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Not yet time for Tim-3



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Anyone who had been hoping for proof-of-concept data soon on targeting Tim-3 will be disappointed: readout from a study of Novartis's sapatolimab, the most advanced Tim-3 project, has been delayed. The company had been expecting complete response data this quarter from the phase 2 [Stimulus-MDS1 study](#) in high-risk myelodysplastic syndrome, but today said a data-monitoring committee had concluded in June that the trial should remain blinded until its progression-free survival readout, slated for 2022 or 2023. CR and PFS are co-primary endpoints of the trial. The next most-advanced Tim-3-targeting asset, Glaxosmithkline's cobolimab, is due to yield data from the phase 2 Amber study in the second half. The Novartis delay is unusual, and depending on the committee's criteria might be due to CR data being neither strong enough to unblind the study, or not sufficiently weak to declare it futile.

Selected oncology projects targeting Tim-3

Project	Company	Detail
<i>Phase 3</i>		
Sabatolimab	Novartis	Ph2 Stimulus-MDS1 readout delayed until 2022/23; ph3 Stimulus-MDS2 readout due 2023; ph2 Stimulus-AML1 , ends Nov 2022
<i>Phase 2</i>		
Cobolimab (TSR-022)	Glaxosmithkline (ex Tesaro)/ Anaptysbio	4 Ph2 dostarlimab combo studies, incl Amber readout H2 2021, Costar-Lung readout H2 2022
RG7769/ RO7121661	Roche	Tim-3/PD-1 bispecific, ph2 three-arm study incl RG6139 (PD1/Lag3 bispecific) and Opdivo ends Aug 2024, ph1 monotherapy, ends May 2023
<i>Phase 1</i>		
Sym023	Les Laboratoires Servier	NCT03311412 , anti-PD-1 combo, ends Nov 2021
BMS-986299	Bristol Myers Squibb	NCT03444753 , +/- Opdivo/Yervoy, ends Nov 2021
BGB-A425	Beigene	NCT03744468 , anti-PD-1 combo, ends Mar 2023
BMS-986258	Bristol Myers Squibb/Five Prime	NCT03446040 , +/- Opdivo, ends Jul 2024
INCAGN2390	Incyte/Agenus	NCT04370704 , anti-PD-1/Lag-3 combo, ends Jul 2023
SHR-1702	Jiangsu Hengrui Medicine	NCT03871855 , +/- anti-PD-1, study status unknown
TQB2618	Sino Biopharmaceutical	NCT04623892 , monotherapy, trial not yet recruiting
<i>Preclinical</i>		
CA-327	Curis	Small-mol PD-L1/Tim-3 inhibitor, likely deprioritised
HLX52	Shanghai Henlius Biotech	-

Source: Evaluate Pharma & company releases.

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