Evaluate Vantage

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Morphosys gets a major tafasitamab endorsement

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Incyte hands across $750m up front and buys $150m of Morphosys equity for rights to the anti-CD19 project.

It's probably fair to say that biotech investors hungry for deals at the start of this week's JP Morgan healthcare jamboree were expecting something bigger than Lilly's buyout of Dermira and the licensing deal Incyte struck today for Morphosys's tafasitamab.

Still, however much M&A the most bullish followers want to see, the latter deal is not to be sniffed at. It represents the joint fifth-biggest single-project licensing transaction by up-front value – $750m – of recent times, and is an amazingly strong endorsement of an asset that still has a lot left to prove.

Tafasitamab, an anti-CD19 MAb with an engineered Fc fragment, has been filed in the US as part of a Revlimid combination for late-line diffuse large B-cell lymphoma. While launch for this use looks likely, the setting might ultimately not amount to much (*Why a 2020 spotlight will fall on tafasitamab, December 24, 2019*).

More important are a front-line DLBCL trial just begun, and the B-Mind bendamustine combo study against Rituxan. However, the latter's planned enrolment has had to be increased from 330 to 450 subjects, which might cause concerns about the magnitude of the expected clinical benefit.

Tafasitamab studies in selected DLBCL studies			
Study	**Design**	**Detail**	**Result**
L-mind	Tafasitamab + Revlimid combo, single-arm	81 r/r DLBCL subjects	ORR 60%, 34/80 CR
Re-Mind	Revlimid monotherapy as "synthetic control"	490 r/r DLBCL subjects	Deemed positive on the basis of 76 subjects matched vs 80 in L-Mind
B-Mind	Tafasitamab + benda vs Rituxan + benda	450 r/r DLBCL subjects, measuring PFS in all-comers and biomarker defined	Passed futility analysis Nov 2019, recommendation to upsize from 330 subjects; topline data Q1 2022
MOR208C107	Tafasitamab + Rituxan + CHOP; tafasitamab + Revlimid + Rituxan + CHOP	60 1st-line DLBCL subjects	Just begun
Source: clinicaltrials.gov & company disclosures.			

All that said, after today's Incyte endorsement such concerns will be seen as less relevant.

Under the tie-up Incyte and Morphosys will co-promote tafasitamab in the US, sharing profits 50/50, while ex-US Incyte will have sole DLBCL rights in return for a royalty. Incyte will fund development along similar lines: 55% of the total cost in the US and 100% outside.

An obvious reason why Incyte struck the deal is the company's need to boost a portfolio that, beyond Jakafi and the bile duct cancer project pemigatinib, has underwhelmed. A less obvious factor is that its pipeline also includes the PI3k delta inhibitor INCB50465/parsaclisib.

Toxicity has plagued delta-specific PI3k inhibition, as shown by Gilead's Zydelig, which is approved but hardly used in chronic lymphoblastic leukaemia. Incyte, however, sees a possible way forward, saying it wants to combine parsaclisib with tafasitamab in B-cell malignancies.

The sellside expects tafasitamab to generate 2024 revenue of $661m, according to *EvaluatePharma* consensus, and Mizuho analysts this morning said for Incyte the project did not come cheap. But, with a pipeline under pressure, when Incyte saw an approvable oncology asset on the table, it likely realised that it had to pay up.

Biggest research-stage single-product deals by up-front value since 2009				
Company	**Partner**	**Project (status)**	**Up front**	**Year**
Astrazeneca	Daiichi Sankyo	Enhertu (pivotal phase II)	$1.4bn	2019
Bristol-Myers Squibb	Nektar	Bempegaldesleukin (phase I/II)	$1.0bn*	2018
Pfizer	Merck KGaA	Bavencio (phase II)	$850m	2014
United Therapeutics	Arena	Ralinepag (phase III)	$800m	2018
Roche	Sarepta	SRP-9001 (phase II)	$750m**	2019
Incyte	Morphosys	Tafasitamab (filed)	$750m***	2020
Celgene	Nogra Pharma	Mongersen (phase II)	$710m	2014
**Plus $850m equity investment, **plus $400m equity investment; ***plus $150m equity investment. Source: EvaluatePharma & company statements.*				

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