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BELGIAN JOURNAL OF MEDICAL ONCOLOGY

Highlights in breast cancer

A.M. Dekker, Msc, MD[1], T. Feys, MSc, MBA[1], K. Punie, MD, PhD[2], H. Wildiers, MD, PhD[2]

At this year's annual meeting of the European Society of Medical Oncology (ESMO) experts shared some game-changing data for the treatment of breast cancer (BC). In advanced HER2+ metastatic breast cancer m(BC), the DESTINY-Breast03 trial performed a head-to-head comparison of T-DM1 and trastuzumab deruxtecan (T-Dxd) following initial treatment with trastuzumab and a taxane, showing a major PFS benefit for T-DXd without major toxicity issues, establishing T-DXd as the new standard of care in this setting. In luminal breast cancer, the final analysis of the GIM-4 study supports the use of 7 years instead of 5 years adjuvant endocrine therapy in postmenopausal patients with hormone receptor positive (HR+)/HER2- early BC. For advanced stage HR+/HER2- BC, the MONALEESA-2 study shows >1y OS benefit when adding the CDK4/6 inhibitor ribociclib to letrozole as first-line treatment. Finally, in triple negative breast cancer (TNBC), the phase III BrighTNess study showed that addition of carboplatin to neoadjuvant chemotherapy provides long term EFS benefit. In metastatic TNBC, OS data of KEYNOTE-355 further support the use of first-line pembrolizumab plus chemotherapy in advanced PD-L1+ TNBC.
(BELG J MED ONCOL 2021;15(8):390-7)

HER2-POSITIVE BREAST CANCER

DESTINY-BREAST03; TRASTUZUMAB DERUXTECAN (T-DXD) IS SUPERIOR COMPARED TO TRASTUZUMAB EMTANSINE (T-DM1) IN THE TREATMENT OF METASTATIC HER2+ BREAST CANCER (AFTER TREATMENT WITH TAXANE AND TRASTUZUMAB).

Patients with previously treated HER2+ mBC will typically experience disease progression in less than a year with the currently available HER2-directed treatment. T-DM1 is the current standard treatment in second-line after treatment with a taxane, trastuzumab and pertuzumab for HER2+ mBC based on the EMILIA trial.[1] Trastuzumab deruxtecan (T-DXd) is a new antibody drug conjugate that was FDA approved in 2019 for patients with unresectable or metastatic HER2+ BC with 2 or more prior anti-HER2-based regimens, based on results of DESTINY-Breast01.[2]

Following this, a large, randomised trial was established for patients with HER2+ mBC after treatment with taxane and trastuzumab. The DESTINY-Breast03 compared the two ADC therapies head-to-head and randomly assigned 524 previously treated patients to receive T-DXd or T-DM1 every 3 weeks. The primary endpoint was PFS measured by blinded independent central review. Secondary endpoints include OS, objective response rate (ORR), duration of response (DoR), PFS by investigator, and safety. T-DXd led to a highly significant and clinically meaningful improvement in PFS. At a median follow-up of 16 months, the median PFS by blinded independent central review was not reached with T-DXd and reached 6.8 months in patients treated with T-DM1 (HR[95%CI]; 0.28[0.22-0.37], p= 7.8×10^{-22}) (*Figure 1*). By investigator review, the median PFS was 25.1 months with T-DXd and 7.2 months with T-DM1 (HR [95%CI] 0.27 [0.20-0.35], p= 6.5×10^{-24}). The significant PFS benefit associated with T-DXd was observed across all predefined subgroups, including those defined by hormone receptor status, prior pertuzumab use, and presence of visceral disease or brain metastases. Confirmed responses

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Keywords: brain metastases, breast cancer, CDK4/6, de-escalation, endocrine therapy, HER2, neoadjuvant, overall survival, pembrolizumab, trastuzumab deruxtecan, trastuzumab duocarmazine, trastuzumab.

