primary objective is to assess BOR per RECIST v1.1; other objectives are dose exploration and safety/tolerability. Tumor cell PD-L1 expression (Ab clone 73-10 [≥80% is comparable to ≥ 50% with 22C3]) was evaluable in 75 pts.

Results: As of March 12, 2018, 80 pts received M7824 for a median of 11.9 (range, 2-66.1) wk, with a median follow-up of 51.1 wk; 10 pts remain on treatment. Investigator-assessed confirmed ORR was 27.5% at 1200 mg and 20% at 500 mg. Clinical activity was observed across PD-L1 subgroups (Table); ORR was 40.7% in PD-L1 + (≥1%) and 71.4% in PD-L1–high (≥80%) pts at 1200 mg. The most common treatment-related adverse events (TRAEs) were pruritus (20%), maculopapular rash (18.8%), decreased appetite (12.5%) and asthenia (11.3%). Grade ≥3 TRAEs occurred in 23 pts (28.8%); 8 pts (500 mg, n = 2; 1200 mg, n = 6) discontinued treatment due to TRAEs. No treatment-related deaths occurred.

Table: 1463P

ORR, n/N; %	500 mg	1200 mg	Total
All PD-L1+	8/40; 20.0	6/31;	11/40; 27.5	11/27;	19/80; 23.8	17/58;
PD-L1 high	19.4	2/6; 33.3	40.7	5/7; 71.4	29.3	7/13; 53.8
Median PFS; OS, mo						
All PD-L1+	1.4; 10.9	1.6;	2.7; NR	6.8;	2.1; 12.2	2.7;
PD-L1 high	10.3	1.5; NR	NR	NR; NR	NR	8.1; NR

NR, not reached.

Conclusions: M7824 had promising efficacy, with encouraging PFS and OS, and ORRs at the RP2D of 1200 mg of 40.7% and 71.4% in PD-L1+ and PD-L1 high pts, respectively. Treatment was well tolerated.

Clinical trial identification: NCT02517398.

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1463P Updated results of M7824 (MSB0011359C): A bifunctional fusion protein targeting TGF-β and PD-L1, in second-line (2L) NSCLC

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Background: 2L+ overall response rates (ORRs) with PD-(L)1 inhibitors in patients (pts) with advanced NSCLC range from 12% to 19% (PD-L1 unselected), and median PFS ranges from 2.3 to 4.0 mo. Inhibiting the transforming growth factor β (TGF-β) pathway, which promotes tumor immunosuppression, may enhance the response to PD-(L)1 therapy. M7824 is an innovative first-in-class bifunctional fusion protein composed of a human IgG1 monoclonal antibody against PD-L1 fused with 2 extracellular domains of TGF-βRII (a TGF-β "trap").

Methods: Pts with advanced NSCLC unselected for PD-L1 who progressed after 1L standard treatment (no prior immunotherapy) were randomized to receive M7824 500 or 1200 mg (n = 40 each) q2w until disease progression, unacceptable toxicity or trial withdrawal in this expansion cohort of the ongoing, phase 1 trial NCT02517398. The