

US approval gives Bristol its mesothelioma head-start



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Friday marked an unusual coup for Bristol Myers Squibb's Opdivo plus Yervoy combo: a US green light for front-line mesothelioma made it the first approval in 16 years for this hard-to-treat cancer. The sharp-eyed will also have noticed the unexpected breadth of the approval, which came in all-comers, even though the supporting study, [Checkmate-743](#), clearly showed the effect to be driven by the 25% of subjects who had the [non-epithelioid histology](#) and represent a minority of mesothelioma patients. There was an impressive 56% reduction in risk of death versus chemo among non-epithelioids given the combo in the study, but those with epithelioid histology had a non-significant 15% reduction. It will be up to Bristol to make the most of the advantage, especially as its checkpoint blocker competition is nowhere to be seen. Keytruda's indication-agnostic approvals mean that some mesothelioma patients can receive the Merck & Co drug, and indeed the Keynote-158 trial, which forms part of the basis for these, did include several with this cancer. But Keytruda recently failed the late-line Promise-meso study, and all phase III trials in this indication except Checkmate-743 have academic groups as primary sponsor.

Selected phase III studies of anti-PD-(L)1 drugs in mesothelioma

Study	Design	Setting	Primary endpoint(s)	Primary sponsor	Data?
<i>Bristol Myers Squibb</i>					
Checkmate-743	Opdivo + Yervoy, vs chemo	1L	OS	Bristol Myers Squibb	mOS 18.1mth vs 14.1mth (p=0.002); mOS in epithelioid 18.7mth vs 16.2mth
Confirm	Opdivo vs placebo	≥2L	PFS & OS	University of Southampton	Primary completion Jul 2021
<i>Merck & Co</i>					
IFCT-1901	Keytruda +/- chemo, vs chemo	1L	PFS & OS	Canadian Cancer Trials Group	Primary completion Jul 2022
Promise-meso	Keytruda vs chemo	≥2L	PFS	European Thoracic Oncology Platform	Fail: HR for PFS 1.06; mOS 10.7mth vs 11.7mth
<i>Astrazeneca</i>					
Dream3R	Imfinzi +/- chemo, vs chemo	1L	OS	PrECOG, LLC	Yet to get under way
<i>Roche</i>					
Beat-meso	Tecentriq + Avastin + chemo, vs Avastin + chemo	1L	PFS & OS	European Thoracic Oncology Platform	Primary completion Oct 2024

Source: [clinicaltrials.gov](#) & scientific papers.

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