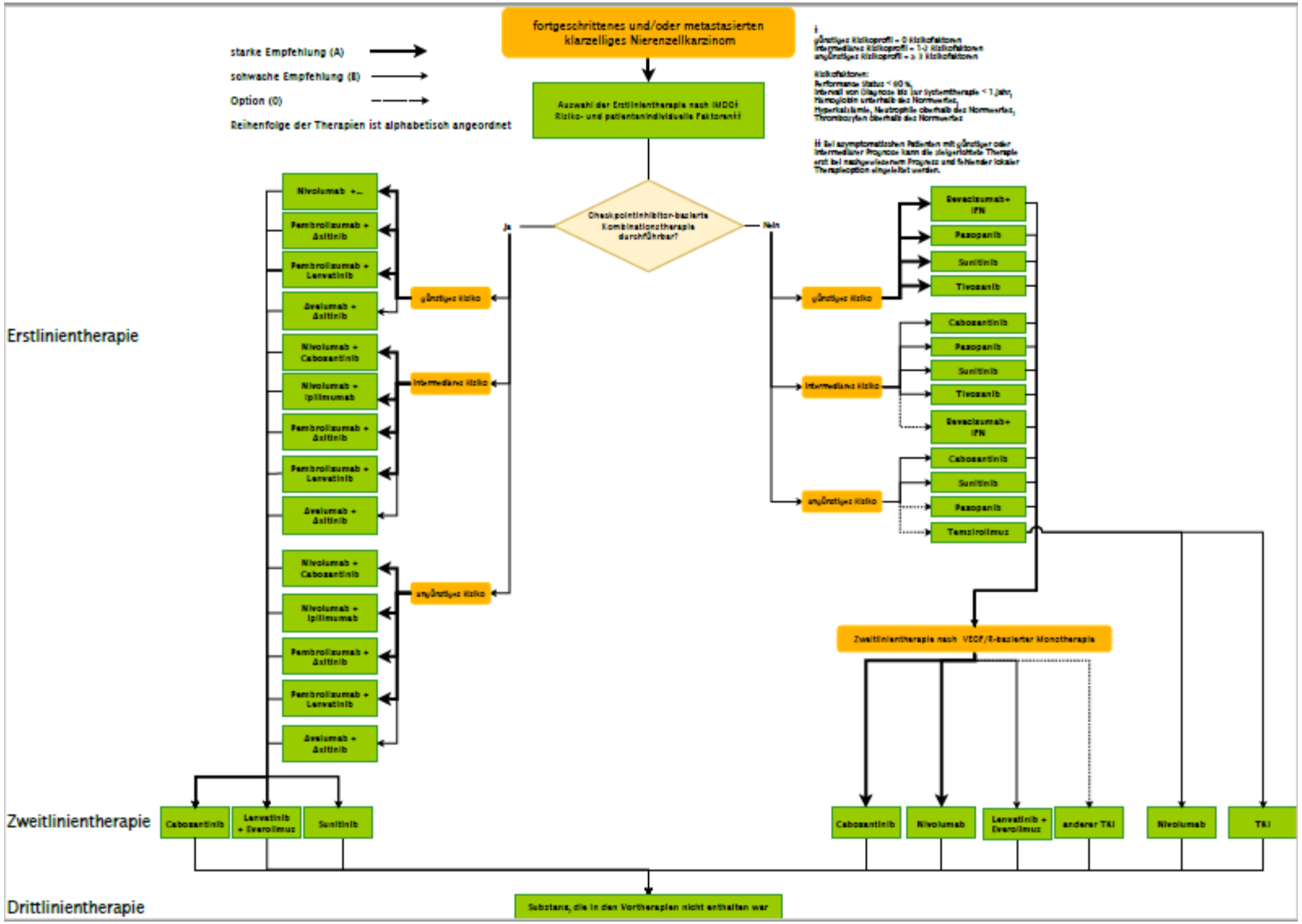
# Standard-Kombinationstherapien + Sequenzen

