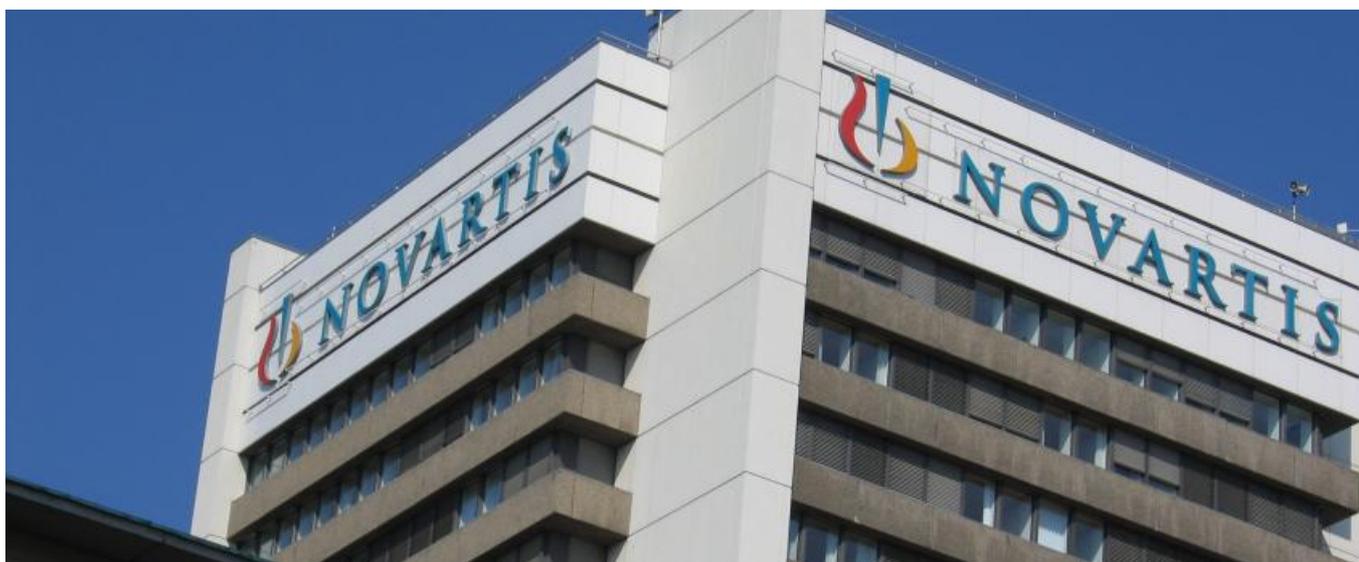


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## Novartis hopes Kymriah acceleration can save its CAR



[Madeleine Armstrong](#)



### Despite manufacturing struggles, Novartis still expects Kymriah to become a blockbuster.

Novartis's CAR-T therapy Kymriah has proven a commercial disappointment so far, and sales figures reported today will not do much to change this view.

But the company still believes that Kymriah can become a blockbuster, and is ramping up its manufacturing capacity this year to help achieve this goal. Novartis also hopes to be able to stop giving non-commercial-grade product away for free in the US soon.

Meanwhile, Novartis's plans for its follow-on CAR-T projects have taken a twist. The company, which previously listed a BCMA-targeting candidate in its pipeline, has now disclosed that it is working on a multiple myeloma study involving two CAR-T projects, one hitting BCMA and the other CD19 – though the latter is not Kymriah but [the the humanised construct CTL119](#).

Perhaps with the BCMA field becoming so crowded that the Swiss company has realised that it needs to do something different to set itself apart. Gilead recently told the JP Morgan conference that it would only pursue BCMA if its asset, KITE-585, was strongly competitive.

Novartis's new oncology head, Susanne Schaffert, told *Vantage* that the group was still pursuing the standalone BCMA project CART-BCMA. Though the company is not understood to have licensed additional constructs from the University of Pennsylvania, its R&D slide also lists CAR-T assets targeting CD22, CD123 and EGFRvIII originated at Penn.

### Stoking the Kymriah fire

Novartis's chief executive, Vas Narasimhan, was adamant that the company's efforts in cell therapy were not just about Kymriah, but also building manufacturing capabilities in this space.

However, this has not gone smoothly, with manufacturing problems holding up sales of Kymriah – something to which Mr Narasimhan admitted at the JP Morgan conference ([JP Morgan 2019 day one roundup - happy days are here again, January 8, 2019](#)).

Stricter specifications for commercial-grade Kymriah, versus the drug used in clinical trials, have apparently forced Novartis to give away some of its product for free, but this is a loophole that the company is closing:

European regulators have already approved wider commercial specifications, and Novartis has submitted a similar request to the FDA.

During today's press conference Ms Schaffert would not give a forecast for 2019 Kymriah sales, but pointed to the planned fourfold increase in manufacturing capacity for guidance.

2018 Kymriah sales came in at \$76m – multiplying this by four would equal \$304m in 2019, well above current EvaluatePharma sellside consensus.

Kymriah sales forecasts (\$m)						
2018 (actual/consensus)	2019e	2020e	2021e	2022e	2023e	2024
76/82	244	454	636	759	882	993

Source: EvaluatePharma.

Novartis's experience with Kymriah does not seem to have put it off other cell and gene therapies: Jay Bradner, president of Novartis's Institute for Biomedical Research (NIBR) said today that, although the group was focused on such projects in haematology, ophthalmology and neurology, it was also "meeting with innovators all the time in other disease spaces".

But a big acquisition appears to be off the cards: Mr Narasimhan said Novartis was looking for bolt-ons of up to \$10bn, but added that any purchases were likely to come in at under \$5bn. "Opportunities in the \$5bn+ space are few and tend to be fully valued."

### Price declines

Novartis's interest in expensive new technologies has not protected it against the price declines that have hit the rest of the industry ([No price relief in 2019, Pfizer confirms, January 29, 2019](#)).

Mr Narasimhan said that net prices of Novartis products had declined in the low single-digit range last year, something he expected to continue in 2019.

The group's Sandoz generics division was hit particularly hard by pricing pressure in the US. Mr Narasimhan reiterated a focus on high-value projects here, such as biosimilars, and also talked up a plan to make Sandoz an autonomous unit within Novartis, which should come to fruition in the next 18 months.

When pressed on whether Novartis might be preparing to spin off Sandoz, Mr Narasimhan replied: "It's part of Novartis and we plan to continue to invest [in Sandoz]." A potential complicating factor to any spin out is the fact that the biologic manufacturing capabilities necessary for biosimilar production for Sandoz are slated to stay within Novartis's innovative products division.

Novartis became the latest group to be punished for lacklustre guidance, with its stock down 1% today. But it appears that this is the new biopharma reality, and investors will need to get used to it.

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