Highlights in genitourinary cancers

T. Vermassen, PhD[1,2], S. Rottey, MD, PhD[1,2], D. De Maeseneer, MD[1,3]

ESMO 2021 again provided a variety of innovations in the management of genitourinary cancers. In prostate cancer (PCa), results of STAMPEDE suggest that early intensification of adjuvant therapy with ADT and abiraterone could become a new standard in high-risk non-metastatic PCa (currently off-label). Studies in metastatic castration-resistant PCa (mCRPC) indicated promising activity of 77Lu-PSMA-617 plus pembrolizumab and of cabozantinib plus atezolizumab. In the field of kidney cancer, patient-reported outcome data of KEYNOTE-564 further support adjuvant pembrolizumab as a new standard of care. Other studies in renal cell cancer (RCC) showed that treatment breaks during tyrosine kinase inhibitor therapy may be highly cost-effective without an effect on patient survival, that antibiotics can severely compromise survival outcomes in nivolumab-treated metastatic RCC patients and that therapeutic targeting of HIF-2α and VEGF may be effective in patients with metastatic clear cell RCC. In addition, cabozantinib proved to be safe and effective in patients with metastatic collecting ducts carcinoma. In urothelial cancer, dose-dense MVAC was identified as a safe and effective neoadjuvant treatment option for patients with muscle-invasive bladder cancer (MIBC). In metastatic urothelial cancer the addition of cetrelimab to erdafitinib seemed to increase treatment effects, while the EphrinB2-blocking agent sEphB4-HAS was found to have synergistic activity with pembrolizumab. Finally, an exploratory analysis of the pivotal IMvigor 130 trial found that cisplatin but not carboplatin seems to enhance anti-tumour immunity.
(BELG J MED ONCOL 2021;15(8):398-405)

PROSTATE CANCER

ANDROGEN DEPRIVATION THERAPY (ADT) + ABIRATERONE (ABI) +/- ENZALUTAMIDE (ENZA) *VS.* ADT ALONE IN HIGH-RISK NON-METASTATIC PROSTATE CANCER (PCA): META-ANALYSIS FROM STAMPEDE

The survival effect of intensifying hormone treatment with abi or enza is clear in metastatic but not in non-metastatic PCa. To address this question, a meta-analysis from STAMPEDE was performed. As part of two separate comparisons, a total of 1,974 non-metastatic node positive or high-risk node negative PCa patients were randomised (1:1) to ADT (control) *vs.* ADT with abi (abi 1,000 mg + prednisolone 5 mg PO QD) or ADT *vs.* ADT with abi + enza (160 mg PO QD) for 2 years. A total of 180 and 306 metastasic events were reported in the research and control group; respectively. Abi-based therapy improved metastasis-free survival and overall survival (OS; *Figure 1*) compared to ADT alone. This treatment effect was consistent in major subgroups and between abi and abi + enza randomization periods. As such, early intensification of adjuvant therapy with ADT and abi in high-risk non-metastatic PCa could become a new standard-of-care (SOC) but this indication is currently off label.[1] These results should also be seen in light of the recent uptake of PSMA PET/CT leading to higher rate of diagnosis of metastatic lesions in this setting.

ARCHES: ENZA + ADT IN METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (mHSPC)

The ARCHES trial previously showed that enza + ADT reduces the risk of radiographic progression. At ESMO, the

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Keywords: immunotherapy, prostate cancer, renal cell carcinoma, targeted therapy, urothelial carcinoma.

Highlights in respiratory oncology

J. Blokken, PharmD, PhD, T. Feys, MSc, MBA

At this year's ESMO meeting, much of the attention in the field of lung cancer went to early-stage non-small cell lung cancer (NSCLC) with interesting results from the Lung Art, COAST, GEMSTONE-301 and IMpower010 trials. For metastatic NSCLC, immunotherapy again walked away with much of the attention. In addition to this, several studies investigated the potential of combining anti-EGFR and anti-angiogenic agents, while others investigated novel targeted agents, including trastuzumab deruxtecan, poziotinib, plinabulin and datopotamab deruxtecan. Finally, we will highlight the most interesting results in other thoracic malignancies, including malignant pleural mesothelioma, extensive-stage small cell lung cancer, thymoma and thymic carcinoma.
(BELG J MED ONCOL 2021;15(8):406-14)

NON-SMALL CELL LUNG CANCER

EARLY-STAGE DISEASE

The phase III Lung ART study enrolled 501 patients with completely resected non-small cell lung cancer (NSCLC) with proven N2 nodal involvement. Patients were allowed to receive pre- operative and/or post-operative chemotherapy and were randomised (1:1) to the control arm (*i.e.* no further treatment) or the post-operative conformal radiotherapy (PORT) arm.

