633P Tolerability and treatment response to darolutamide (DARO) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) in the phase III ARAMIS trial

K. Fizazi[1], N. Shore[2], M.R. Smith[3], T.L. Tammela[4], M-A. Le Berre[5], O. Petrenciuc[6], C. Zurth[7], I. Kuss[7]

[1]Institut Gustave Roussy, University of Paris-Saclay, Villejuif, France; [2]Carolina Urologic Research Center, Atlantic Urology Clinics, Myrtle Beach, SC, USA; [3]Genitourinary Malignancies Program, Massachusetts General Hospital Cancer Center and Harvard Medical School, Boston, MA, USA; [4]Tampere University Hospital, University of Tampere, Tampere, Finland; [5]SAS, Bayer Healthcare, Loos, France; [6]Pharmaceuticals, Bayer Healthcare, Whippany, NJ, USA; [7]Pharmaceuticals, Bayer AG, Berlin, Germany

Background: Androgen receptor inhibitors (ARIs) approved for treating nmCRPC are associated in varying degrees with certain adverse events (AEs), e.g., fatigue, risk of falls or rash. In phase III studies, dose modification and discontinuation due to AEs was higher with ARIs vs placebo. Reduced dose, compliance patterns and treatment fidelity may impact drug efficacy. Tolerability of DARO and association of prostate-specific antigen (PSA) decline in response to DARO treatment with metastasis-free survival (MFS) in the ARAMIS trial are reviewed.

Methods: 1509 patients with nmCRPC and PSA doubling time (PSADT) ≤10 months were randomised 2:1 to DARO 600 mg twice daily (n=955) or placebo (PBO; n=554) while continuing androgen deprivation therapy. AEs and dose modifications were assessed every 16 weeks. The association between PSA decline from baseline in response to DARO treatment and MFS was evaluated using the Cox proportional hazards model. An association with overall survival will be investigated.

Results: DARO was well tolerated; 97.2% of patients on DARO received the full planned dose. Patients treated with DARO did not have an increase in treatment discontinuation due to AEs vs PBO (8.9% vs 8.7%). Few patients had dose modifications for any reason (15.2% vs 9.7% for DARO vs PBO). Almost all of the patients on DARO with discontinuation due to AEs or dose modifications were able to resume and re-establish the indicated dose (91.7% vs 88.9% for DARO vs PBO). In the ARAMIS trial, 50.9% of patients on DARO had a maximal PSA response (≥90% decrease from baseline) vs 1.8% of patients on PBO. Pharmacodynamic modelling showed that longer MFS was positively associated with maximum decrease in PSA from baseline.

Conclusions: Favourable tolerability of DARO at the recommended dose of 600 mg twice daily was associated with low rates of dose reduction and treatment discontinuation, which in turn may lead to extended survival with longer duration of treatment with DARO. It is important to further assess the real-world tolerance of different ARIs in men with nmCRPC.

Clinical trial identification: NCT02200614.

Editorial acknowledgement: Editorial assistance was provided by Lucy Smithers, PhD, Charlotte Simpson, PhD, and Annabel Ola, MSc, all of Scion, London, and supported by Bayer.

Legal entity responsible for the study: Bayer AG and Orion Pharma.

Funding: Bayer AG and Orion Pharma.

