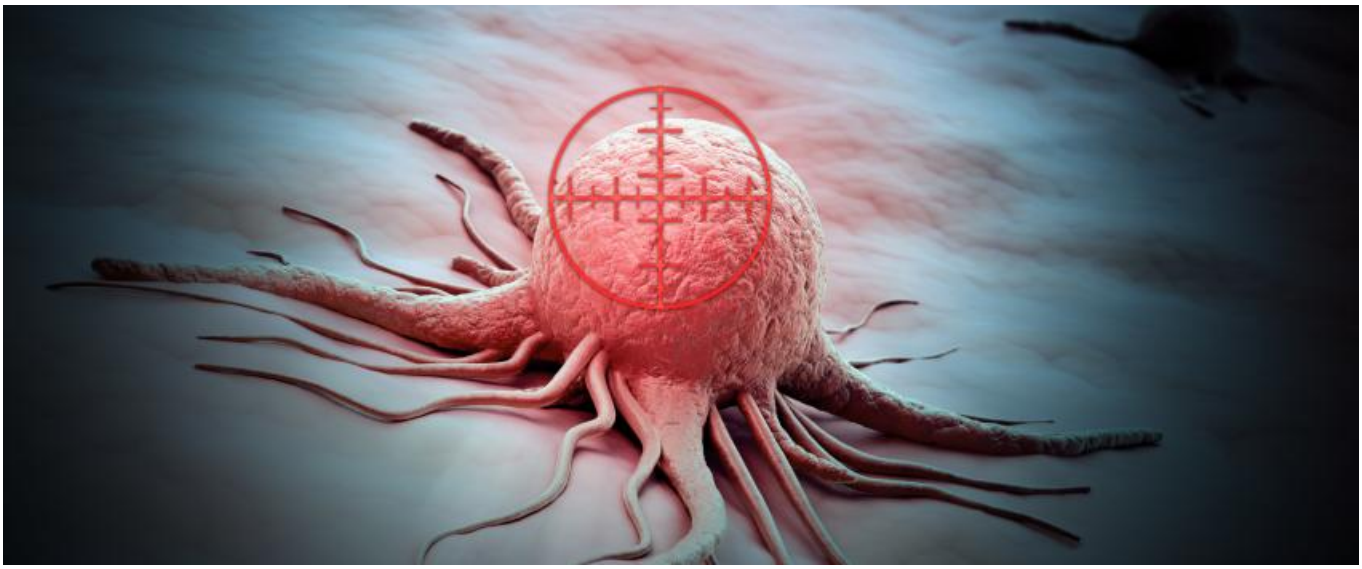
Evaluate Vantage

April 05, 2022

Despite slow progress, Boehringer keeps faith in oncology

Madeleine Armstrong



The group highlights its ambitions in cancer again, but is at least two years away from launching a new product.

This time last year Boehringer Ingelheim looked like it was finally making progress in oncology, a field it has been trying to crack, without a meaningful success, for several years. Fast forward 12 months and little appears to have changed.

The group is still "fully committed" to Kras inhibition, its global head of innovation, Michel Pairet, tells *Evaluate Vantage*. But the pace of development here seems glacial, with the first clinical data not expected until 2023 at the earliest.

Boehringer's most advanced oncology agent is not a Kras inhibitor but an MDM2-p53 antagonist known as BI 907828. A pivotal trial recently started in liposarcoma, but even if all goes well that project is not set to hit the market until 2024, Mr Pairet says.

He hopes that if this comes to pass, it will be just the start. "That will be our first new launch in oncology and the beginning of a series of new launches." Boehringer, of course, already has the marketed cancer drugs Vargatef and Gilotrif, but both have disappointed commercially.

Still, there are doubts about some of the targets Boehringer is currently going after, such as Sting agonism, on which Aduro called time in 2020, and the CD47-SIRPα pathway. The latter has come under scrutiny lately after disappointing results with ALX Oncology's evorpacept and a toxicity signal with Gilead's magrolimab.

"CD47-SIRPα comes in different colours," Mr Pairet notes, saying this is another area to which Boehringer is "committed".

Idiopathic pulmonary fibrosis

Outside cancer, the idiopathic pulmonary fibrosis project BI 1015550 might be one to watch. Data from a phase 2 trial are slated for presentation at the American Thoracic Society meeting on May 16, and Mr Pairet describes these results as "very promising".

Phase 3 development is set to start this year; Boehringer plans to investigate BI 1015550 both as monotherapy and in combination with existing IPF drugs: Boehringer's Ofev and Roche's Esbriet.

These products are not considered disease modifying, and new options have proven hard to come by. Despite Ofev's shortcomings it is still Boehringer's second-biggest drug, with 2021 sales of €2.5bn ($2.7bn) announced today.

The group's top seller is the Lilly-partnered SGLT2 inhibitor Jardiance, whose expansion into areas outside diabetes continues. It was approved in the US in February for heart failure with preserved ejection fraction (HFpEF), and could soon add chronic kidney disease to its list of indications: last month the Empa-Kidney study was stopped early for efficacy.

It will be interesting to see how Jardiance stacks up against Astrazeneca's rival SGLT2 Farxiga, which already has chronic kidney disease on its label following a win in the Dapa-CKD study.

Jardiance will also be going up against Farxiga in post-myocardial infarction patients, with studies of both agents, Empact-MI and Dapa-MI respectively, set to complete next year.

In the nearer term, Boehringer's efforts to get its first solo approval in the autoimmune space will come under the spotlight. Its IL-36 inhibitor spesolimab is due an FDA approval decision by June in generalised pustular psoriasis (GPP) flares.

However, GPP is a very rare disease, and Boehringer has bigger plans for spesolimab, with phase 2 trials ongoing in hidradenitis suppurativa and Crohn's. The asset is still in play in palmoplantar pustulosis, Mr Pairet says, despite his previous hints of lacklustre efficacy in this indication.

Selected Boehringer Ingelheim pipeline highlights

Project	Description	Status, trial details
Spesolimab	Anti-IL-36 MAb	Awaiting FDA decision in GPP flares; ph2 in hidradenitis suppurativa & Crohn's with fistulas or bowel obstruction
BI 1015550	PDE4B inhibitor	Ph2 data to be presented at ATS in May 2022
BI 907828	MDM2-p53 antagonist	Pivotal ph2/3 in liposarcoma completes Mar 2024
BI 1701963	Sos1 inhibitor (Kras)	Ph1 Krystal-14 + Mirati's adagrasib; ph1 + BI 1823911
BI 1823911	Kras G12C-selective inhibitor	Ph1 + BI 1701963
Effi-dem (BI 765063/OSE-172)*	Anti-SIRPα MAb	Ph1 (NCT03990233 & NCT05068102) + BI 754091 (PD-1 inhibitor) in solid tumours; ph1 + BI 754091 + BI 836880 (anti-VEGF/Ang2) in head & neck/liver cancers

**Partnered with OSE Immunotherapeutics. ATS=American Thoracic Society; GPP=generalised pustular psoriasis. Source: Evaluate Pharma & clinicaltrials.gov.*