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Chinese Language Podcast: BIOSECURE Act, US PD-1 Approval, ADC Updates

by Brian Yang

Guest speaker and lawyer Kevin Duan joins Brian Yang and Dexter Yan to discuss the planned US BIOSECURE Act, the US approval of BeiGene's anti-PD-1 drug and the latest antibody-drug conjugates in development at Chinese pharma firms.

The proposed BIOSECURE Act is advancing through the US Congress after the Senate voted in favor of passing the associated bill, creating worry among industry insiders in China about the planned legislation's unintended consequences. (Also see "*China Biotechs, CDMOs Embrace Uncertain Future, New Options Amid WuXi Woes*" - Scrip, 19 Mar, 2024.)

In this latest Chinese-language podcast, editors Brian Yang and Dexter Yan, along with guest, lawyer Kevin Duan, discuss the significance, potential scope and impact of the law, how potentially affected companies should prepare and likely next steps.

Also in the US, the Food and Drug Administration recently approved *BeiGene, Ltd.*'s anti-PD-1 antibody Tevimbra (tislelizumab) after a long 20-month wait. (Also see "*US Tevimbra Approval Validates BeiGene's Asia-Heavy Global Trial Approach*" - Scrip, 17 Mar, 2024.)

As the approval was largely based on a Phase III trial that had the majority of its participants from Asia, what are some of the lessons to be learned about clinical study design for other biopharma companies eyeing US product approvals? Also discussed is the competitive landscape for the drug's approved indication and the prospects for tislelizumab to move into the first-line setting.

China's originators of antibody-drug conjugates (ADCs) have continued venturing into more therapeutic targets, including EGFR x HER3. (Also see "*Chinese ADC Developers Unveil More Target Combos In Bispecific Drive*" - Scrip, 13 Mar, 2024.) What are the latest developments at *Biokine Therapeutics Ltd.* and partner *Bristol Myers Squibb Company* and what are other ADC developers doing to catch up across various targets?

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