

Microbiotica's Roche deal sets up new microbiome test



[Madeleine Armstrong](#)



A deal between the microbiome specialist Microbiotica and Roche's Genentech division has raised hopes in the sector again.

Two years ago, the failure of Seres Therapeutics' therapeutic bacterial formulation SER-109 badly knocked the microbiome space. Yesterday's deal between the UK group Microbiotica and Roche's Genentech division could raise hopes again – but this much-hyped sector still has a lot to prove.

The partnership, which will involve applying Microbiotica's microbiome knowhow to Roche's inflammatory bowel disease pipeline, could initially lead to biomarkers predicting which patients are more likely respond to drug therapy or suffer adverse events. But Microbiotica has higher hopes in the long term.

The company believes the partnership will also produce live bacterial therapies and new targets for more conventional IBD medicines, Mike Romanos, Microbiotica's chief executive officer, tells *EP Vantage*. And it might even expand into other areas such as cancer.

Going live

There is evidence that the microbiome affects patients' responses to cancer drugs and Roche would appear to be the perfect partner with which to test this theory. "We had discussions with [Roche's] oncology people as well, and they're very interested," Mr Romanos says.

But for now the two groups are focused on IBD with the collaboration, which could be worth \$534m if all goes to plan. Mr Romanos will not give further details on the financials, except to say that the first milestone payments should not be too far away, "because live bacterial products get developed very quickly".

He also does not say which Roche candidates were covered by the deal, but adds: "It's a significant part of the pipeline."

Roche's IBD pipeline appears to comprise etrolizumab and RG7880. Roche also has a phase I candidate that it is developing for undisclosed inflammatory diseases, RG6174, but it is unclear whether IBD is one of these conditions.

Roche's IBD pipeline				
Project	Indication(s)	Mechanism	Status	2024e sales (\$m)
Etrolizumab	Ulcerative colitis, Crohn's	Anti-beta 7 integrin MAb	Phase III	479
RG7880	Ulcerative colitis, Crohn's	Anti-IL-22 MAb	Phase I	-

Source: Company website, EvaluatePharma.

As for how the collaboration will work in practice, Mr Romanos says that the group will take faecal samples from patients in Roche's clinical studies and analyse each patient's microbiome "to the highest level of precision that's ever been done. From that we'll discern signatures of the bacteria in each individual and combine that with all the other data from that individual."

If these signatures can identify responders to particular drugs, they could be used to select patients for clinical trials or treatment. Microbiome signatures could also pinpoint in advance which patients are likely to have severe side effects. "You could say that these patients should never go on the drug," the chief exec says.

The next step for the project would be using this knowledge to create therapies incorporating live bacteria. These could be given alongside drugs to alter a patient's microbiome, conceivably converting them from non-responders to responders, or damping down troublesome side effects.

These live bacterial products could also be used as drugs in their own right, Mr Romanos believes.

On top of the Roche partnership, Microbiotica has its own preclinical live bacterial candidate for ulcerative colitis, which Roche has the option to take on at a later point.

Still, Mr Romanos admits that "most pharma companies are not yet interested in live bacterial products". Perhaps if the Microbiotica-Roche project yields targets that could be drugged by more conventional means, other big players might take notice.

Spore sceptics

There is still scepticism surrounding the microbiome, particularly since the Seres blow-up in 2016 ([Seres failure a kick in the gut to microbiome field, August 1, 2016](#)).

But Mr Romanos has a potential explanation for the failure of SER-109 in its phase II trial. "It is quite a crude product - it's total spores of bacteria from faeces, they're not isolated or defined or anything."

He adds that spore-based products, although potentially easier to manufacture, might not colonise the gut and alter the microbiome as effectively as non-spore formers. "Spores are hard, encased versions of the bacteria designed to survive in harsh elements. We're not going for spore-based products."

The Seres stumble might have set back the microbiome field, but it has not killed it off, Mr Romanos says. "I think that any new area won't immediately succeed. The antibody area took a long time before it became the biggest segment of the drug industry - 10 or 20 years. And gene therapy went away and came back."

Microbiotica hopes to overcome some of the mistakes previously made by microbiome players. The deal with Roche is a good start, but there is still a way to go before there is substance to back up the microbiome hype.

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