Disclosure: K. Fizazi: Honoraria (self), Non-remunerated activity/ies, KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche: Janssen; Honoraria (self), Non-remunerated activity/ies, KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. : Amgen; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. Bayer; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. Astellas Pharma; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. Sanofi; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. : Orion Pharma; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. Curevac; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche: AstraZeneca; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. : ESSA; Honoraria (self), KF has received personal fees and non-financial support from Janssen and Amgen, and personal fees from Bayer, Astellas Pharma, Sanofi, Orion Pharma, Curevac, AstraZeneca, ESSA, and Roche. N. Shore: Honoraria (self), Non-remunerated activity/ies, NS has received personal fees and non-financial support from Bayer and Janssen: Bayer; Honoraria (self), Non-remunerated activity/ies, NS has received personal fees and non-financial support from Bayer and Janssen: Janssen; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Tolmar; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Ferring; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Medivation; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Amgen; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Pfizer; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: AstraZeneca; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Genentech/Roche; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Myovant Sciences; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Astellas Pharma; Honoraria (self), personal fees from Tolmar, Ferring, Medivation, Amgen, Pfizer, AstraZeneca, Genetech/Roche, Myovant Sciences, Astellas Pharma, and Merck: Merck; Non-remunerated activity/ies, non-financial support from Dendreon: Dendreon. M.R. Smith: Honoraria (self), Research grant/Funding (self), MRS has received grants and personal fees from Bayer, Amgen, Janssen, and Lilly: Bayer; Honoraria (self), Research grant/Funding (self), MRS has received grants and personal fees from Bayer, Amgen, Janssen, and Lilly: Amgen; Honoraria (self), Research grant/Funding (self), MRS has received grants and personal fees from Bayer, Amgen, Janssen, and Lilly: Janssen; Honoraria (self), Research grant/Funding (self), MRS has received grants and personal fees from Bayer, Amgen, Janssen, and Lilly: Lilly; Honoraria (self), personal fees from Astellas Pharma, Novartis, and Pfizer: Astellas Pharma; Honoraria (self), personal fees from Astellas Pharma, Novartis, and Pfizer: Novartis; Honoraria (self), personal fees from Astellas Pharma, Novartis, and Pfizer: Pfizer. T.L. Tammela: Research grant/Funding (self): Bayer; Research grant/Funding (self): Lidds AB; Research grant/Funding (self): Astellas Pharma; Honoraria (self): Janssen. M-A. Le Berre: Full/Part-time employment: Bayer Healthcare. O. Petrenciuc: Full/Part-time employment: Bayer Healthcare. C. Zurth: Full/Part-time employment: Bayer AG. I. Kuss: Full/Part-time employment: Bayer AG.

https://doi.org/10.1016/j.annonc.2020.08.892

634P Impact of metastatic lymph node burden on survival in patients with mHSPC from the "docetaxel comparison" of the STAMPEDE trial

A.M. Haran[1], A. Ali[2], A. Hoyle[1], T. Hambrock[3], Y. Jain[3], C. Brawley[4], C. Amos[4], J. Calvert[4], G. Attard[5], H. Douis[6], M.K. Parmar[7], M.R. Sydes[4], N.D. James[8], N.W. Clarke[1]

[1]The Departments of Surgery and Urology, The Christie and Salford Royal Hospitals, Manchester, UK; [2]Genito-Urinary Cancer Research Group, Division of Cancer Sciences, The University of Manchester, Manchester, UK; [3]Department of Radiology, The Christie NHS Foundation Trust, Manchester, UK; [4]MRC Clinical Trials Unit at UCL, Institute for Clinical Trials and Methodology, London, UK; [5]Research Department of Oncology, University College London Cancer Institute, London, UK; [6]Department of Radiology, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK; [7]MRC Clinical Trials Unit at UCL, Institute for Clinical Trials and Methodology, London, London, UK; [8]Oncology, The Royal Marsden NHS Foundation Trust and Institute of Cancer Research, London, UK

Background: Increasing metastatic burden is associated with worsening prognosis. However, none of the current burden definitions consider metastatic lymph node volume, number and distribution. In this exploratory analysis of cross-sectional baseline staging scans from the STAMPEDE "docetaxel comparison" we evaluate metastatic lymph node burden as a prognostic factor.

Methods: 629 patients with metastatic disease randomised between 2005 and 2013 to Arm A (androgen deprivation therapy (ADT)) or Arm C (ADT + docetaxel) with available baseline scans were analysed. Lymph node analysis was done using the UK Royal College of Radiologists diagnostic criteria with central review of CT/MRI scans performed jointly by a radiologist and urologist. Annotation of lymph node number and size was completed for both regional and non-regional sites. Overall survival (OS) and failure-free survival (FFS) were used as endpoints. Hazard ratios were obtained separately for each treatment group using multivariable Cox regression analysis adjusted for age (<70 or ≥70), WHO PS (0 or 1-2), nodal status (N0, N1 or NX), NSAID or aspirin use (uses either or no), Gleason score (≤7, 8-10 or unknown), bone metastases counts (<5 or ≥5) and concomitant metastatic site (only metastatic lymph nodes, bone (+/-NRLN) or any visceral (+/-bone)).

