short review

memo (2021) 14:70–75
https://doi.org/10.1007/s12254-020-00667-0

memo
magazine of european medical oncology

Genitourinary cancers—best of ASCO 2020

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Received: 29 August 2020 / Accepted: 11 November 2020 / Published online: 11 December 2020

Summary The aim of this short review is to summarize "clinical practice changing" abstracts about genitourinary cancers from this year's ASCO Annual Meeting. The phase 3 JAVELIN Bladder 100 trial showed astonishing overall survival (OS) data up to 22 months in metastatic urothelial carcinoma (mUC), using a novel gold standard in the first-line setting of mUC—immunotherapy maintenance with avelumab after response to platinum-based chemotherapy. In the first-line treatment of metastatic RCC (mRCC), two phase 2 trials (OMNIVORE and HCRN GU16-260) evaluated the efficacy of a novel sequential strategy, nivolumab monotherapy followed by ipilimumab rescue if nonresponse to nivolumab, confirming that this therapeutic concept is less effective as upfront combination treatment. Finally, updated 24-month progression-free survival (PFS) and OS rates of the KEYNOTE-426 are presented, showing efficacy most in intermediate- and poor-risk patients for the combination pembrolizumab plus axitinib compared with sunitinib. According to the impressive data from the HERO trial, the US Food and Drug Administration granted relugolix priority review as the first oral GNRH receptor antagonist in advanced prostate cancer. Moreover, ^{18}F-DCFPyL-PET/CT is a promising diagnostic tool for biochemical recurrence as the CONDOR trial confirmed diagnostic superiority of PyL-PET/CT compared with conventional imaging in detecting occult metastasis even in low PSA values. In nonmetastatic castration-resistant prostate cancer (nmCRPC), final OS data of ARAMIS, PROSPER and SPARTAN evaluating efficacy and safety of second-generation antiandrogens versus placebo were presented. In patients with mCRPC progressing after docetaxel, 177Lu-PSMA-617 demonstrated improved rates of 50% reduction in PSA relative to cabazitaxel (TheraP study).

Keywords Urothelial cancer · RCC · Prostate cancer · ASCO · 2020

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Urothelial carcinoma

First-line treatment in metastatic urothelial carcinoma (mUC)

Switch maintenance immunotherapy after platinum-based chemotherapy

After a long drought since the introduction of cisplatin-based chemotherapy in the late 1980s [1], the treatment landscape for mUC has changed dramatically due to the US Food and Drug Administration (and the European Medicines Agency) approval of novel therapeutic agents as presented in Fig. 1.

In the first-line, various phase 3 trials are currently evaluating efficacy of combining chemotherapy (Cx) plus immunotherapy (IO) compared to standard of care (SOC) alone (Fig. 2). However, first interim analyses confirmed that the KEYNOTE-361 and DANUBE trial did not meet their primary endpoints of improving overall survival (OS) versus SOC [2, 3]. Additionally, interim analysis from IMvigor130 demonstrate that OS outcome in the combination arm compared with SOC did not cross the prespecified interim efficacy boundary for statistical significance [4].

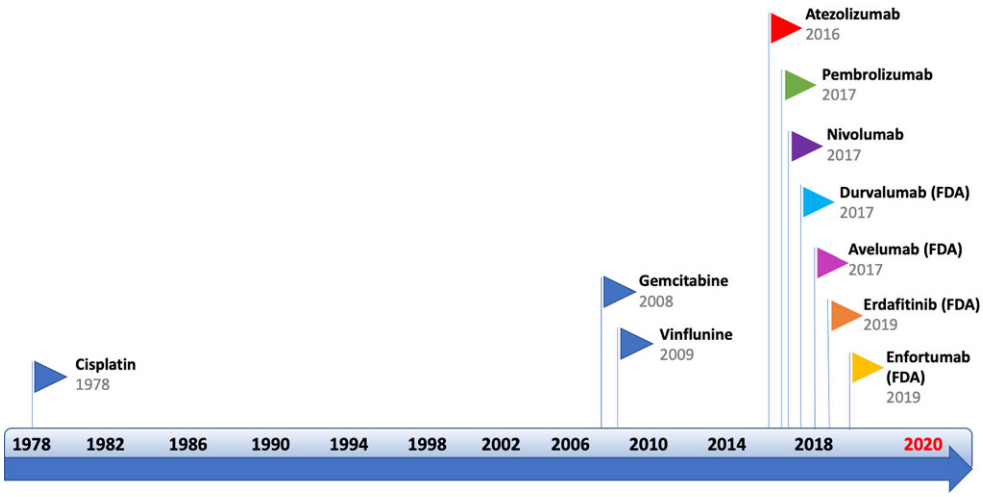

Fig. 1 Treatment landscape of the US Food and Drug Administration (and the European Medicines Agency) approved therapeutic agents in metastatic urothelial carcinoma