The primary analysis of the Lung ART trial demonstrated a non-statistically significant effect of PORT on disease-free survival (DFS, HR[95%CI]: 0.86[0.68-1.08], p= 0.18). However, PORT was associated with a significant 55% reduction in the risk of mediastinal relapse (HR[95%CI]: 0.45[0.30-0.69]). Surprisingly, more deaths were observed in the PORT arm as compared to the control arm (15% *vs.* 5%). Evidence for differential efficacy led to the investigation of patterns of failure and prognostic factors for PORT efficacy. Among DFS events, there were 161 (54%) metastatic relapses (including 61 (21%) brain metastases), 106 (36%) mediastinal relapses, and 29 (10%) deaths. Mediastinal relapse mainly occurred within nodes that were initially involved (66% in control arm, 47% in PORT arm) and occurred significantly less in the PORT arm (unadjusted sub-distribution HR[95%CI]: 0.46[0.3-0.7]). The three most frequent sites of mediastinal relapse were stations 7 (47%), 4L (42%) and 4R (37%) for left-sided tumours and stations 4R (48%), 2R (44%) and 7 (41%) for right-sided tumours. Finally, the analysis identified quality of resection (p< 0.0001), extent of mediastinal involvement (p= 0.01) and lymph node ratio (number of involved nodes divided by the number of resected nodes, p= 0.04) as prognostic factors for DFS.[1]

Previously, the placebo-controlled, phase III PACIFIC study established consolidation durvalumab as standard of care (SoC) for patients with unresectable Stage III NSCLC who did not progress after concurrent chemoradiotherapy (cCRT).[2] Building on the success of this trial, additional immunomodulation through combination therapy is now being explored to improve clinical outcomes in this patient population. COAST is a global, open label, randomised, phase II study of consolidation durvalumab alone or in combination with the anti-CD73 monoclonal antibody (mAb) oleclumab or the anti-NKG2A mAb monalizumab. In total, 189 patients with histologically/cytologically documented unresectable Stage III NSCLC, ECOG PS 0/1 and no progression after cCRT were randomised (1:1:1) within maximum 42 days post cCRT,

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Keywords: Atalante-1, BEVERLY, BFAST, CASPIAN, CheckMate 743, COAST, DESTINY-Lung01, DUBLIN-3, EMPOWER-Lung 3, EORTC-ETOP NIVOTHYM, GEMSTONE-301, IMpower010, Lung Art, malignant pleural mesothelioma, NSCLC, PORT, SCLC, thymic carcinoma, thymoma, TROPION-PanTumor01, WJOG9717L study, ZENITH20-4

Highlights in digestive oncology

H. Dedecker, MD, L-A Teuwen, MD, T. Vandamme, MD, PhD, H. Prenen, MD, PhD, M. Peeters, MD, PhD

The 2021 edition of ESMO was held virtually between the 16th and 21st of September 2021. The main goal of this overview is to highlight the most striking abstracts in the field of digestive oncology for daily clinical practice. First, the upper gastro-intestinal tract tumours will be discussed, followed by an overview of the congress highlights related to cancers of the lower gastro-intestinal tract.

(BELG J MED ONCOL 2021;15(5):415-20)

UPPER GASTRO-INTESTINAL TRACT

IMMUNOTHERAPY FOR ADVANCED GASTRIC, GASTRO-OESOPHAGEAL JUNCTION OR OESOPHAGEAL CANCER

The **Checkmate 649 study** is a randomised phase III study evaluating first-line programmed death (PD)1 inhibitor therapies in patients with metastatic gastric cancer (GC), gastro-oesophageal junction cancer (GEJC), or oesophageal adenocarcinoma (EAC) irrespective of PD-L1 status. During ESMO 2021, long-term follow-up data (24 months) of this trial were presented on the comparison of nivolumab plus chemotherapy *vs.* chemotherapy alone. In addition, the study also reported the first results on the combination of nivolumab and ipilimumab *vs.* chemotherapy in patients with a PD-L1 combined positive score (CPS) of ≥5.[1]

The combination of nivolumab and chemotherapy continued to demonstrate a sustained clinically meaningful long-term survival benefit *vs.* chemotherapy with a median overall survival (OS) of 13.8 and 11.6 months, respectively (HR[95%CI]: 0.79[0.71-0.88]). At the 24-month landmark, this translated into an OS rate of 28% for nivolumab plus chemotherapy as compared to only 19% in the chemotherapy alone arm. Adding nivolumab to chemotherapy also significantly improved the progression free survival (PFS), resulting in a median PFS of 7.7 and 6.9 months, for nivolumab plus chemotherapy and chemotherapy alone, respectively (HR[95%CI]: 0.79[0.70-0.89]) (*Figure 1*). As such, these findings strongly support the nivolumab-chemotherapy combination as as a new standard first-line treatment in advanced GC/GEJC/EAC.[1] In contrast, the combination of nivolumab and ipilimumab did not significantly improve the OS when compared to chemotherapy in patients with a PD-L1 CPS of ≥5 or greater (median OS: 11.2 *vs.* 11.6 months; HR[95%CI]: 0.89[0.71-1.10]), or among all randomised patients (median OS: 11.7 *vs.* 11.8 months; HR[95%CI]: 0.91[0.77-1.07]). Similarly, no meaningful improvement in PFS was observed between nivolumab plus ipilimumab and chemotherapy (CPS ≥5: median PFS 2.8 *vs.* 6.3 months; HR[95%CI]: 1.42[1.14-1.76]; all randomised patients: median PFS 28 *vs.* 7.1 months; HR[95%CI]: 1.66[1.40-1.95]).[1]

