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AstraZeneca Pays \$2bn To Keep Up With The Joneses

by Elizabeth Cairns

Bristol Myers Squibb and Lilly have recently done billion-dollar radiopharmaceuticals deals, and now the UK group wants a piece of the market. But can it make its Fusion fusion work?

<u>AstraZeneca PLC</u> first involved itself with <u>Fusion Pharmaceuticals Inc.</u> in 2020, striking a deal to develop novel alpha emitters. Now the UK giant has made a more definitive move, paying \$2bn upfront to take Fusion over.

In doing so, the UK major is following the path blazed by its big pharma peers <u>Bristol Myers Squibb Company</u> and <u>Eli Lilly and Company</u>, both of which have closed acquisitions of radioconjugate developers in the last few months. But it is the success of <u>Novartis AG</u> that all these groups are trying to emulate.

AstraZeneca is paying \$21 per share in cash for Fusion, plus a contingent value right of \$3 per share in cash payable upon the achievement of a specified regulatory milestone – likely the approval of Fusion's lead asset, FPI-2265. If this is paid out, the deal will be worth a total of \$2.4bn.

Key Takeaways

- AstraZeneca has bought radiopharmaceuticals developer Fusion Pharmaceuticals for \$2bn upfront
- It gets four clinical-stage assets, one of which is due an imminent Phase II readout, plus manufacturing facilities
- Stock in several other radiopharmaceuticals groups is up on further takeover speculation



FPI-2265 is designed to treat prostate cancer by binding to prostate-specific membrane antigen (PSMA) and delivering the radioisotope actinium 225. The agent is in a Phase II trial, TATCIST, interim data from which are imminent.

Pipeline

The bar for Fusion to raise was set by the leading radiopharmaceutical in prostate cancer, Novartis's Pluvicto (lutetium Lu 177 vipivotide tetraxetan). Pluvicto was approved for third-line metastatic castration-resistant prostate cancer (mCRPC) in 2022, and could move into the second-line setting on the basis of its PSMAfore trial, which reported full data last year. In PSMAfore, Pluvicto achieved 12.0 months radiographic progression-free survival (rPFS) and a 59% rPFS benefit over androgen pathway inhibitor control (Also see "ESMO 23: Pluvicto Fulfils <u>Promise For Prostate Cancer Label Expansion</u>" - Scrip, 18 Oct, 2023.).

According to Jefferies analysts, when TATCIST reports Fusion wants to see responses of around 50% in pre-Pluvicto and 30-50% post-Pluvicto patients on the measure of PSA50 (a reduction of 50% in prostate-specific antigen levels), plus good safety. (Also see "What's New, And What's Coming, In Radiopharmaceuticals" - Scrip, 2 Feb, 2024.) A response rate of 40% or more, with PFS of at least six months in post-Pluvicto patients, and a response rate of at least 50% and at least 10 months' PFS in pre-Pluvicto enrollees, would be welcome.

The data drop from TATCIST will come at the AACR meeting, being held in San Diego in early April. This will give the first indication of whether AstraZeneca's move will pay off.

Behind FPI-2265, Fusion has three other radiopharmaceuticals in the works. FPI-1434 is in a Phase I/II study in a range of solid tumors from which data might emerge later this year. And the Phase I study of FPI-2059, also in solid tumors, could report a year later.

FPI-2068, an EGFR-cMET targeted radioconjugate, began a Phase I trial in solid tumors late last year, though data are not expected before 2026. This agent emerged from the earlier collaboration between AstraZeneca and Fusion. All these assets use actinium 225 as their radioactive payload.

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In addition to the assets themselves, AstraZeneca gets the ability to make more. Fusion has onsite manufacturing and supply chain abilities for actinium-based therapies; the importance of this kind of capacity became clear a couple of years ago when Novartis had to suspend production of Pluvicto and its other main radioconjugate Lutathera owing to "potential quality issues" in its manufacturing processes.



Chain Reaction

While the Fusion buy is big pharma's latest acquisition of a radiopharmaceutical company, it may not be the last. A handful of smaller groups have promising assets in mid- or late-stage studies, and have seen their share prices rise on the basis that they look like tempting targets.

<u>Actinium Pharmaceuticals, Inc.</u>, <u>Cellectar Biosciences, Inc.</u> and Perspective Therapeutics were all up by around 15% in early trade today – for an analysis of their important assets <u>please click here</u>. Perspective could be of particular interest to any putative buyers since it too has in-house manufacturing capabilities. Watch this space.