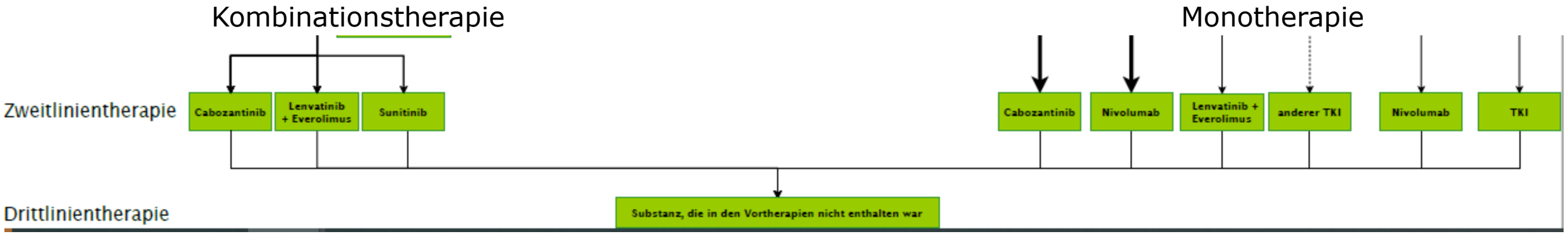
publiziert bei: AWMF online
Das Portal der wissenschaftlichen Medizin

Leitlinienprogramm Onkologie

## S3-Leitlinie Diagnostik, Therapie und Nachsorge des Nierenzellkarzinoms

Version 4.0 – Februar 2023
AWMF-Registernummer: 043-017OL






| 7.14 | **Konsensbasiertes Statement** | **neu 2020** |
|---|---|---|
| **EK** | Nach Versagen einer Checkpointinhibitor-basierten Erstlinientherapie ist kein Standard etabliert. | |
| | Starker Konsens | |

# CaboPoint: interim results from a phase 2 study of cabozantinib after checkpoint inhibitor therapy in patients with advanced renal cell carcinoma

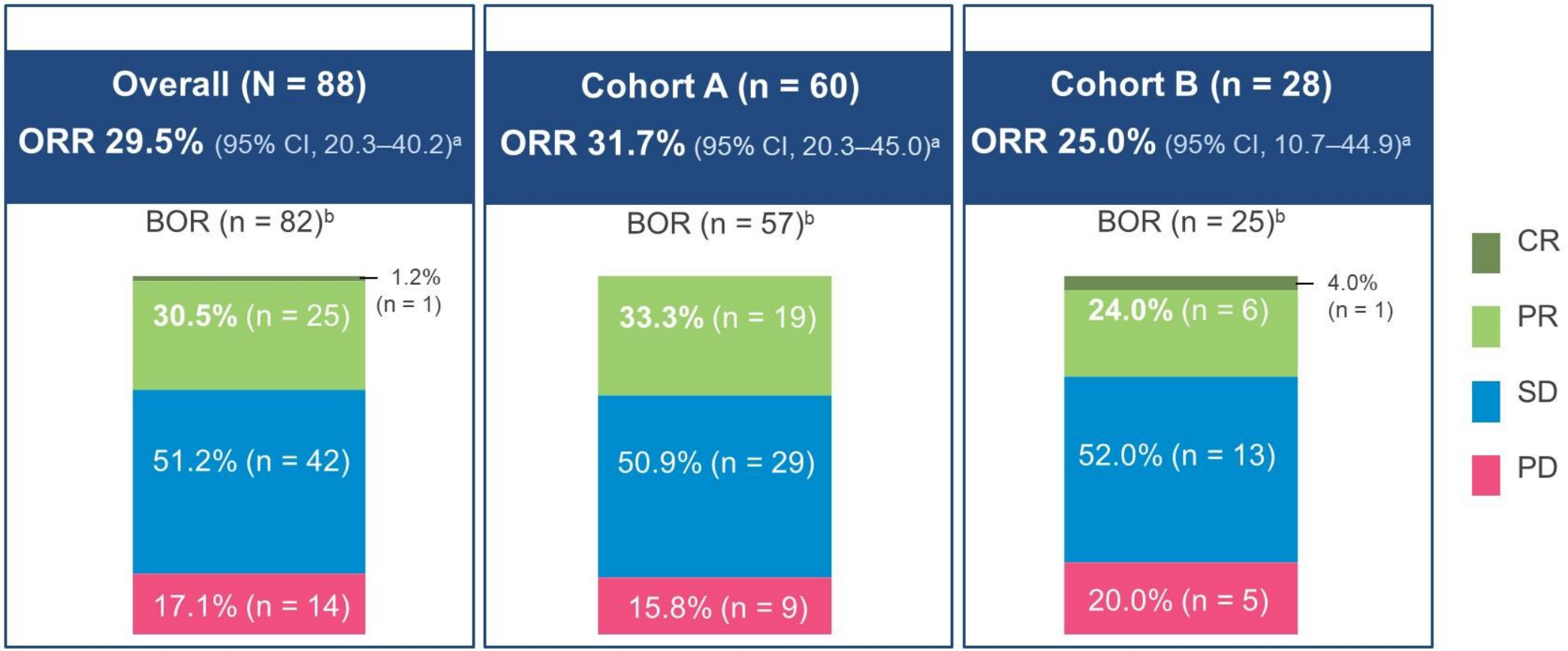
Laurence Albiges[a], Thomas Powles[b], Anand Sharma[c], Balaji Venugopal[d], Jen Bedke[e], Pascale Dutailly[f], Bryan Qvick[g], Lidia Martin-Couce[h], Valerie Perrot[f], Viktor Gruenwald[i]

