Sessions scientifiques XV, XVI, XVII, XVIII, XIX
Dimanche (a.m.), 11 novembre 2012

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Session scientifique XV

Objectifs éducatifs : À la fin de cette session les participants apprendront le nouvel algorithme canadien de la prise en charge des symptomes urinaires bas de remplissage chez l'homme.

8 h 40 - 9 h 00
Revue des lignes directrice de l'hyperactivité vésicale chez l'homme - CUA/AUC
Conférencier : Bruno Laroche
Modérateur : Le Mai Tu

9 h 10 - 9 h 45
Programme d'auto-formation des compétences transverseles en ligne
Conférencier : Fred Saad
Modérateur : François Benard

Session scientifique XVI

Objectifs éducatifs :
À la fin de cette session, le participant pourra :
- Proposer l'investigation de base pour confirmer le diagnostic.
- Établir un plan de traitement efficace avec la famille.
- Identifier les situations spécifiques nécessitant une réference en urologie-pédiatrique.

10 h 00 - 10 h 30
Dysfonction d'élimination
Conférenciers : Stéphane Bolduc
Modérateur : Diego Barrieras

Session scientifique XVII

Objectifs éducatifs : À la fin de cette session, le participant connaîtra les nouveaux développements en recherche clinique et fondamentale.
Modérateur : Frédéric Pouliot

10 h 40 - 10 h 49
Effect of denosumab on prolonging bone-metastasis free survival in men with non-metastatic castrate-resistant prostae cancer presenting with aggressive prostate-specific antigen kinetics
Fred Saad;[1] Matthew R. Smith;[2] Neal Shore;[3] Stephane Oudard;[4] Kurt Miller;[5] Bertrand Tombal;[6] Paul Sieber;[7] Karim Fizazi;[8] Peter Van Veldhuizen;[9] Ronaldo Damiao;[10] Gavin Marx;[11] Juan Morote;[12] Amy Feng;[13] Roger Dansey;[13] Carsten Goessl[13]
[1]University of Montreal Hospital Centre, CRCHUM, Montreal, QC; [2]Massachusetts General Hospital Cancer Center, Boston, MA; [3]Carolina Urological Research Center, Myrtle Beach, SC; [4]Georges Pompidou Hospital, Paris, France; [5]Charite Berlin, Berlin, Germany; [6]Université Catholique de Louvain Cliniques Universitaires Saint Luc, Bruxelles, Belgium; [7]Urological Associates of Lancaster, Lancaster, PA; [8]Institut Gustave Roussy, University of Paris Sud, Villejuif, France; [9]Kansas City VA Medical Center, Kansas City, MO; [10]Hospital Universitario Pedro Ernesto, Rio de Janeiro, Brazil; [11]Sydney Haematology and Oncology Clinic, Wahroonga NSW, Australia; [12]Hospital Vall d'Hebron, Barcelona, Spain; [13]Amgen Inc., Thousand Oaks, CA
Introduction: Denosumab, an anti-RANK-ligand monoclonal antibody, has been shown to prolong bone-metastasis free survival (BMFS) by a median 4.2 months and with a 15% risk reduction vs. placebo in men with non-metastatic castrate-resistant prostate cancer (CRPC) and baseline prostate-specific antigen (PSA) value ≥8.0 ng/ml and/or PSA doubling time (DT) ≤10.0 months. The objective of this analysis was to determine the efficacy of denosumab in men at greatest risk for bone metastases. BMFS was evalu-

Table 1.

Population	Sample size	BMFS median (months)	BMFS treatment difference (months)	HR	95% CI	*p* value
All patients	D: 716 P: 716	D: 29.5 P: 25.2	4.2	0.85	0.73 - 0.98	0.028
PSADT <6 months	D: 419 P: 427	D: 25.9 P: 18.7	7.2	0.77	0.64 - 0.93	0.0064

BMFS: bone-metastasis free survival; PSADT: prostate-specific antigen doubling time HR: hazard ratio; CI: confidence interval; D: denosumab; P: placebo.

