

Bavencio's forgotten lung cancer readout is a dud



[Jacob Plieth](#)

It is a measure of the stranglehold that Keytruda has on front-line lung cancer that the failure of Bavencio in the Javelin Lung 100 trial in this setting was today revealed as a mere footnote in Pfizer's fourth-quarter earnings. Not that Pfizer and Merck KGaA had not maximised the trial's chances of success: Javelin had twice been enlarged, was refocused on PD-L1 expressers and had its primary endpoints overhauled. But protracted delays – readout had originally been slated for April 2019, before being put back four times – meant that Keytruda made hay while Javelin's results receded into near irrelevance. Today Pfizer said Bavencio had shown "clinical activity" but failed to beat chemo on the OS and PFS co-primary endpoints. In the changing NSCLC environment it is possible that control cohort patients went on to receive efficacious anti-PD-(L)1 therapy, including Keytruda, but it is increasingly looking as though Bavencio simply is not a particularly good drug. Its last US approval, in first-line bladder cancer maintenance, occurred in mid-2020.

Selected trials of anti-PD-(L)1 MABs in 1st-line NSCLC

Product	Company	Study	Outcome
Monotherapies...			
Keytruda	Merck & Co	Keynote-042	Positive, US approved for PD-L1 $\geq 1\%$
Tecentriq	Roche	Impower-110	Positive, US approved for PD-L1 $\geq 50\%$
Libtayo	Sanofi/Regeneron	Empower-Lung 1	Positive, US approved for PD-L1 $\geq 50\%$
Tuoyi (toripalimab)	Shanghai Junshi/Coherus	Choice-01*	Positive for mPFS vs chemo in all-comers
Bavencio	Merck KGaA/Pfizer	Javelin Lung 100	Failed for mPFS & mOS vs chemo
Imfinzi	Astrazeneca	Pearl	Completion (OS in PD-L1 $\geq 25\%$ is primary endpoint) Jun 2022**
...and combinations			
Keytruda + chemo	Merck & Co	Keynote-189 & 407	Approved in all-comers
Opdivo + Yervoy + chemo	Bristol Myers Squibb	Checkmate-9LA	Approved in all-comers
Imfinzi + tremelimumab + chemo	Astrazeneca	Poseidon	Positive for mPFS & mOS vs chemo in all-comers, but no apparent regulatory action
Tyvyt (sintilimab) + chemo	Lilly/Innovent	Orient-11*	Positive for mPFS vs chemo in all-comers; US adcom 10 Feb 2022
Libtayo + chemo	Sanofi/Regeneron	Empower-Lung 3	Positive for mPFS vs chemo in all-comers; US Pdufa date 19 Sep 2022
Sugemalimab + chemo	Cstone/EQRX	Gemstone-302	Positive for mPFS vs chemo in all-comers

*Notes: *China study; **completion was originally Jul 2020, and PFS was a co-primary endpoint. Source: [clinicaltrials.gov](#) & company statements.*

[More from Evaluate Vantage](#)

Evaluate HQ
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

© Copyright 2023 Evaluate Ltd.