Results: 178/629 (29%) patients had nodal metastases with a median maximum diameter of 2.1 (range 1.0 to 8.1) cm and median minimum diameter of 1.2 (range 0.9 to 3.9) cm. 87/629 (14%) patients had 5 or more nodes. Patients with ≥5 metastatic nodes had worse OS compared to patients with <5 nodes in both the ADT group (HR=1.61, 95%CI 1.12−2.31, p=0.013; 5yr KM estimated OS 27% for ≥5 NRLN vs 40% for <5NRLN) and ADT + docetaxel group (HR=1.79, 95%CI 1.10−2.92, p=0.024; 5yr OS 35% vs 53%). FFS was also worse for patients with ≥5 nodes in the ADT group (HR=1.51, 95%CI 1.07−2.14, p=0.024) and the ADT + docetaxel group (HR=1.78, 95%CI 1.12−2.81, p=0.018).

Conclusions: Increased metastatic burden of 5 or more nodal metastases is an independent prognostic factor for poorer outcomes in patients with mHSPC treated with ADT or ADT + docetaxel and should be considered for inclusion along with bone metastases counts in future metastatic burden definitions.

Clinical trial identification: NCT00268476; ISRCTN78818544.

Legal entity responsible for the study: University of Manchester and the Medical Research Council Clinical Trials Unit (MRC CTU), University College London.

Funding: Has not received any funding.

Disclosure: G. Attard: Advisory/Consultancy, Personal fees & non-financial support outside the submitted work: Sanofi Aventis; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Astellas; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Medivation; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Abbott Laboratories; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Essa Pharmaceuticals; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Bayer Healthcare Pharmaceuticals; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Janssen; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Roche/Ventana; Non-remunerated activity/ies, Personal fees & non-financial support outside the submitted work: Pfizer; Advisory/Consultancy, Personal fees: Novartis; Advisory/Consultancy, Personal fees: Millennium Pharmaceuticals; Advisory/Consultancy, Personal fees: Takeda; Advisory/Consultancy, Personal fees: Veridex; Advisory/Consultancy, Personal fees and share of royalty income from abiraterone : Institute of Cancer Research (ICR); Research grant/Funding (self), Grants outside of the submitted work: AstraZeneca; Research grant/Funding (self), Grants outside of the submitted work: Arno Therapeutics; Research grant/Funding (self), Grants

outside of the submitted work: Innocrin Pharma; Research grant/Funding (self), Grants outside of the submitted work: Veridex. H. Douis: Research grant/Funding (self), Grant during the conduct of the study: Janssen. M.K. Parmar: Research grant/Funding (institution), Non-remunerated activity/ies: Astellas; Research grant/Funding (self), Non-remunerated activity/ies: Clovis Oncology; Research grant/Funding (self), Non-remunerated activity/ies: Novartis; Research grant/Funding (self), Non-remunerated activity/ies: Pfizer; Research grant/Funding (institution), Non-remunerated activity/ies: Sanofi. M.R. Sydes: Non-remunerated activity/ies, Grants and non-financial support outside the submitted work: Astellas; Non-remunerated activity/ies, Grants and non-financial support outside the submitted work: Clovis Oncology; Non-remunerated activity/ies, Grants and non-financial support outside the submitted work: Novartis; Non-remunerated activity/ies, Grants and non-financial support outside the submitted work: Pfizer; Non-remunerated activity/ies, Grants, personal fees and non-financial support outside the submitted work: Janssen; Advisory/Consultancy, Personal fees outside the submitted work: Eli Lilly. N.D. James: Leadership role, other: Sanofi; Leadership role, other: Novartis; Advisory/Consultancy, Non-remunerated activity/ies, grants, personal fees and non-financial support: Janssen. N.W. Clarke: Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: Sanofi Aventis; Advisory/Consultancy, Received fees for consultation and lectureships during this study and outside of submitted work : Janssen; Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: Astellas; Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: Pfizer; Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: AstraZeneca; Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: Bayer; Advisory/Consultancy, Received fees for consultation and lectureships outside the submitted work: Ferring Pharmaceuticals. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.893

635P ARCHES - The role of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo (PBO) in metastatic hormone-sensitive prostate cancer (mHSPC): Post hoc analyses of efficacy by baseline prostate-specific antigen (PSA) levels

