

J&J study halt reveals a crisis in follow-on antibody approaches



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The quiet suspension of enrolment into a phase I trial of Johnson & Johnson/Genmab's anti-CD123 bispecific, JNJ-63709178, marks the second time this asset has been put on clinical hold. J&J would not tell *Vantage* the reasons for the suspension, beyond confirming the grade 3 adverse event listed in the Clinicaltrials.gov database. The previous hold, also due to an undisclosed serious adverse event, lasted seven months before being lifted in April 2017. JNJ-63709178's troubles look like the tip of the iceberg for follow-on antibody approaches such as bispecifics and antibody-drug conjugates (ADCs), many of which have recently hit the buffers. A phase I trial of Seattle Genetics' CD123-targeting ADC, SGN-CD123A, was terminated in May, while last year J&J handed the CD19-targeting bispecific duvortuxizumab back to its originator, Macrogenics. Though one of the leading players, ADC Therapeutics, recently started a pivotal phase II study of its anti-CD19 ADC, ADCT-402, in total 10 ADC projects have suffered setbacks so far this year.

Selected recent setbacks for antibody-drug conjugates and bispecifics

Project	Target, approach	Developer(s)	Setback	Date reported
JNJ-63709178	CD123, bispecific	J&J/Genmab	Phase I study on second clinical hold	Jul 2018
XMT-1522	Her2, ADC	Mersana Therapeutics	Phase I study on clinical hold	Jul 2018
RG7882	Muc16, ADC	Roche/Seattle Genetics	Discontinued	Jul 2018
Denintuzumab mafodotin	CD19, ADC	Seattle Genetics	Two phase II studies terminated	Jul 2018
HKT288	CDH6, ADC	Novartis/Immunogen	Phase I study terminated	Jun 2018
ADCT-401/MEDI3726	PSMA, ADC	Astrazeneca/ADC Therapeutics	Phase I study suspended	Jun 2018
SGN-CD123A	CD123, ADC	Seattle Genetics	Phase I study terminated	May 2018
ADCT-502	Her2, ADC	ADC Therapeutics	Phase I study terminated	Apr 2018
Glembatumumab vedotin	GPNMB, ADC	Celldex	Discontinued	Apr 2018
SC-007	Undisclosed, ADC	Abbvie	Phase I study terminated	Apr 2018
AGS67E	CD37, ADC	Astellas	Phase I study suspended	Mar 2018
Duvortuxizumab	CD19, bispecific	J&J/Macrogenics	Phase I study terminated, deal scrapped	Aug 2017

Source: company documents & clinicaltrials.gov.

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