

Two more stumbles for I-O agents



[Jonathan Gardner](#)

Chalk up two more defeats in immuno-oncology. Bristol-Myers Squibb today conceded that its confirmatory small-cell lung cancer trial of Opdivo failed to show a survival benefit over chemotherapy, while Immune Design shelved a trial of its cancer vaccine CMB305 in combination with Tecentriq in patients with synovial sarcoma. Opdivo's lung cancer miss in previously treated patients will once again raise the question of whether the US FDA should withdraw the drug's accelerated approval in this setting, which it won in August. More readouts with Opdivo in SCLC, in combination with other agents, are due soon, along with data from rivals Keytruda and Imfinzi, while Roche has already reported positive first-line data with Tecentriq ([World Lung 2018 – Roche gives rivals a small-cell target to shoot for, September 25, 2018](#)). For Immune Design, the CMB305 decision was made after an ad hoc review of the Synovate trial that indicated the combo with Tecentriq would not yield a survival benefit in relapsed patients. The group said it would prioritise its TLR4 agonist G100 instead, allowing it to extend its cash runway another six months, into 2021. Shares fell 41% in early trading today.

Confirmatory PD-(L)1 trials that have failed

Company	Drug	Setting	Trial	Date
Roche	Tecentriq	2L bladder	IMVigor 211	May 2017
Merck & Co	Keytruda	2L head & neck	Keynote-040	July 2017
Merck & Co	Keytruda	2L gastric	Keynote-061	Dec 2017
Bristol-Myers Squibb	Opdivo	2L small cell lung	Checkmate-331	Oct 2018