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Akeso's Xia Looks Beyond Summit Deal To Independent Global Development, Sales

by Dexter Yan

Last December, China's Akeso struck a major agreement worth up to $5bn with Summit Therapeutics, which set a new record in terms of total deal value for a single asset in the Chinese biopharma sector. Akeso founder and CEO Michelle Xia is now planning to pursue a more independent path in taking the firm global.

After striking a licensing deal valued at up to $5bn for a bispecific antibody with US biotech *Summit Therapeutics plc* in December, Chinese bioventure *Akeso Inc.*'s founder, chairwoman and CEO Michelle Xia shared her thoughts about the transaction and beyond in wide-ranging audio interview with *Scrip*.

With extensive international industry experience at companies including *Bayer AG* and *PDL BioPharma, Inc.* in the US, the executive brings a broad perspective to the role.

Depicting the deal as the right collaboration at the
right time and with the right people, Xia pointed out that Summit had demonstrated determination to move Akeso's anti-PD-1/VEGF bispecific antibody ivonescimab into the clinic outside China. In the "right hands" that Summit extended to fast-track its partner's go-global efforts, the CEO also saw advantages to partnering with a smaller firm over far more resource-rich big pharma.

Two months into the alliance, Xia disclosed the ivonescimab program was progressing at "very good" speed in the US. As of mid-February, the two partners had held several consultations with the Food and Drug Administration on the shape of planned clinical studies, which are expected to be backed by existing data from several Phase III trials with the antibody in Chinese patients with non-small cell lung cancer (NSCLC).

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One of the trials is evaluating ivonescimab as monotherapy versus *Merck & Co., Inc.*'s blockbuster Keytruda (pembrolizumab) for the first-line treatment of PD-L1-positive NSCLC, while another is studying the bispecific agent plus chemotherapy against chemotherapy in EGFR inhibitor-resistant non-squamous NSCLC.

Given that PD-1/L1 checkpoint inhibitors have established themselves on a solid footing in the lung cancer treatment landscape, Xia acknowledged that a head-to-head study would be the acid test for any potential future game changer. "If we have successful trials in the future, that will be a breakthrough in NSCLC," she said. "We have confidence but science will tell us the results."

AKESO FOUNDER, CHAIRWOMAN AND CEO MICHELLE XIA *Source: Akeso*

Looking Further Ahead

Although Akeso successfully developed the world's first double checkpoint inhibitor bispecific antibody, the PD-1/CTLA-4-targeted cadonilimab, and is now making a name for itself on the world stage with ivonescimab, Xia declined to label the firm as only focused on bispecific antibodies.

To date, it has had approvals in China for two anti-PD-1 antibodies - Annike (penpulimab) and Puyouheng (pucotenlimab). The first was commercialized by compatriot firm *Sino Biopharmaceutical Limited* and the latter by another domestic licensing partner, *Lepu Biopharma Co., Ltd.*

Summit Bets On Akeso IO Bispecific Despite China Firms' Issues With US FDA

By Alaric DeArment

06 Dec 2022

Deal Snapshot: Akeso has already sought to secure FDA approval for its PD-1 inhibitor, but the agency has shown reluctance to approve drugs based on China-only data.

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Two other monoclonal antibodies, the anti-IL-12/23 asset ebdarokimab for autoimmune diseases and PCSK9-targeting ebronucimab for metabolic disorders, are also nearing new drug application filings in China in 2023, Xia said. Other pipeline assets in earlier clinical stages include the anti-CD47 antibody ligufalimab and anti-TIGIT antibody AK127.

Moreover, Akeso is setting its sights on modalities other than the antibody platform it is best

known for, with ongoing early-stage R&D into cell therapies and antibody-drug conjugates also underway, the executive noted.

Some of these candidates will hopefully ultimately fulfil Xia's ambitions for Akeso to truly go global, the strategy for which includes conducting worldwide clinical development single-handedly, the executive noted. Notably, it already took one of the first steps in the Summit deal by seeking co-branding of ivonescimab in the US, Canada, Europe and Japan following regulatory approvals.

"We wish more people globally to know us and recognize the Akeso brand," the executive added. This and all our other podcasts are available on the Pharma Intelligence channel on *Apple Podcasts*, *Google Podcasts*, *SoundCloud*, *TuneIn* and *Spotify Podcasts*, and via smart speakers if one of these platforms has been set up as your default podcast provider.

China Approves World's First Bispecific IO Drug Amid PD-1/L1 Glut

By Dexter Yan

01 Jul 2022

Akeso's PD-1/CTLA-4-targeting therapy cadonilimab has been the front-runner in the bispecific antibody field in China, leading about 50 other similar agents under development by domestic pharma firms. With a new conditional approval, it has also gained a head start over home-grown PD-1/L1 antibody rivals in the cervical cancer space.

Read the full article here

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- Platform buildup and choice of targets (07:22)
- Cadonilimab versus PD-1 (11:32)

- Licensing prospects for cadonilimab (14:43)
- Bispecific antibody versus ADC (17:10)
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