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**MEETING SUMMARY**  
**ASCO 2018 and WCGIC 2018**

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**CANCERS OF UPPER GI TRACT**

# DISCLAIMER



## **Please note:**

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**OVERALL SURVIVAL RESULTS FROM A  
PHASE III TRIAL OF  
TRIFLURIDINE/TIPIRACIL VS. PLACEBO IN  
PATIENTS WITH METASTATIC GASTRIC  
CANCER REFRACTORY TO STANDARD  
THERAPIES**

**Taberero et al. WCGIC 2018, LBA-002**

# TRIFLURIDINE/TIPIRACIL VS. PLACEBO IN METASTATIC GASTRIC CANCER

- **Patient population:** patients with metastatic gastric or GE junction cancer who had at least 2 lines of prior systemic therapy
  - More than 50% had  $\geq 3$  prior treatments
- **Dose:** Trifluridine/Tipiracil (TAS102) 35 mg/m<sup>2</sup> d 1–5, 8–12 of a 28-day cycle
- **Primary endpoint:** Overall survival

# TRIFLURIDINE/TIPIRACIL VS. PLACEBO IN METASTATIC GASTRIC CANCER: RESULTS

	n	Median OS (months)	Median PFS (months)
TAS102	337	5.7	2.0
Placebo	170	3.6	1.8
p value		0.0003	<0.0001
HR		0.69	0.57

40% of patients had a prior gastrectomy, but there was no difference in outcomes compared to those who did not have a gastrectomy

# TRIFLURIDINE/TIPIRACIL VS. PLACEBO IN METASTATIC GASTRIC CANCER: CONCLUSION

- Trifluridine/Tipiracil will likely become a treatment option for refractory advanced gastric or GE junction cancer

**KEYNOTE-061: PHASE 3 STUDY OF  
PEMBROLIZUMAB VS. PACLITAXEL FOR  
PREVIOUSLY TREATED ADVANCED GASTRIC  
OR GASTROESOPHAGEAL JUNCTION  
CANCER**

**Shitara et al. WCGIC 2018, LBA-005**



# KEYNOTE-061: PEMBROLIZUMAB VS. PACLITAXEL FOR ADVANCED GASTRIC/GE JUNCTION CANCER

- **Patient population:** patients with advanced gastric or GE junction cancer that had progressed after first-line treatment with platinum and fluoropyrimidine therapy
- **Dose:**
  - Pembrolizumab: 200 mg q 3 weeks
  - Paclitaxel: 80 mg/m<sup>2</sup> days 1, 8, 15 of a 28-day cycle
- The study initially enrolled all-comers, but then restricted enrollment to patients with PD-L1+
- **Primary endpoint:** Overall survival

# KEYNOTE-061: PEMBROLIZUMAB VS. PACLITAXEL FOR ADVANCED GASTRIC/GE JUNCTION CANCER: RESULTS

	n	Median OS (months)	Median PFS (months)	ORR%	Gr3+ AE
Pembrolizumab	296	9.1	1.5	15.8%	14.3%
Paclitaxel	296	8.3	4.1	13.6%	34.8%
p value		0.0425*			
HR		0.82			

The greatest OS benefit with pembrolizumab was seen in subgroups of patients with ECOG PS 0, PD-L1+ (CPS  $\geq$ 10), and MSI-H

# KEYNOTE-061: PEMBROLIZUMAB VS. PACLITAXEL FOR ADVANCED GASTRIC/GE JUNCTION CANCER: CONCLUSIONS

- Pembrolizumab will not replace paclitaxel (+ ramucirumab) in the 2<sup>nd</sup>-line setting for advanced gastric/GE junction cancers
- Although pembrolizumab did not significantly improve OS vs paclitaxel, this study still confirms the activity of pembrolizumab in patients with advanced gastric or GE junction cancer
- Study highlights the importance of careful patient selection for pembrolizumab: PD-L1+, MSI-H



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