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ated in a subset of men with PSADT ≤6 months (previous report in Smith MR, et al: J Clin Oncol. 23:2918-2925, 2005).
Methods: 1432 men with non-metastatic CRPC (baseline [median] PSA: 12.3 ng/mL, PSADT: 5.1 months, ADT duration: 47.1 months) were randomized 1:1 to receive monthly subcutaneous denosumab 120 mg or placebo. The first patient enrolled February 2006; primary analysis cut-off was July 2010, when >660 men had developed bone metastasis or died. The primary endpoint was BMFS (time to first bone metastasis or death from any cause). BMFS results are presented for men with baseline PSADT ≤6 months.
Results: Median BMFS in the placebo group of men with PSADT≤6 months was 6.5 months shorter than for the placebo group in the full population (18.7 months vs. 25.2 months), indicating that these men are at particularly high risk. In this group of men with PSADT <6 months, denosumab prolonged BMFS by a median of 7.2 months and with a 23% reduction in risk compared with placebo (Table 1).
Conclusions: Patients with shortened PSADT are at higher risk of developing bone metastasis and denosumab is markedly effective at prolonging BMFS in this subset of patients.

10 h 49 - 10 h 58
MDV3100, an androgen receptor signalling inhibitor (ARSI), improves overall survival in prostate cancer patients post-docetaxel: Results from the phase 3 AFFIRM study

Fred Saad;[1] Howard I. Scher;[2] Karim Fizazi;[3] Peter F.A. Mulders;[4] Mary Ellen Taplin,[5] Cora N. Sternberg;[6] Kurt Miller;[7] Ronald De Wit;[8] Mohammad Hirmand;[9] Bryan Selby;[9] Johann S. de Bono;[10] for the AFFIRM
[1]University of Montreal, Montreal, QC; [2]Memorial Sloan-Kettering Cancer Center, New York, NY; [3]Institut Gustave Roussy, University of Paris Sud, Villejuif, France; [4]Radboud University Medical Centre, Nijmegen, Netherlands; [5]Dana-Farber Cancer Institute, Department of Medicine, Division of Oncology, Boston, MA; [6]Department of Oncology, San Camillo Forlanini Hospital, Rome, Italy; [7]Department of Urology, Charité Universitätsmedizin, Berlin, Germany; [8]Department of Medical Oncology, Rotterdam Cancer Institute/Erasmus University Medical Center, Netherlands; [9]Medivation, San Francisco, CA; [10]Royal Marsden Hospital, Sutton, UK
Introduction: MDV3100, a novel ARSI, competitively inhibits binding of androgens to the androgen receptor (AR), inhibits AR nuclear translocation, and inhibits AR-DNA binding (Tran et al, Science.2009; 324:787). MDV3100 was developed based on activity in prostate cancer cell model systems with overexpressed AR and was active in a Phase 1-2 trial of prostate cancer patients with progressive castration resistant disease (CRPC) (Scher et al, Lancet.2010; 375:1437). The AFFIRM trial evaluated if MDV3100 could prolong overall survival in CRPC patients post docetaxel.
Methods: In this randomized, double-blind, placebo-controlled, multinational Phase 3 study (NCT00974311), patients who had ≤2 docetaxel-based regimens were randomized 2:1 to MDV3100 160 mg/d or placebo. Corticosteroids were allowed but not required. Patients were stratified by baseline ECOG performance status and mean brief pain inventory score. The primary endpoint was overall survival (OS). Secondary efficacy endpoints included radiographic progression-free survival, time to first skeletal-related event, and time to PSA progression.
Results: 1,199 patients were randomized between Sept 2009 and Nov 2010. Based on a planned interim analysis at 520 death events, the Independent Data Monitoring Committee recommended halting the study and placebo patients offered MDV3100 due to a significant OS benefit. Patients on MDV3100 had a median OS of 18.4, an increase of 4.8 months compared to placebo (13.6 months), p<0.0001, hazard ratio 0.631. Results for the secondary endpoints and safety will also be presented.
Conclusion: MDV3100 significantly improved OS in men with post-docetaxel CRPC reducing the risk of death by 37% compared to placebo.