A. Alcaraz[1], R.Z. Szmulewitz[2], N. Shore[3], E.D. Crawford[4], D.P. Petrylak[5], J. Holzbeierlein[6], A. Villers[7], A.A. Azad[8], B. Alekseev[9], T. Iguchi[10], F. Gomez-Veiga[11], B. Rosbrook[12], J. Sugg[13], G.P. Haas[14], A. Stenzl[15], A.J. Armstrong[16]

[1]Urology, Hospital Clinic de Barcelona, Barcelona, Spain; [2]Medicine, The University of Chicago, Chicago, IL, USA; [3]Urology, Carolina Urologic Research Center, Myrtle Beach, SC, USA; [4]Urology, University of California, San Diego, CA, USA; [5]Medical Oncology, Yale Cancer Center, New Haven, CT, USA; [6]Urology, The University of Kansas Medical Center, Kansas City, KS, USA; [7]Urology, University Hospital Centre, Lille University, Lille, France; [8]Oncology, Monash Health, Melbourne, Australia; [9]Oncology, Hertzen Moscow Cancer Research Institute, Moscow, Russian Federation; [10]Urology, Osaka City University Graduate School of Medicine, Osaka, Japan; [11]Urology, Hospital Universitario de Salamanca, GITUR-IBSAL, Salamanca, Spain; [12]Clinical Statistics, Pfizer Inc., San Diego, CA, USA; [13]Biostatistics, Astellas Pharma Inc., Northbrook, IL, USA; [14]Global Medical Affairs, Astellas Pharma Inc., Northbrook, IL, USA; [15]Urology, University Hospital, Eberhard Karls University, Tuebingen, Germany; [16]School of Medicine, Duke Cancer Institute Center for Prostate and Urologic Cancers, Durham, NC, USA

Background: The clinical benefit of ENZA + ADT versus PBO + ADT in reducing the risk of radiographic progression-free survival (rPFS) events has been shown in men with mHSPC, regardless of baseline PSA levels (> or ≤ median value) [ARCHES; NCT02677896]. Here, the aim was to further analyze efficacy outcomes by various baseline PSA categories.

Methods: Patients with mHSPC were randomized 1:1 to ENZA (160 mg/day) + ADT or PBO + ADT. Prior ADT and up to six cycles of prior docetaxel were permitted before baseline assessment of PSA levels and study treatment initiation. *Post hoc* analyses of the primary endpoint (rPFS) and other secondary endpoints by different baseline PSA categories at time of randomization were conducted to assess the efficacy of ENZA + ADT.

Results: In the overall population (N=1150), >90% received prior ADT and 18% had prior docetaxel treatment. Median duration (range) of prior ADT was 1.6 months (0.03–55.3) for ENZA + ADT patients versus 1.6 months (0.03–198.8) for PBO + ADT patients. Of the overall population with available baseline PSA values (n=1146), 135 patients had ≤0.2 μg/L, 388 patients had >0.2–4 μg/L, and 623 patients had >4 μg/L PSA at baseline (Table). Across these subgroups, the beneficial effect of ENZA + ADT on rPFS was observed, irrespective of baseline PSA (Table); similar results were also observed with other endpoints such as time to PSA progression and time to castration resistance.

Conclusions: These *post hoc* analyses demonstrate the clinical benefit of ENZA + ADT versus PBO + ADT based on rPFS and secondary clinical endpoints in patients with mHSPC, irrespective of patients' baseline PSA values.

Table: 635P

	PSA baseline categories		
Endpoint, HR (95% CI)[a]	**≤0.2 μg/L (n=63;[b] n=72[c])**	**>0.2–4 μg/L (n=194;[b] n=194[c])**	**>4 μg/L (n=315;[b] n=308[c])**
rPFS[d]	0.60 (0.27, 1.32)	0.32 (0.20, 0.51)	0.41 (0.30, 0.57)
Time to PSA progression[e]	0.21 (0.05, 1.00)	0.12 (0.06, 0.25)	0.21 (0.14, 0.30)
Time to castration resistance	0.43 (0.20, 0.96)	0.26 (0.17, 0.41)	0.27 (0.20, 0.37)

[a]HR <1 favors ENZA + ADT; HR >1 favors PBO + ADT;
[b]ENZA + ADT;
[c]PBO + ADT;
[d]Assessed by independent central review or death within 24 weeks of treatment discontinuation;
[e]PSA progression was defined as a ≥25% increase and an absolute increase of ≥2 ng/mL above the nadir, confirmed by a second consecutive value ≥3 weeks later CI, confidence interval; HR, hazard ratio

Clinical trial identification: ARCHES; NCT02677896.