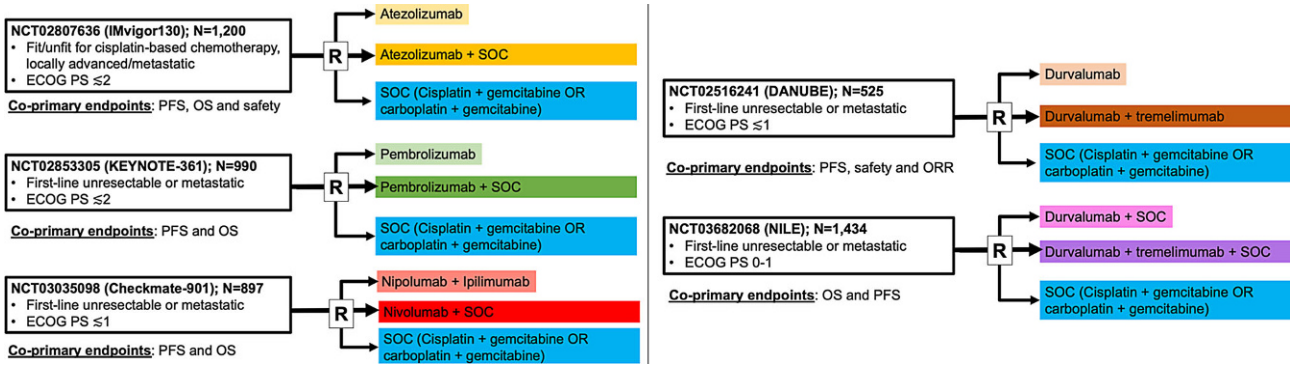

Fig. 2 Ongoing phase 3 trials evaluating combination of chemotherapy and immunotherapy in the first-line setting compared to standard-of-care (platinum-based chemotherapy) alone in metastatic urothelial carcinoma. *ORR* objective response rate; *PFS* progression-free survival; *OS* overall survival; *PS* performance status; *SOC* standard of care

A novel therapeutic strategy—first-line maintenance with avelumab in mUC patients who have not progressed with platinum-based Cx induction—was presented for the first time in JAVELIN Bladder 100 with astonishing OS data. A total of 700 patients with unresectable, locally advanced or mUC without disease progression after 4–6 cycles of gemcitabine with either cisplatin or carboplatin were randomized 1:1 to receive maintenance avelumab every 2 weeks plus best supportive care (BSC, $n=350$) or BSC alone ($n=350$). Avelumab plus BSC significantly prolonged OS versus BSC alone in all randomized patients (median OS: 21.4 vs. 14.3 months; $p=0.0005$) as well as in patients with PD-L1 positive tumors (median OS: NR vs. 17.1 months; $p=0.0003$). An OS benefit was also observed across all prespecified subgroups [5]. Outcomes are consistent with the phase II trial HCRN GU14-182 (median OS: pembrolizumab vs. placebo: 22 vs. 18.7 months) [6]. A comparison of both trials is presented in Table 1. Avelumab was well tolerated, confirming no grade 4/5 immune-related adverse event. Platinum-based chemotherapy is still the best initial therapy achieving highest overall response rates, does not require PD-L1 testing for treatment selection and sets patient up for best OS to subsequent checkpoint inhibitor. Post platinum switch maintenance is preferred over treatment break as timing for next line checkpoint inhibitor in patients with stable disease or response after Cx. Moreover, it is unlikely that patients who do not respond to platinum-based Cx would have benefited from first-line checkpoint inhibition as the addition of a checkpoint inhibitor to platinum-based Cx did not significantly improve overall response rates (ORR) in the IMvigor130 study (47% vs. 44%) [4]. According to these findings, FDA approved avelumab for the maintenance treatment in patients that has not progressed with first-line platinum-based Cx.

