Evaluate Vantage

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Astra shakes hands with Daiichi to take on Roche

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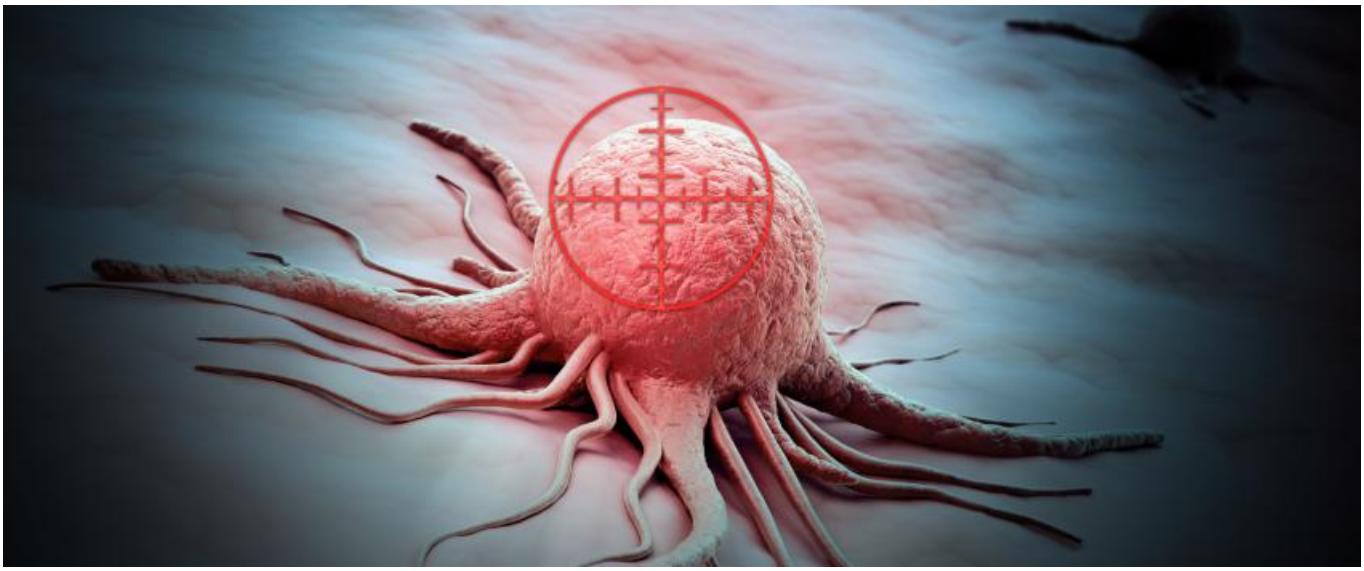

UK group bets billions on an Her2 project slated for late-line patients and those with lower expression of the target protein.

Astrazeneca has bet its future on becoming an oncology player, and today's tie-up with Daiichi Sankyo on the breast cancer project DS-8201 represents a significant new wager. The UK-based group needs the agent, a HER2-targeting antibody drug conjugate, to carve out a niche in a space that Roche has sought to wall off from competition.

Astra is paying $1.35bn up front to license the agent early in its pivotal programme, and selling shares to finance the deal. Its investors did not take the news well, sending its stock down 6% today. The company must believe the bold move will be worth it if DS-8201 can find some room to grow in patients who have progressed on Her2-targeting agents as well as those who have lower expression of the protein.

Daiichi stated today that it plans to submit DS-8201 to the US FDA by the end of September for accelerated approval, based on data from the phase II Destiny Breast01 study; a 2020 filing had previously been expected. The data will be presented at an upcoming medical meeting, but presumably Astra has been permitted to see it ahead of pulling the trigger on the licensing deal.

The deal gives Astra co-development and commercialisation rights globally outside of Japan, where Daiichi has exclusive rights. Of the up-front fee, half is to be paid now and half in a year's time. Milestones total $5.6bn, with $3.8bn on regulatory and development progress and $175m on sales goals, bringing the biodollar value of the deal to $6.9bn.

Showing the belief it has in DS-8201, Astra is selling $3.5bn in shares, half of which will be used to finance the Daiichi deal, and the other half to retire debt. Investors experiencing dilution will be perhaps more eager than normal to see this deal succeed.

Blockbuster

If the sellside is to be believed, Astra is placing a careful bet. The consensus forecast puts sales at $1.4bn, giving DS-8201 a risk-adjusted net present value of $6bn.

One justification for the scope of the deal is that the Her-targeting component of DS-8201 is trastuzumab, the active ingredient of Roche's monoclonal antibody Herceptin, and as such its safety and efficacy profile is well-known. Trastuzumab is also a component of Roche's own ADC, Kadcyla.

Daiichi has approached the development of DS-8201 strategically, seeking to first gain approval in patients

who have progressed on Kadcyla – itself a treatment for patients who have progressed on Herceptin – as well as seeking out the population of low Her2 expressers, where DS-8201 could become the first targeted treatment.

The project has gained US FDA breakthrough therapy designation for the Kadcyla-progression population, which likely gives Daiichi, and now Astra, confidence that the phase II remission data will be sufficient for a filing.

Beyond those two unmet needs, Daiichi has plotted out some bigger targets. It is testing DS-8201 a head-to-head against Kadcyla in the the Destiny-Breast03 trial, and is also evaluating the project in gastric cancer, where Herceptin is used in first-line disease.

Breaking Roche’s stranglehold in Her2-expressing cancer, with the help of an agent the Swiss group developed and commercialised no less, will be a big task. Astra, however, has been making waves in oncology, as is already forecast to climb from number seven to four in market share by 2024 thanks to Tagrisso, Imfinzi and Lynparza.

Taking on Roche in its own backyard could be a risky strategy, but if it pays off it could help Astra rise even higher.