[a]Medical Oncology, Gustave Roussy, Université Paris-Saclay, France; [b]Barts Cancer Institute, Queen Mary University of London, London, UK; [c]Mount Vernon Cancer Centre, Northwood, UK; [d]Beatson West of Scotland Cancer Centre and University of Glasgow, Glasgow, UK; [e]Department of Urology, Eberhard Karls University Tübingen, Tübingen, Germany; [f]Ipsen, Boulogne-Billancourt, Paris, France; [g]Ipsen Pharma GmbH, Munich, Germany; [h]Ipsen Pharma, Barcelona, Spain; [i]Essen University Hospital, West German Cancer Center, Clinic for Medical Oncology & Clinic for Urology, Essen, Germany

606

ASCO GU | San Francisco, CA, USA | February 16–18, 2023

# Results: interim efficacy (3 months analysis)




[a]Investigator-assessed ORR was calculated based on the number of patients in each analysis population. [b]Percentages of best response (CR, PR, SD, and PD) were calculated based on the number of patients with non-missing values. BOR, best overall response; CI, confidence interval; CR, complete response; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.

# Abstract LBA4500 (Choueiri): CONTACT-03

| Clinical Question: | Does “re-challenge” with ICI+TKI improve outcomes vs TKI alone in patients previously treated with ICI-based therapy? |
|---|---|


PRESENTED BY: David A. Braun, MD, PhD @BraunMDPhD

# Does re-challenge with ICI improve response? No

*No difference in:*
- *Response*
- *Primary PD rate*
- *Disease control*
- *Duration of response*

| | RECIST 1.1 per central review[a] | | RECIST 1.1 per investigator[a] | |
|---|---|---|---|---|
| | Atezo + Cabo (n=259) | Cabo (n=254) | Atezo + Cabo (n=263) | Cabo (n=259) |
| **Confirmed objective response, n, (%) [95% CI]** | 105 (40.5) [34.5, 46.8] | 104 (40.9) [34.8, 47.3] | 100 (38.0) [32.1, 44.2] | 108 (41.7) [35.6, 48.0] |
| Complete response, n (%) | 0 | 2 (0.8) | 4 (1.5) | 2 (0.8) |
| Partial response, n (%) | 105 (40.5) | 102 (40.2) | 96 (36.5) | 106 (40.9) |
| Stable disease, n (%) | 131 (50.6) | 121 (47.6) | 127 (48.3) | 120 (46.3) |
| Progressive disease, n (%) | 11 (4.2) | 13 (5.1) | 24 (9.1) | 17 (6.6) |
| Not evaluable or missing, n (%) | 12 (4.6) | 16 (6.3) | 12 (4.6) | 14 (5.4) |
| **Ongoing response at data cutoff, n/N (%)[b]** | 53/105 (50.5) | 55/104 (52.9) | 58/100 (58.0) | 48/108 (44.4) |
| **Median duration of response (range), mo** | 12.7 (2.1+ to 22.9+) | 14.8 (2.3+ to 25.6+) | NE (2.1+ to 23.2+) | 12.2 (2.1+ to 25.6+) |

Choueiri, ASCO 2023, LBA4500.

