DotBio announces that its partner Junshi Biosciences has received approval from NMPA to advance JS207 into clinical studies

- The first oncology candidate developed with DotBio's proprietary DotBody technology, JS207, is expected to enter human studies soon
- JS207 is a next-generation cancer antibody against VEGF and PD-1 with broad applicability in multiple oncology indications
- DotBio is eligible to receive a milestone payment from Junshi Biosciences in relation to the approval of the Investigational New Drug application from China's National Medical Products Administration

Singapore, September, 7, 2023 – DotBio, the biopharmaceutical company pushing the boundaries of antibody therapeutic modalities to bring more effective therapies to patients, today announced that its partner, Junshi Biosciences has received approval of its Investigational New Drug (IND) application from China's National Medical Products Administration (NMPA) for the Phase I clinical trial of JS207, which incorporates DotBody technology. JS207 is a recombinant, humanized, bispecific antibody for advanced malignant tumours that combines an anti- Vascular Endothelial Growth Factor (VEGF) DotBody module and Junshi Biosciences' anti-Programmed Death-1(PD-1) antibody.

"We are thrilled to see the first molecule containing a DotBio-engineered DotBody module receive approval to enter the clinic, an important validation of our DotBody platform technology. JS207 is an exciting, highly targeted, next-generation cancer therapy that was rapidly designed using our platform technology and is just one example of how we can apply our modular approach to antibody discovery and progress it into the clinic," **said Ignacio Asial, Chief Executive Officer of DotBio.** "This very specific combination of anti-VEGF and anti-PD-1 addresses tumour growth and the tumour's immune evasion tactics simultaneously. JS207 could provide a much needed new treatment option for cancer patients."

DotBio's anti-VEGF module was discovered through the company's patented DotBody technology platform. The platform enables the generation of multi-specific antibodies in record time, through prefabricated modules which are optimised for high stability and easy integration into more complex antibody molecules.

The modularity of the DotBody platform powers a rapid prototyping engine that compares thousands of antibody prototypes in parallel before the ideal candidate is selected for an indication. JS207 is the first next generation cancer therapy enabled by the DotBody technology to receive regulatory approval to enter clinical development.

JS207 was engineered by combining DotBio's anti-VEGF module and Junshi Biosciences' anti-PD-1 antibody into a single therapeutic agent, binding to both PD-1 and VEGF with high affinity. VEGF is overexpressed in most solid tumour types, leading to an angiogenic 'switch' where new blood vessels form around a tumour and allow it to grow exponentially. Many tumours overexpress the proteins PD-L1 or PD-L2, which suppress the immune system by binding to PD-1 present on certain immune cells. The combination therapy of a PD-1 blocking antibody and a VEGF blocking agent has shown strong efficacy in a variety of tumour types, such as renal cell carcinoma, non-small cell lung cancer and hepatocellular carcinoma.

JS207 inhibits the interaction between PD-1 and its ligands, PD-L1 and PD-L2, while concurrently obstructing the VEGF pathway. This dual-action mechanism allows JS207 to harness the benefits of both immunotherapies and anti-angiogenic treatments to achieve more powerful anti-tumour activity. At the time of this announcement, there is no bispecific antibody drug with similar targets that has received regulatory marketing approval.

DotBio and Junshi Biosciences entered into a commercial licensing agreement in 2022, under which Junshi Biosciences obtained licenses to develop and commercialise DotBody modules against oncology targets. JS207 has quickly achieved a number of development milestones, from engineering through to NMPA filing and approval in 18 months. Under the agreement, Junshi Biosciences has the right to generate additional therapeutic candidates using DotBio's technology.

As JS207 moves through the clinic, DotBio is eligible to receive development-based milestone payments as well as royalties on sales following commercialisation of the asset. JS207's IND approval will trigger a milestone payment for DotBio.

About DotBio

DotBio is a highly innovative biopharmaceutical company with a mission to harness next-generation antibody technologies to bring more effective therapies to patients. DotBio takes an innovative therapeutic approach towards the ideal treatment: the rapid prototyping of multi-functional antibodies to identify molecules with synergistic activity combinations, optimal architectures and unique mechanisms of action. DotBio's approach involves the use of its modular DotBody technology platform, its CoFi and Hot-CoFi stabilization technologies, high-throughput miniaturized assays and data analytics to generate unique therapeutic molecules that target both extracellular and intracellular disease drivers. DotBio is a platform company with a growing portfolio of assets, including numerous target-specific DotBody modules, as well as numerous preclinical assets in the immuno-oncology field.

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