Evaluate Vantage

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Ash 2022 – Arcellx data secure a Gilead buy-in

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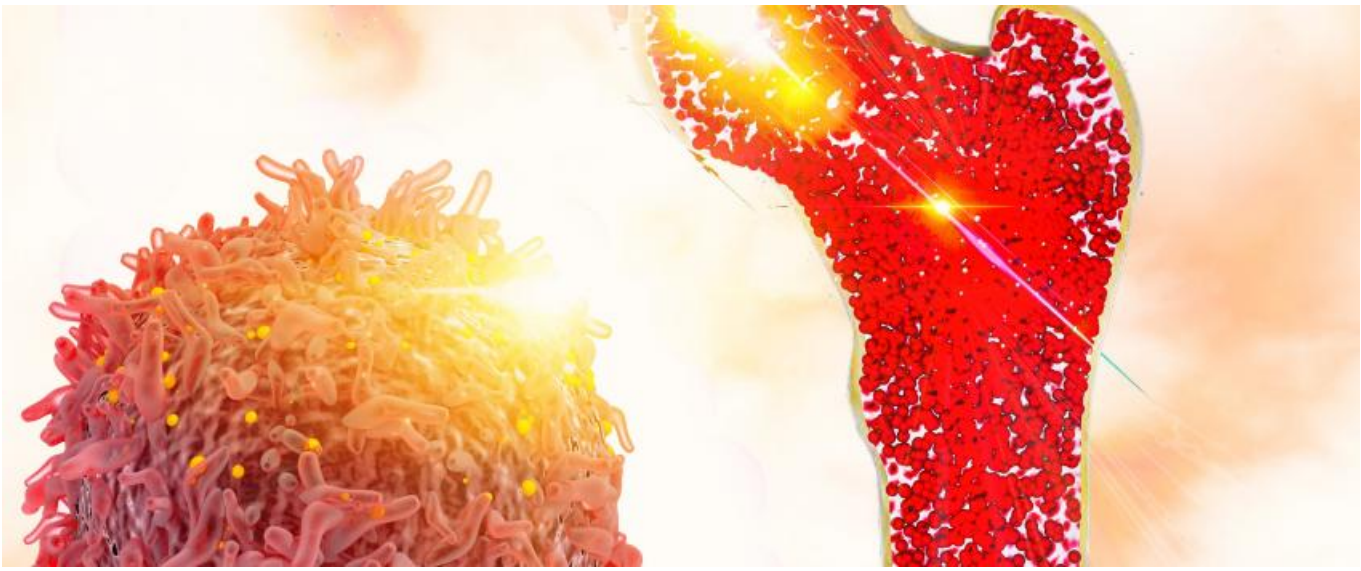


Gilead has licensed CART-ddBCMA as this cell therapy continues putting all patients into remission. Can it compete against Carvykti and Tecvayli?

With Arcellx's CART-ddBCMA maintaining its 100% track record of putting multiple myeloma patients into remission, according to data being presented at Ash, Gilead heard enough to sign on the dotted line. Friday's licensing deal saw the big biotech hand across $225m in cash and make a $100m equity investment for rights to the project.

An investor update made available ahead of Arcellx's Ash poster on Sunday sheds more light on the latest cut of the phase 1 CART-ddBCMA study that secured Gilead as a partner. J&J's approved rival BCMA-directed Car-T therapy, Carvykti, has set a high bar which, once again, CART-ddBCMA seems to have met. The Gilead deal adds a key endorsement.

Being competitive in this space is especially hard given the huge number of BCMA-targeting projects in development, and the added availability as of October of J&J's Tecvayli, a T-cell engaging MAb.

Best in class?