# Is cabozantinib effective after prior ICI? Yes

*METEOR: ORR 21%*

*CaboPoint: ORR 29.5%*

| | RECIST 1.1 per central review[a] | | RECIST 1.1 per investigator[a] | |
|---|---|---|---|---|
| | Atezo + Cabo (n=259) | Cabo (n=254) | Atezo + Cabo (n=263) | Cabo (n=259) |
| **Confirmed objective response, n, (%) [95% CI]** | 105 (40.5) [34.5, 46.8] | 104 (40.9) [34.8, 47.3] | 100 (38.0) [32.1, 44.2] | 108 (41.7) [35.6, 48.0] |
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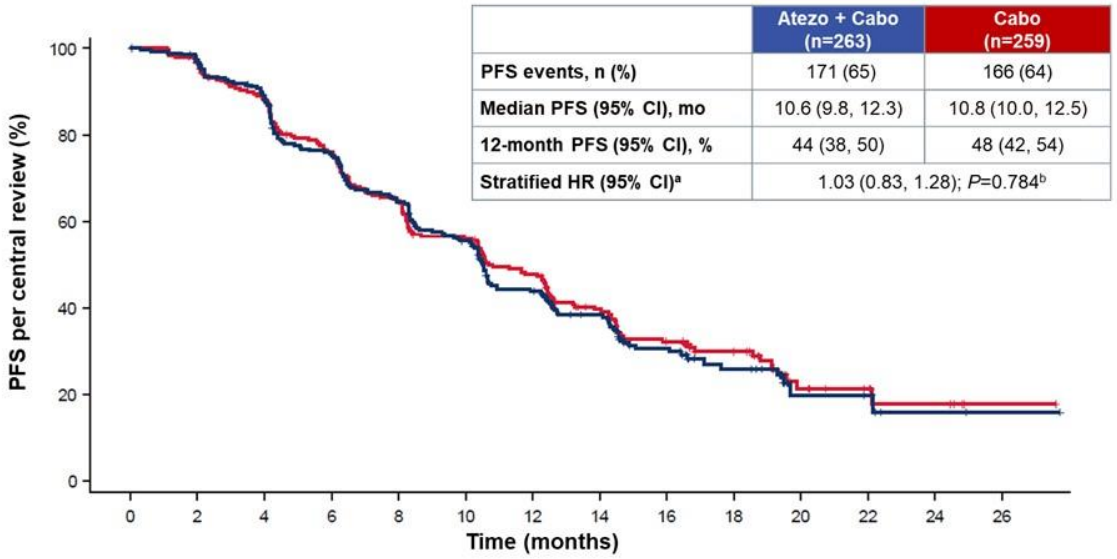
Choueiri, ASCO 2023, LBA4500; Choueiri, N Engl J Med, 2015; Albiges, ASCO GU 2023.

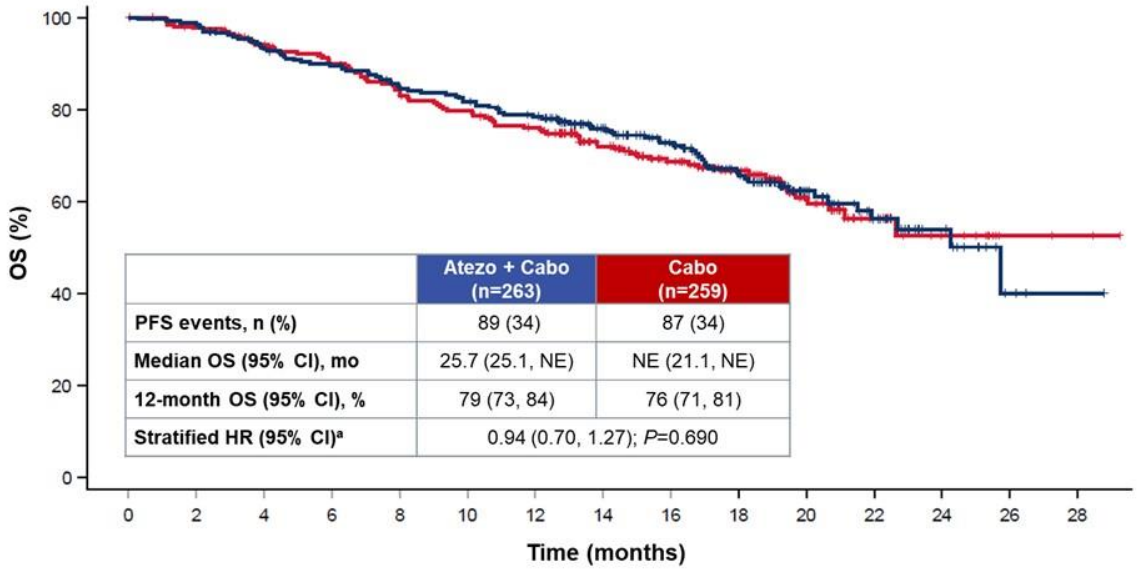
# Does re-challenge with ICI improve survival? No