Adjuvant setting after radical cystectomy (RC)

Adjuvant atezolizumab in locally advanced muscle-invasive bladder cancer after RC

IMvigor010 is the first phase 3 trial evaluating the benefit of adjuvant atezolizumab versus observation in patients with extravesical disease or pN+ status not treated with neoadjuvant chemotherapy (NAC) or patients with pathological nonresponse to NAC (≥ypT2 or ypN+) after RC. Briefly, IMvigor010 did not met its primary endpoint of disease-free survival,

Table 1 Overview of results from the phase 3 JAVELIN Bladder 100 trial [5] in comparison to the phase 2 HCN GU14-182 study [6] presented at ASCO 2019

	JAVELIN Bladder 100 (Powles et al., Abstract LBA1), ASCO 2020	HCRN GU14-182 (Galsky et al., Abstract #4504), ASCO 2019
Phase	3	2
Population	700	107
Number of cycles of platinum-based 1st line Cx	4–6	≤8
Cisplatin-based Cx	55.4%	70.1%
Best response to 1st line Cx		
CR/PR	504 (72%)	76 (71%)
SD	196 (28%)	31 (29%)
Visceral metastases	55%	66%
IO maintenance after Cx response	Avelumab 10 mg/kg q2w	Pembrolizumab 200 mg q3w up to 24 months
Comparator	BSC	Placebo
Crossover allowed at progression	No	Yes (51.9%)
Median OS (months)	21.4 vs. 14.3	22.0 vs. 18.7
Median PFS (months)	3.7 vs. 2.0	5.4 vs. 3.0
Any grade ≥4 irAEs	0%	11%
Treatment discontinuation due to AEs	11.9%	–
Median FU (months)	*19.6*	*14.7*

AE adverse event; *BSC* best supportive care; *Cx* chemotherapy; *OS* overall survival; *PFS* progression-free survival; *FU* follow-up; *CR* complete response; *PR* partial response; *SD* stable disease; *IO* immunoncology

Table 2 Results of the phase II OMNIVORE [9] and HCRN GU16-260 [10] trial testing efficacy of nivolumab induction followed by ipilimumab rescue in patients without response to nivolumab monotherapy

	OMNIVORE (McKay et al., Abstract #5005)	HCRN GU16-260 (Atkins et al., Abstract #5006)
Phase	2	2
Population (n)	83	123
ccRCC (%)	95%	100%
1st line (n)	42	123
≥2nd line (n)	41	–
IMDC 1st line, n (%)		
Good	13 (31%)	30 (24%)
Intermediate	22 (52%)	80 (65%)
Poor	7 (17%)	12 (10%)
A) Nivolumab induction	240 mg q2w or 480 mg q4w for 6 months	240 mg q2w × 6 360 mg 3 weeks × 4 480 mg q4w ~ 11 months
Response to Nivo induction		
ORR	7/42 (17%)	39/123 (32%)
CR	0%	6%
B) Ipilimumab rescue	*Nivolumab + Ipilimumab × 2*	*Nivolumab + Ipilimumab × 4*
Response to Ipi rescue		
ORR	2/57 (4%)	4/30 (13%)
CR	0%	0%
Median FU (months)	19.5	15.9

ccRCC clear cell renal cell carcinoma; *CR* complete response; *IMDC* International Metastatic RCC Database Consortium; *ORR* objective response rate; *FU* follow-up

and no prespecified subgroup (including high PD-L1 expression) showed treatment benefit with adjuvant atezolizumab. OS follow-up is still ongoing (median follow-up: 21.9 months) [7].

Renal cell carcinoma

First-line therapy in metastatic renal cell carcinoma

Updated efficacy and safety data from pembrolizumab plus axitinib

The KEYNOTE-426 continues to show efficacy in the treatment of untreated, advanced metastatic renal cell carcinoma (mRCC) compared with sunitinib in the first-line setting. The 24-month OS rate was 74% vs. 66% ($p<0.001$), the 24-month PFS rate 38% vs. 27% ($p<0.0001$), the objective response rate (ORR) 60% vs. 40% ($p<0.0001$) and the complete response (CR) rate 9% vs. 3%, respectively. The combination benefitted intermediate- and poor-risk patients the most, whereas patients with IMDC favorable risk did not significantly benefit from this combination (24-month OS rate: 85% vs. 88%; 24-month PFS rate: 45% vs. 35%; ORR: 69.6% vs. 50.4%). Exploratory landmark analysis demonstrated that greater depth of tumor shrinkage was linked with increased OS in the combination arm. In detail, patients with ≥80% tumor reduction had similar survival as patients with CR within 6 months after randomization [8].