ORIENT-16 is the first double-blind, phase III trial in a Chinese population with advanced gastric or gastro-oesophageal adenocarcinoma demonstrating statistically significant OS benefit with the PD-1 inhibitor sintilimab in combination with chemotherapy (capecitabine and oxaliplatin) compared to chemotherapy alone. This OS benefit was observed in all randomised patients (median OS: 15.2 *vs.* 12.3 months; HR[95%-CI]: 0.766[0.626-0.936]; p= 0.009) as well as in patients with a CPS of ≥5 (median OS: 18.4 *vs.* 12.9 months; HR[95%CI]: 0.660[0.505-0.864]; p= 0.0023), meeting the co-primary endpoints of the study. The safety profile of the sintilimab-chemotherapy combination was well manageable. As such, sintilimab plus chemotherapy provides a new standard first-line treatment option for Chinese patients with advanced GC/GEJC.[2]

ORIENT-15 is a global randomised, double-blind, multi-centre, phase III study, comparing the efficacy and safety of sintilimab or placebo in combination with chemotherapy

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Keywords: gastric, gastro-oesophageal junction, ipilimumab, nivolumab, oesophageal adenocarcinoma.

Highlights in head and neck Cancer

W. Lybaert, MD

ESMO Congress 2021 was held from the 16th till the 21st of September, once again in a virtual format. During this congress, more immunotherapy data were shown in the neoadjuvant setting of resectable head and neck cancer, in the concomitant radiotherapy setting and first-line recurrent/metastatic disease. In addition, a nomogram was created for patients undergoing concomitant chemoradiotherapy that can be used as a web-based tool for our clinic. Other data underscore that treatment of elderly patients with a head and neck cancer nowadays require a comprehensive geriatric assessment. In this report, these and other important studies related to head-and-neck cancer will be discussed, together with some comments on the clinical relevance of these findings.
(BELG J MED ONCOL 2021;15(8):421-7)

IMMUNOTHERAPY ARRIVING IN NEOADJUVANT SETTING OF RESECTABLE HNSCC: PROMISING, BUT NOT YET READY FOR THE CLINIC

Anno 2021, the PD-1 inhibitor pembrolizumab alone or in combination with chemotherapy is known to improve the overall survival (OS) compared to chemotherapy alone in patients with R/M HNSCC that are PD-L1 positive (CPS-score ≥1). This strategy has also been adopted by the most recent ESMO guidelines for the treatment of head and neck cancer (HNC).[1] In contrast, in the concomitant setting with radiotherapy and chemotherapy, results obtained with immunotherapy have been rather disappointing (e.g., the recent negative JAVELIN Head and Neck 100 trial with avelumab).[2] Immunotherapy is now also making its first steps in the neoadjuvant setting. However, the safety and efficacy of neoadjuvant immunotherapy with PD-L1 with or without CTLA-4 blockade has not yet been explored. At ESMO 2021, we saw the **safety and efficacy data of a single dose of preoperative durvalumab (D) with or without tremelimumab (T) in patients with resectable HNSCC.**[3] Patients with locally advanced, but resectable HNSCC were eligible for this study. Enrolled patients were randomised into D or D+T, stratified by primary site and human papilloma (HPV) infection status. A single dose of preoperative D (1,500 mg) or D+T (1,500 mg+75 mg) was administered, with surgery planned 2 to 8 weeks later for curative resection. Postoperative (chemo)radiation was prescribed based on standard guidelines, followed by maintenance with D every 4 weeks for 1 year. The primary study objective was local recurrence rate, while secondary endpoints included pathologic response, safety, tolerability, OS and exploration of immune dynamics. In total, 44 patients were enrolled and received surgical resection with available data for pathologic response (D: 20 patients, D+T: 24 patients). Most cancers in the study were oropharyngeal (N= 22), followed by hypopharyngeal (N= 9), cancer of the oral cavity (N= 8) and laryngeal cancer (N= 5). Human papilloma virus-mediated cancer was observed in 20 patients (45.4%). Neoadjuvant D+/-T proved to have an acceptable safety profile and was not associated with delays in surgery or unexpected adverse events. A radiologic tumour response was seen in 33.3% with D and 29.2% in D+T. Pathological downstaging was observed in 23.8% of