***PFS***




| | Atezo + Cabo (n=263) | Cabo (n=259) |
|---|---|---|
| PFS events, n (%) | 171 (65) | 166 (64) |
| Median PFS (95% CI), mo | 10.6 (9.8, 12.3) | 10.8 (10.0, 12.5) |
| 12-month PFS (95% CI), % | 44 (38, 50) | 48 (42, 54) |
| Stratified HR (95% CI)[a] | 1.03 (0.83, 1.28); *P*=0.784[b] | |

***OS***




| | Atezo + Cabo (n=263) | Cabo (n=259) |
|---|---|---|
| PFS events, n (%) | 89 (34) | 87 (34) |
| Median OS (95% CI), mo | 25.7 (25.1, NE) | NE (21.1, NE) |
| 12-month OS (95% CI), % | 79 (73, 84) | 76 (71, 81) |
| Stratified HR (95% CI)[a] | 0.94 (0.70, 1.27); *P*=0.690 | |

Choueiri, ASCO 2023, LBA4500.

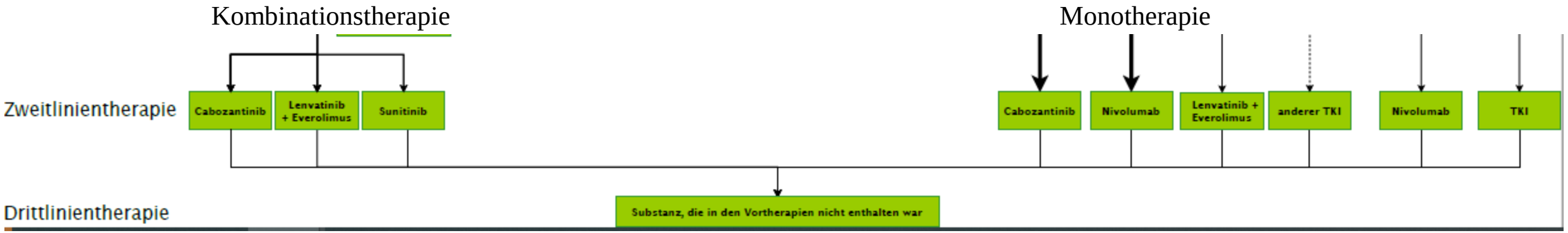
# Is re-challenge with ICI+TKI more toxic than TKI alone? Yes

| Adverse event, n (%) | Atezo + Cabo (n=262) | Cabo (n=256) |
|---|---|---|
| **Any-cause AE** | 262 (100) | 254 (99.2) |
| Any-cause treatment-related AE | 252 (96.2) | 249 (97.3) |
| **Grade 3 or 4 AE** | 177 (67.6) | 158 (61.7) |
| Grade 3 or 4 treatment-related AE | 145 (55.3) | 121 (47.3) |
| **Death due to AE** | 17 (6.5) | 9 (3.5) |
| Death due to treatment-related AE | 3 (1.1)[a] | 0 |
| **Serious AE** | 126 (48.1) | 84 (32.8) |
| Serious treatment-related AE | 63 (24.0) | 30 (11.7) |
| **AE leading to withdrawal from a trial drug** | 41 (15.6) | 10 (3.9) |
| AE leading to withdrawal from atezo | 29 (11.1) | – |
| AE leading to withdrawal from cabo | 25 (9.5) | 10 (3.9) |
| **AE leading to interruption or reduction of a trial drug** | 240 (91.6) | 223 (87.1) |
| AE leading to interruption of atezo[b] | 159 (60.7) | – |
| AE leading to interruption or reduction of cabo | 234 (89.3) | 223 (87.1) |

Choueiri, ASCO 2023, LBA4500.

