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Eisai Boards Fast Boat To China In HER2-Targeting ADC Deal With Bliss

by Alaric DeArment

The Japanese drug maker is the second in the space of a month to partner up with a Chinese biotech firm for a HER2-targeting antibody-drug conjugate, as ADCs gain more interest from large pharma firms.

With the success of *AstraZeneca PLC* and *Daiichi Sankyo Co., Ltd.*'s Enhertu (fam-trastuzumab daruxtecan-nxki), a number of drug makers are hoping to get in on the HER2 game as well, in some cases looking to companies in China developing HER2-targeting antibody-drug conjugates (ADC). Japanese drug maker *Eisai Co., Ltd.* is the latest firm to take that route with a development partnership centered on Bliss Biopharmaceutical Co. Ltd.'s Phase I/II ADC candidate.

Hangzhou, China-based BlissBio said 7 May that it had signed a clinical trial collaboration agreement with Eisai with an option for strategic collaboration for BB-1701, its eribulin payload-based ADC against HER2 for the treatment of various cancers. Under the terms of the deal, BlissBio will receive an undisclosed upfront payment and milestones to co-develop BB-1707 with Eisai through an option period.

If Eisai exercises its option to enter a strategic collaboration to license the drug, BlissBio will receive an exercise option payment and be eligible for development and commercial milestones up to an aggregate of $2bn, with Eisai receiving rights to develop and commercialize the drug for territories outside of Greater China.

Originally winning a nod from the US Food and Drug Administration in 2019, Enhertu is approved for certain pretreated patients with HER2-positive or HER2-low expression breast cancer, non-small cell lung cancer (NSCLC) and gastroesophageal junction cancer.

Enhertu has seen its sales grow to blockbuster levels, with those outside of Japan reaching $1.2bn for the full year of 2022, up from $426m in 2021. (Also see "*AstraZeneca Confident For Next*

Decade Despite Upcoming Patent Cliff" - Scrip, 9 Feb, 2023.)

Me-Too HER2 ADCs Getting More Attention

HER2 is a longstanding target for cancer drugs, with *Roche Holding AG* building a franchise starting with Herceptin (trastuzumab) in 1998 and expanding that to include the next-generation Perjeta (pertuzumab), the combination product Phesgo (pertuzumab/trastuzumab) and the ADC Kadcyla (trastuzumab emtansine) – which continues to make it a valuable business for Roche despite biosimilar competition for trastuzumab.

Roche's desire to maintain its foothold in HER2 has led it to China as well: it announced a deal with China-based *Zion Pharma Limited* on 9 May, paying $70m up front to develop the Phase I, blood brain barrier-penetrant, oral, HER2-targeting tyrosine kinase inhibitor ZN-A-1041, with milestone payments of up to $610m.

ADCs have been around for a long time too, and Enhertu's success has led a number of players to try to get a seat at the table as well and develop their own candidates, particularly in China.

The American Association for Cancer Research (AACR) annual meeting in April featured at least three Chinese biotech companies stepping into the ring to develop their own me-too HER2-targeting ADCs, with potential benefits in terms of safety and efficacy. *Jiangsu Hengrui Pharmaceuticals* showcased SHR-A1811, which was the most advanced of the three, having entered two Phase III studies in China for HER2-positive and HER2-low expression breast cancers.

The drug features a lower drug-to-antibody ratio than Enhertu – 5.7, versus eight for the AstraZeneca/Daiichi Sankyo drug – which is designed to deal with adverse events associated with Enhertu, such as interstitial lung disease. Next up were *Duality Biologics*' Phase I/IIa DB-1303 and *Biokin Pharmaceutical*'s Phase I BL-M01D1. (Also see "*AACR: Chinese Pharma Firms Showcase Enhertu Fast-Followers*" - Scrip, 18 Apr, 2023.)

In looking to China for a HER2 candidate to incorporate into its pipeline, Eisai joins *BioNTech SE*, which licensed DualityBio's candidate ahead of the AACR meeting, along with a topoisomerase-1 inhibitor-based ADC, for $170m upfront and development and commercial milestone payments potentially totaling more than $1.5bn.

Eisai joins a growing list of companies seeking out new potential pipeline candidates from Chinese firms – *Johnson & Johnson*, which licensed, developed and ultimately won approval for *Legend Biotech Corp.*'s BCMA-targeting CAR-T therapy for multiple myeloma, Carvykti (ciltacabtagene autotemcel), stands out as a prominent example. And Eisai's move is also indicative of the growing interest across the industry in ADCs.

Twelve ADCs have cleared the FDA since 2017, and in March, *Pfizer Inc.* put up $43bn to acquire ADC specialist *Seagen Inc.* (Also see "*BioNTech Gets In On ADC Action With DualityBio Licensing Deal*" - Scrip, 3 Apr, 2023.)