Editorial acknowledgement: Medical writing and editorial assistance were provided by Beatrice Vetter-Ceriotti, PhD, and Lauren Smith from Complete HealthVizion, funded by the study sponsors.

Legal entity responsible for the study: Astellas Pharma Inc. and Pfizer Inc.

Funding: This study was funded by Astellas Pharma Inc. and Pfizer Inc., the co-developers of enzalutamide.

Disclosure: A. Alcaraz: Travel/Accommodation/Expenses: Astellas Pharma; Travel/Accommodation/Expenses: Olympus; Travel/Accommodation/Expenses: Ipsen; Travel/Accommodation/Expenses: Bayer; Travel/Accommodation/Expenses: Janssen. R.Z. Szmulewitz: Advisory/Consultancy: AstraZeneca; Advisory/Consultancy, Research grant/Funding (self): Abbvie; Advisory/Consultancy: Exelixis; Advisory/Consultancy: Merck; Advisory/Consultancy: Amgen; Advisory/Consultancy, Research grant/Funding (self): Janssen Oncology; Advisory/Consultancy: Sanofi; Honoraria (self), Advisory/Consultancy, Research grant/Funding (self): Astellas Pharma Inc. ; Advisory/Consultancy: Pfizer; Travel/Accommodation/Expenses: Corcept Therapeutics; Licensing/Royalties, Patent licensed by University of Chicago of which I am co-inventor to Corcept Therapeutics for combination AR/GR inhibition in prostate cancer: University of Chicago; Research grant/Funding (self): Incyte; Research grant/Funding (self): Macrogenics. N. Shore: Advisory/Consultancy, Speaker Bureau/Expert testimony: Bayer; Advisory/Consultancy: Janssen Scientific Affairs; Advisory/Consultancy, Speaker Bureau/Expert testimony: Dendreon; Advisory/Consultancy: Tolmar; Advisory/Consultancy: Ferring; Advisory/Consultancy: Medivation / Astellas; Advisory/Consultancy: Amgen; Advisory/Consultancy: Pfizer; Advisory/Consultancy: AstraZeneca; Advisory/Consultancy: Genentech / Roche; Advisory/Consultancy: Myovant Sciences; Advisory/Consultancy: Astellas Pharma Inc; Advisory/Consultancy: Merck; Speaker Bureau/Expert testimony: Janssen. E.D. Crawford: Speaker Bureau/Expert testimony: Ferring; Speaker Bureau/Expert testimony: Bayer; Non-remunerated activity/ies, Astellas provided medical writing for this abstract: Astellas Pharma Inc. . D.P. Petrylak: Advisory/Consultancy, Research grant/Funding (institution): Bayer; Advisory/Consultancy: Exelixis; Advisory/Consultancy, Research grant/Funding (institution): Pfizer; Advisory/Consultancy, Research grant/Funding (institution): Roche; Advisory/Consultancy: Astellas Pharma Inc.; Advisory/Consultancy, Research grant/Funding (institution): AstraZeneca; Advisory/Consultancy, Research grant/Funding (institution): Lilly; Advisory/Consultancy: Amgen; Advisory/Consultancy: Boehringer Ingelheim; Advisory/Consultancy, Research grant/Funding (institution): Bristol-Myers Squibb; Advisory/Consultancy, Research grant/Funding (institution): Clovis Oncology; Advisory/Consultancy: Incyte; Advisory/Consultancy: Janssen; Advisory/Consultancy: Pharmacyclics; Advisory/Consultancy, Research grant/Funding (institution): Seattle Genetics; Advisory/Consultancy: Urogen Pharma; Advisory/Consultancy, Research grant/Funding (institution): Advanced Accelerator Applications; Advisory/Consultancy: Ipsen; Speaker Bureau/Expert testimony: Celgene; Speaker Bureau/Expert testimony, Research grant/Funding (institution): Sanofi; Shareholder/Stockholder/Stock options: Bellicum Pharmaceuticals; Shareholder/Stockholder/Stock options: Tyme; Research grant/Funding (institution): Progenics; Research grant/Funding (institution): Endocyte; Research grant/Funding (institution): Genentech; Research grant/Funding (institution): Merck; Research grant/Funding (institution): Astellas Medivation; Research grant/Funding (institution): Novartis; Research grant/Funding (institution): Innocrin Pharma; Research grant/Funding (institution): MedImmune. J. Holzbeierlein: Research grant/Funding (institution): Astellas Pharma Inc. ; Research grant/Funding (institution): MDxHealth. A. Villers: Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: Astellas Pharma Inc. ; Travel/Accommodation/Expenses: Janssen-Cilag; Research grant/Funding (institution): IPSEN. A.A. Azad: Honoraria (self), Advisory/Consultancy: Janssen; Honoraria (self), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Astellas Pharma Inc. ; Honoraria (self), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): Novartis; Honoraria (self), Advisory/Consultancy: Tolmar; Honoraria (self), Speaker Bureau/Expert testimony: Bayer; Honoraria (self), Advisory/Consultancy: Telix Pharmaceuticals; Honoraria (self), Speaker Bureau/Expert testimony: Amgen; Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: Sanofi; Advisory/Consultancy, Research grant/Funding (institution): AstraZeneca; Advisory/Consultancy, Research grant/Funding (institution): Pfizer; Advisory/Consultancy, Research grant/Funding (institution): Bristol-Myers Squibb; Research grant/Funding (institution), Travel/Accommodation/Expenses: Merck Serono; Research grant/Funding (institution): GlaxoSmithKline; Research grant/Funding (institution): Aptevo Therapeutics; Research grant/Funding (institution): MedImmune; Research grant/Funding (institution): Bionomics; Research grant/Funding (institution): Synthorx. B. Alekseev: Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: AstraZeneca; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Astellas Pharma Inc. ; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Bayer; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Bristol-Myers Squibb; Advisory/Consultancy, Speaker Bureau/Expert testimony: Ferring; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Janssen; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self): Merck; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Sanofi; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: Pfizer; Travel/Accommodation/Expenses: MSD; Research grant/Funding (self): Bavarian Nordic; Research grant/Funding (self): ICON Clinical Research. T. Iguchi: Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self): Astellas Pharma Inc. ; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self): Bayer Yakuhin; Advisory/Consultancy, Speaker Bureau/Expert testimony: Janssen; Speaker Bureau/Expert testimony: Sanofi. F. Gomez-Veiga: Non-remunerated activity/ies, Astellas Pharma Inc. provided medical writing for preparation of this abstract: Astellas Pharma Inc. B. Rosbrook: Shareholder/Stockholder/Stock options, Full/Part-time employment: Pfizer. J. Sugg: Full/Part-time employment: Astellas Pharma Inc.; Shareholder/Stockholder/Stock options: AstraZeneca. G.P. Haas: Full/Part-time employment: Astellas Pharma Inc. A. Stenzl: Advisory/Consultancy, Travel/Accommodation/Expenses: Ipsen; Advisory/Consultancy: Roche; Advisory/Consultancy, Research grant/Funding (self), Travel/Accommodation/Expenses: Janssen; Advisory/Consultancy: Alere; Advisory/Consultancy: Bristol-Myers Squibb; Advisory/Consultancy: Steba Biotech; Travel/Accommodation/Expenses: Sanofi/Aventis; Travel/Accommodation/Expenses: CureVac; Travel/Accommodation/Expenses: Ferring; Speaker Bureau/Expert testimony: GBA; Licensing/Royalties: Patent A290/99 Implantable incontinence device; Licensing/Royalties: AT00/0001:C-Trap, implantable device to treat urinary incontinence; Licensing/Royalties: 2018/6579 Gene-expression signature for subtype and prognostic prediction of renal cell carcinoma; Research grant/Funding (self): Karl Storz; Research grant/Funding (self): Astellas Pharma Inc. ; Research grant/Funding (self): AstraZeneca; Research grant/Funding (self): Medivation. A.J.