Nivolumab monotherapy followed by ipilimumab salvage

A novel sequential strategy (nivolumab monotherapy and ipilimumab salvage in patients without response to nivolumab monotherapy) was presented by two phase 2 trials (OMNIVORE and HCRN GU16-260) during ASCO 2020. Results of both trials are presented in Table 2. In summary, these studies provide evidence that nivolumab monotherapy (ORR: 17–32%, CR: 0–6%) as well as ipilimumab rescue strategy (ORR: 4–13%, CR: 0%) are less effective as upfront combination therapies [9, 10].

Immunotherapy biomarker analyses in mRCC

Exploratory biomarker analyses—including immunohistochemistry of PD-L1 (tumor cells and combined positive score), whole exome and RNA sequencing—from CheckMate214 demonstrated that genomic biomarkers and immune-related gene signatures were not predictive for PFS or OS with nivolumab plus ipil-

imumab. Additionally, no significant differences were noticed for OS in patients with high vs. low angiogenesis scores. Thus, immunotherapy biomarkers in RCC are lacking and this analysis corroborate the fact that further research is needed to identify genetic mutations involved in RCC tumors [11].

New therapeutic targets in hereditary RCC

Von Hippel–Lindau disease

Results from the first oral inhibitor of hypoxia-inducible factor (HIF)-2α (MK-6482) in patients with von Hippel–Lindau (VHL) disease and ≥1 measurable localized clear-cell RCC demonstrated high efficacy, as 87% of patients had a significant decrease in size of target lesions. In terms of objective response, 28% had a confirmed ORR. MK-6482 was also well tolerated as only 3% of patients discontinued therapy due to adverse events [12]. According to this data, MK-6482 was approved by the FDA for the treatment of patients with VHL-associated RCC who have tumors of less than 3 cm, unless surgery is necessitated.

Prostate cancer

Imaging in biochemically recurrent prostate cancer

^{18}F-DCFPyL-PET/CT

^{18}F-DCFPyL, a lysine-linked, urea-based small molecule that targets the extracellular domain of PSMA with high affinity, can detect prostate cancer at low PSA and, thus, is a promising diagnostic tool to detect biochemical recurrence and identify areas of occult metastasis [13, 14]. CONDOR showed diagnostic superiority of Pyl-PET/CT to conventional imaging in 208 men with biochemically relapsed prostate cancer after definitive therapy for localized disease and negative SOC imaging. The median PSA was low with 0.8 ng/ml, about half the patients had a PSA <1 ng/ml and 70% had a PSA level <2 ng/ml. The primary endpoint (correct localization rate) was met confirming excellent positive predictive values of 89%, 87% and 84% for the three independent readers, regardless of PSA values. Moreover, Pyl-PET/CT led to clinical management changes in 64% of patients due to PSMA-PET findings. Finally, PyL was well tolerated, with headache as the most common adverse event in 1.9% [15].

Advanced hormone-sensitive prostate cancer

Relugolix as the first oral GNRH receptor antagonist

Relugolix is the first oral GNRH receptor antagonist, being evaluated in the HERO phase 3 trial in 934 patients with hormone-sensitive advanced prostate cancer to receive relugolix 120 mg orally once daily after a single one loading dose of 360 mg ($n=622$) or leuprolide acetate 3-month depot injection ($n=308$). The primary endpoint was to achieve and maintain serum testosterone suppression to castration (<50 ng/dL) through 48 weeks. Key secondary endpoints included castration rates at day 4 and 15, profound castration (<20 ng/dL) rates at day 15, PSA response rate at day 15, and FSH levels at week 24. In all, 96.7% of men on relugolix achieved and maintained castration through 48 weeks compared to 88.8% on leuprolide, demonstrating noninferiority ($p<0.0001$) of relugolix to leuprolide. All secondary efficacy endpoints demonstrated the superiority of relugolix over leuprolide ($p<0.0001$). In the testosterone recovery subset ($n=184$), relugolix had faster testosterone recovery 90 days after therapy discontinuation. Finally, the incidence of major adverse cardiovascular events (MACE) was lower in the relugolix group than in the leuprolide group (2.9% vs. 6.2%). In patients with a history of MACE, a MACE event occurred less in patients on relugolix compared to patients on leuprolide (3.6% vs. 17.8%), resulting in a 54% reduction in risk of MACE on relugolix [16].