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Keywords: immunotherapy durvalumab +/- tremelimumab in resectable head and neck squamous cell carcinoma (HNSCC); avelumab + cetuximab + concomitant radiotherapy in locally advanced HNSCC (LA-HNSCC); nomogram to assess prognosis in patients receiving concomitant chemoradiotherapy in LA-HNSCC; nivolumab + ipilimumab vs. EXTREME as first-line treatment for recurrent/metastatic HNSCC (R/M HNSCC); pembrolizumab in second-line for nasopharyngeal carcinoma; comprehensive geriatric assessment in the elderly with HNSCC; after salvage surgery and no reirradiation adjuvant metronomic chemotherapy; cabozantinib in second- or third-line radioiodine-refractory differentiated thyroid cancer.

Highlights in gynaecological oncology

A. Enguita, PhD, T. Feys, MSc, MBA

The 2021 annual ESMO meeting featured several presentations with the potential to shift the standard of care in gynaecological cancers. In cervical cancer, Keynote-826 identified pembrolizumab + chemotherapy (with or without bevacizumab) as a potential new standard of care for patients with persistent, recurrent, or metastatic cervical cancer. In addition, also the antibody drug conjugate tisotumab vedotin showed encouraging and durable anti-tumour activity in this setting. In the field of the ovarian cancer, PARP inhibition again walked away with most of the attention, but also the glucocorticoid receptor modulator relacorilant and combination therapy with the immune checkpoint inhibitor atezolizumab and bevacizumab yielded interesting data. Also for patients with advanced endometrial cancer, ESMO 2021 proved to be of interest, with important updates on the use of pembrolizumab in this setting.
(BELG J MED ONCOL 2021;15(8):428-35)

CERVICAL CANCER

Platinum-based chemotherapy has been the long-standing standard treatment for patients with persistent, recurrent, or metastatic cervical cancer (mainly: platinum, paclitaxel, and bevacizumab). More recently, immune checkpoint inhibitors such as pembrolizumab or cemiplimab demonstrated their efficacy in patients with previously treated cervical cancer. To date, however, there were no clinical data on the combined use of a PD-L1 inhibitor and chemotherapy. The latter was assessed in Keynote-826 and the first results of this trial were presented in the presidential session of ESMO 2021. Keynote-826 trial is a randomised, double-blind, phase III study including a total of 617 patients. To be eligible for the study, patients had to have persistent, recurrent, or metastatic cervical cancer, did not receive prior systemic chemotherapy (radiotherapy and chemoradiotherapy permitted) and had to have an ECOG performance status of 0-1. Patients were randomly assigned to receive pembrolizumab (200 mg) or placebo every 3 weeks for up to 35 cycles plus platinum-based chemotherapy. Bevacizumab could be added to the treatment per investigator discretion. The co-primary endpoints of the trial were overall survival (OS) and progression-free survival (PFS) per RECIST v1.1.1 After a median follow-up of 22 months, the study showed significant improvements in PFS and OS for patients treated with pembrolizumab. In patients with a combined positive score (CPS) of ≥1, pembrolizumab+ chemotherapy +/- bevacizumab was associated with a median PFS of 10.4 months as compared to 8.2 months in the control arm (HR[95%CI]: 0.62[0.50-0.77]; p< 0.001). At 12-months, this translates into a PFS rate of 45.5% and 34.1%, respectively (*Figure 1*). Also in all-comers and in patients with a CPS ≥10, a significantPFS benefit was seen for patients in the pembrolizumab arm (median PFS: 10.4 *vs.* 8.2 months; HR[95%CI]: 0.65[0.53-0.79]; p< 0.001 and 10.4 *vs.* 8.1 months; HR[95%-CI]: 0.58[0.44-0.77]; p< 0.001). The PFS benefit for pembrolizumab was seen in all investigated subgroups, irrespective of age, ECOG status, CPS score and concomitant bevacizumab use. Importantly, the advantage in terms of PFS also translated into a significant OS benefit. In the CPS ≥1 population, the median OS was not reached with pembrolizumab as compared to 16.3 months in the control arm (HR [95%CI]: 0.64[0.50-0.81]; p< 0.001). At the 2-year landmark, this corresponds to an OS rate of 53% with the pembro-

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Maui, HI, United States

BGICC 2022
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