

Saturday June 1 Press Briefing: ASCO Press Releases with links to abstracts

Announcement: Minimal Common Oncology Data Elements (mCODETM), a collaboration between ASCO®, the MITRE Corporation, and the Alliance for Clinical Trials in Oncology Foundation

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Abstract LBA1008: Phase III MONALEESA- 7 trial of premenopausal patients withHR+/HER2– advanced breast cancer (ABC) treated with endocrine therapy ± ribociclib: Overall survival (OS) results.

Conclusions: RIB + ET demonstrated a clinically and statistically significant longer OS than ET alone in premenopausal pts with HR+/HER2– ABC. This is the first time that a CDK4/6 inhibitor or any targeted



agent + ET has demonstrated significantly longer OS vs ET alone as initial endocrine-based therapy. Clinical trial information: <u>NCT02278120</u>

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Abstract LBA9015: Five-year long-term overall survival for patients with advanced NSCLC treated with pembrolizumab: Results from KEYNOTE-001.

Conclusions: In KEYNOTE-001, 5-y OS rate was 23.2% in treatment-naive pts and 15.5% in previously treated pts with advanced NSCLC treated with pembro, compared to a historical rate of ~5% (per SEER 2008–2014), prior to the introduction of anti–PD-1 therapy. 5-y OS rate was at least 25% in pts with PD-L1 TPS \geq 50% in both pt populations in KEYNOTE-001. Clinical trial information: <u>NCT01295827</u>

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Abstract LBA4007: Pembrolizumab with or without chemotherapy versus chemotherapy for advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma: The phase 3 KEYNOTE-062 study.

Conclusions: As 1L therapy for advanced GC, P was noninferior to C for OS in CPS ≥ 1 with clinically meaningful improvement for OS in CPS ≥ 10 . P+C did not show superior OS and PFS in CPS ≥ 1 and OS in CPS ≥ 10 . The safety profile was more favorable for P vs C. Clinical trial information: NCT02494583

| CPS ≥1 | P+C | С | Р | С |
|------------------------------|-----------------------------------|-------|---|-------|
| ^a Median, mo (95% | N=257 | N=250 | N=256 | N=250 |
| CI) | | | | |
| OS^{a} | 12.5 (10.8-13.9)/ 11.1 (9.2-12.8) | | 10.6 (7.7-13.8)/11.1 (9.2-12.8) | |
| HR (95% CI)/ ^b | 0.85 (0.70, 1.03) | | 0.91 (0.74-1.10) | |
| 99.2% CI | <i>P</i> =0.046 | | 0.91^{b} (0.69-1.18); NI margin = 1.2 | |
| PFS ^a | 6.9 (5.7-7.3)/ 6.4 (5.7-7.0) | | 2.0 (1.5-2.8)/6.4 (5.7-7.0) | |
| HR (95% CI) | 0.84 (0.70-1.02); <i>P</i> =0.039 | | 1.66 (1.37-2.01) | |
| ORR, % (95% CI) | 48.6 (42.4-54.9)/36.8 (30.8-43.1) | | 14.5 (10.4-19.4)/36.8 (30.8-43.1) | |
| CPS ≥10 | N=99 | N=90 | N=92 | N=90 |
| OS^{a} | 12.3 (9.5-14.8)/10.8 (8.5-13.8) | | 17.4 (9.1-23.1)/10.8 (8.5-13.8) | |
| HR (95% CI) | 0.85 (0.62-1.17); <i>P</i> =0.158 | | 0.69 (0.49-0.97) | |
| PFS ^a | 5.7 (5.5-8.2)/6.1 (5.3-6.9) | | 2.9 (1.6-5.4)/6.1 (5.3-6.9) | |
| ORR, % (95% CI) | 52.5 (42.2-62.7)/36.7 (26.8-47.5) | | 25.0 (16.6-35.1)/36.7 (26.8-47.5) | |

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