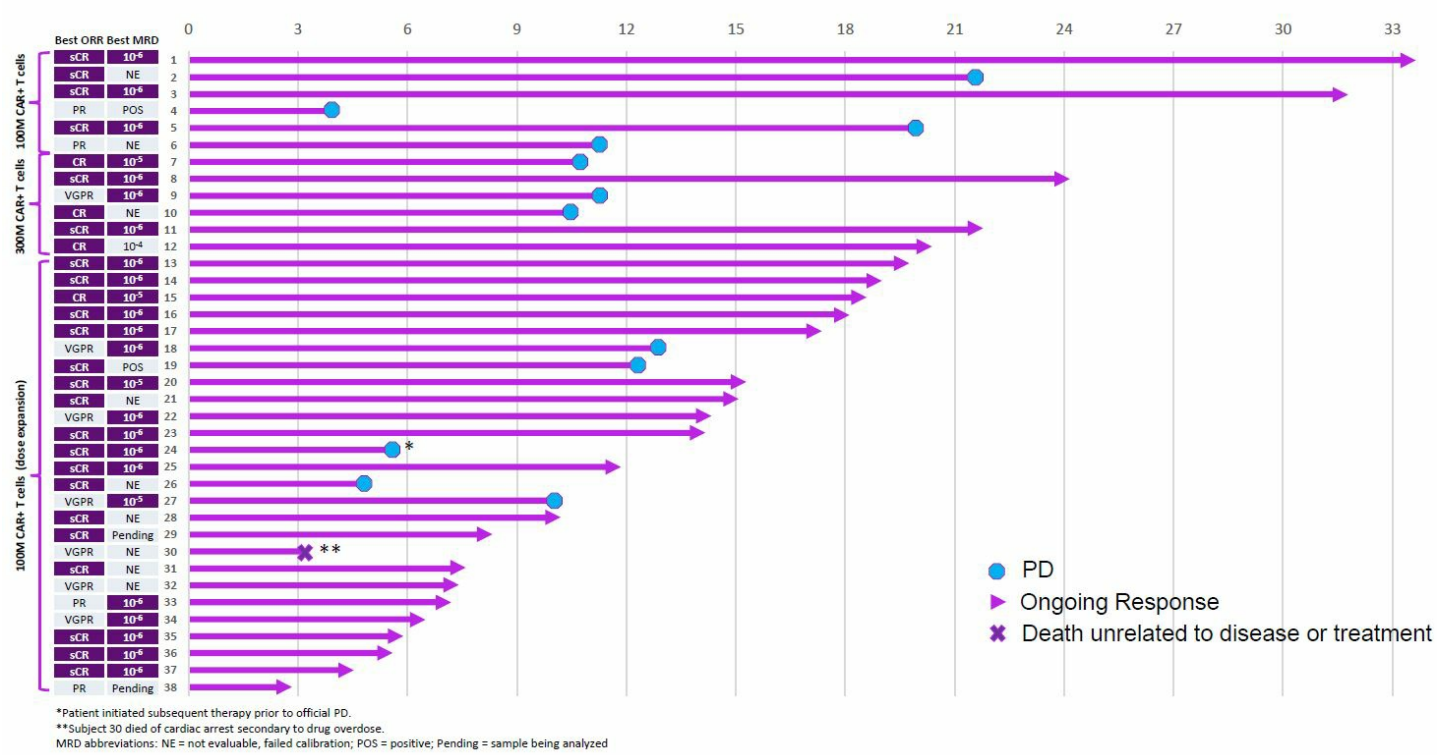
The last time Arcellx presented CART-ddBCMA data, at Asco in June, it argued that the project, which is autologous but uses an artificial binding domain to hit BCMA, had "best-in-class potential". This was on the basis of efficacy in line with Carvykti in an arguably harder-to-treat population, with possibly better safety to boot.

At Ash it is adding seven patients to bring the evaluable dataset to 38 as of an October 31 cutoff. All 31 patients previously detailed had gone into remission, and so have the extra seven patients now presented. And 27 of those 38 responses are complete.

So far so good, and it must also be stressed that safety remains relatively clean: among grade 3 events there is just one cytokine release syndrome and two neurotoxicity cases. This is the same state of play as at the Asco data cutoff.

However, many of the remissions are not proving durable. Close inspection of the swimmers plot shows that 12 patients initially responding to CART-ddBCMA have relapsed, most by around 12 months, and in addition there was one death, though this was unrelated to disease or treatment.

Accordingly, at 18 months the response rate stands at 50% – 11 of 22 patients.



Source: Arcellx presentation.

No matter, Gilead has clearly seen enough. Arcellx says CART-ddBCMA's synthetic binding region – instead of an antibody-derived one – results in more transduced cells being Car-positive than with Carvykti, allowing lower effective cell dosing and less toxicity; the data continue to bear this out.

It is notable that Gilead was until now an outlier among cell therapy players in not having an anti-BCMA therapy. Its legacy company Kite Pharma had been developing such a Car-T project, coded KITE-585, but this never progressed beyond preclinical trials. Gilead canned it after deeming it insufficiently competitive and incurred an $820m write-off as a result.

On Friday Arcellx closed up 29%. Whatever doubts remain about its data, investors should be relieved that of all the developmental BCMA projects Gilead could have chosen, it decided to pick CART-ddBCMA.

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