# Abstract LBA4500 (Choueiri): CONTACT-03

| | |
|---|---|
| **Clinical Question:** | Does “re-challenge” with ICI+TKI improve outcomes vs TKI alone in patients previously treated with ICI-based therapy? |
| **Findings:** | • Addition of atezolizumab to cabozantinib did NOT improve response or progression-free survival vs cabozantinib alone<br>• Atezolizumab + cabozantinib had significantly higher G3-4 AEs<br>• Cabozantinib is effective therapy for ICI-refractory RCC (ORR ~40%) |




| 7.15 | Konsensbasierte Empfehlung | neu 2020 |
|---|---|---|
| EK | Nach Versagen einer Kombinationstherapie aus Nivolumab+Ipilipumab sollte eine TKI-basierte Therapie verabreicht werden (Zulassungsstatus beachten*).<br>*Nur bei Sunitinib deckt der Zulassungstext auch einen Einsatz nach einer Therapie mit Nivolumab+Ipilimumab ab. Bei allen anderen TKIs handelt es sich um einen Off-Label-Use. | |
| | Konsens | |

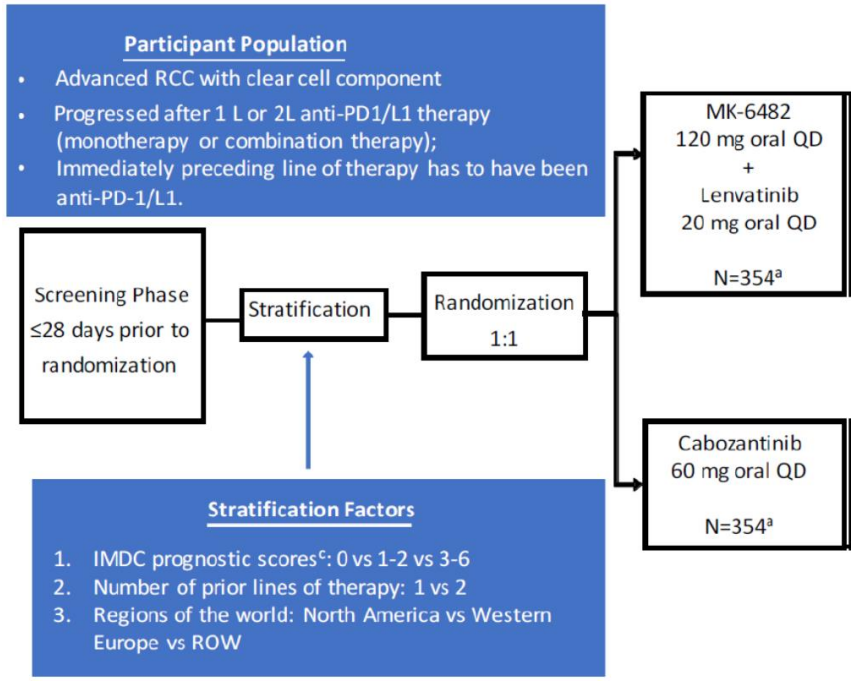
| 7.16 | Konsensbasierte Empfehlung | modifiziert 2022 |
|---|---|---|
| EK | Nach Versagen einer Kombinationstherapie aus Avelumab + Axitinib, Nivolumab + Cabozantinib, Pembrolizumab+Axitinib oder Pembrolizumab + Lenvatinib sollte eine TKI-basierte Therapie verabreicht werden (Zulassungstatus beachten*).<br>*Bei Sunitinib, Cabozantinib und Lenvatinib+Everolimus deckt der Zulassungstext diese Indikation ab. | |
| | Starker Konsens | |

# Fazit

- **Adjuvante Therapie**

- **Sequenz in der metastasierten Situation**
  1. Kombination CPI + CPI bzw. CPI + TKI
  2. Zweitlinie – TKI bzw. TKI + mTOR bzw. Studien
  3. Bisher nicht genutzte TKI bzw. TKI + mTOR

- **Ausblick**
  1. HIF 2α Inhibitor + TKI in der Zweit- / Drittlinie




- **Differenzierte Therapieentscheidung und optimales Nebenwirkungsmanagement sind essentiell für Lebensqualität, Therapieansprechen und Überleben**