Nonmetastatic castration-resistant prostate cancer

Efficacy and safety update for darolutamide, enzalutamide and apalutamide

Final survival data of three phase 3 trials (ARAMIS, PROSPER and SPARTAN) evaluating efficacy and patient risk–benefit of second-generation anti-androgens (darolutamide, enzalutamide and apalutamide) versus placebo for the treatment of nonmetastatic castration-resistant prostate cancer (nmCRPC) were presented [17–19]. A detailed overview of outcomes of all three randomized clinical trials are described in Table 3. In summary, all three second-generation anti-androgens significantly delayed (i) time to pain progression, (ii) time to first chemotherapy and (iii) time to first symptomatic skeletal event, reducing risk of death in up to 31% and prolonging OS for 12–14 months. Treatment-related adverse events such as hypertension, hot flush, bone fracture, rash or fatigue were similar between the three agents.

Metastatic castration-resistant prostate cancer

177Lu-PSMA-617 theranostics (LuPSMA) versus cabazitaxel post docetaxel

TheraP is the first randomized phase 2 study of LuPSMA determing its activity and safety relative to the SOC option cabazitaxel in metastatic castration-resistant prostate cancer (mCRPC) post docetaxel. Patients were randomized 1:1 and treated with LuPSMA ($n=99$) or cabazitaxel ($n=101$). The primary endpoint (decrease in PSA ≥50% from baseline [PSA 50-RR]) was met demonstrating improved rates of 50% reduction in PSA for LuPSMA relative to cabazitaxel, resulting in a 29% absolute improvement in this rate. The secondary endpoint (PSA progression-free survival) has currently not met criteria to reject the null hypothesis (HR = 0.69; $p=0.02$). Concerning side effects, the most

Table 3 Updated outcome and descriptive parameters of the three phase 3 trials evaluating efficacy of enzalutamide [17], darolutamide [18] and apalutamide [19] versus placebo in the treatment of nonmetastatic castration-resistant prostate cancer

	SPARTAN (Small et al., Abstract #5516)	ARAMIS (Fizazi et al., Abstract #5514)	PROSPER (Sternberg et al., Abstract #5515)
Phase	3	3	3
Population (*n*)	1207	1509	1401
Anti-androgen	Apalutamide	Darolutamide	Enzalutamide
Comparator	Placebo	Placebo	Placebo
Survival events (death), %	428 (35%)	254 (17%)	466 (33%)
Reduction in risk of death, %	22%	31%	27%
Median OS (months)	73.9 vs. 59.9 HR: 0.78; $p = 0.016$	NR vs. NR HR: 0.69; $p = 0.0003$	67 vs. 56.3 HR: 0.73; $p = 0.0011$
Time to pain progression	HR: 0.57	HR: 0.65	–
Time to first chemotherapy	HR: 0.63	HR: 0.58	33% vs. 65%
Time to first SSE	N/A	HR: 0.48	–
Any grade ≥3 AEs	55.9%	26.3%	48%
Therapy discontinuation (%)	15.2% vs. 8.4%	9%	17% vs. 9%
Median FU (months)	*52*	*29*	*48*

AE adverse event; *FU* follow-up; *OS* overall survival; *NR* not reached; *SSE* symptomatic skeletal event; *HR* hazard ratio

common from LuPSMA were dry eyes, dry mouth and thrombocytopenia. The most common grade 3 or 4 toxicity was thrombocytopenia (11%) [20].

Take Home Messages

- Avelumab as first-line maintenance therapy will be the new standard of care for patients with metastatic urothelial cancer who have not progressed on platinum-based induction chemotherapy.
- Concerning first-line therapy of mRCC, updated analyses of the KEYNOTE-426 (pembrolizumab plus axitinib) continues to show therapeutic superiority compared with sunitinib, especially in intermediate and poor IMDC risk patients.
- ^{18}F-DCFPyL-PET/CT is an encouraging diagnostic tool in biochemically recurrent prostate cancer to detect occult metastases regardless of PSA levels.
- In advanced prostate cancer, relugolix is the first oral GNRH receptor antagonist demonstrating rapid, sustained suppression of testosterone superior to leuprolide, with lower risk of major cardiovascular adverse events.
- Second-generation antiandrogens continue to show overall survival benefit versus placebo in the treatment of nonmetastatic castration-resistant prostate cancer.

Funding Open access funding provided by University of Innsbruck and Medical University of Innsbruck.

Conflict of interest R. Pichler, G. Tulchiner, and J. Bektic declare that they have no competing interests.

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