10 h 58 - 11 h 07
Results of Phase 3 study of abiraterone acetate (AA) in chemotherapy-naïve patients (PTS) with metastatic castration-resistant prostate cancer (MCRPC): Interim analysis (IA) of COU-AA-302

Fred Saad;[1] Matthew R Smith;[2] Johann S de Bono;[3] Arturo Molina;[4] Christopher Logothetis;[5] Paul De Souza;[6] Karim Fizazi;[7] Paul Mainwaring;[8] Jose MR Piulats;[9] Siobhan Ng;[10] Joan Carles;[11] Peter FA Mulders;[12] Thian Kheoh;[4] Thomas Griffin;[4] Eric J Small;[13] Howard I Scher;[14] Dana Rathkopf;[14] Charles J Ryan[13]
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Introduction: AA blocks androgen biosynthesis and improves overall survival (OS) in mCRPC pts post-docetaxel. COU-AA-302 compared clinical benefit of AA + prednisone (P) vs. placebo (PL) + P in chemotherapy-naïve asymptomatic or mildly symptomatic mCRPC patients.
Methods: Pts (n=1088) were randomized 1:1 to AA (1000 mg) + P (5 mg BID) or PL + P at 151 centres in 12 countries. Radiographic progression-free survival (rPFS) and OS were primary endpoints. Median times were estimated using K-M method (LR statistic used for inference). Lan-DeMets α-spending function was used (OS).
Results: OS, rPFS and secondary endpoints (Table 1) favored AA, as concluded by Independent Data Monitoring Committee, who unanimously recommended unblinding study, crossing pts to AA from PL at 43% of total events. Median follow up is 22.2 mos. Grade 3/4 AEs (AA + P vs. PL + P): hypertension 3.9% vs. 3.0%; hypokalemia 2.4% vs. 1.9%; ALT↑ 5.4% vs. 0.7%; AST↑ 3.0% vs. 0.9%.
Conclusions: AA + P resulted in clinically and statistically significant effects on rPFS and all secondary endpoints, and strong trend for increased OS at IA. Median OS in PL arm is longest (27.2 mos) seen in any phase

Table 1.

	AA + P (median, mos)	PL + P (median, mos)	HR (95% CI)	*p* value
rPFS*	NR	8.3	0.43 (0.35, 0.52)	<0.0001
OS†	NR	27.2	0.75 (0.61, 0.93)	0.0097
Time to opiate use (cancer-related pain)	NR	23.7	0.69 (0.57, 0.83)	0.0001
Time to chemotherapy initiation	25.2	16.8	0.58 (0.49, 0.69)	<0.0001
Time to ECOG-PS deterioration	12.3	10.9	0.82 (0.71, 0.94)	0.0053
Time to PSA progression	11.1	5.6	0.49 (0.42, 0.57)	<0.0001

rPFS: Radiographic progression-free survival; OS: overall survival; AA: abiraterone acetate; P: prednisone; PL: placebo; HR: hazard ratio; CI: confidence interval; NR: not reached; ECOG-PS: Eastern Cooperative Oncology Group performance status; PSA: prostate-specific antigen. *rPFS analysis: clinical cut off date (CCO) 12/20/2010. Other analyses: CCO 12/20/2011; †Pre-specified alpha level 0.0008.

3 mCRPC study, although median OS in AA arm has not been reached. Present results confirmed acceptable safety/tolerability profile of AA.

Session scientifique XVIII

Objectifs éducatifs : À la fin de cette session, les participants seront en mesure de :

1. Reconnaître l'importance de la maladie métastatique cérébrale et spinale sur le pronostic vital des patients.
2. Énumerer les différentes options thérapeutiques offertes aux patients atteints de maladie métastatique cérébrale et spinale.
3. Reconnaître l'importance des traitements sur le pronostic fonctionnel des patients atteints de maladie métastatique cérébrale et spinale.

11 h 07 - 11 h 37
Métastases et neuro-chirurgie
Conférenciere : Geneviève Lapointe
Neurochirurgien, Hôpital de l'Enfant-Jésus
Modérateur : Fred Saad

Session scientifique XIX

Objectifs éducatifs : À la fin de cette session, le participant aura l'occasion verifié les connaissances acquises lors du congrès, en répondant à des questions à choix multiples sur des sujets précis en urologie tout en comparant ses réponses à celles de ses collègues.

11 h 47 - 12 h 30
Avez-vous retenu l'éssentiel du congrès ?
Conférenciers : Thierry Lebeau
Marie-Paule Jammal
Frédéric Pouliot

12 h 30
Clôture de la réunion