Sound Biologics Announces Breakthrough Approval of PSB205 by the National Medical Products Administration in China

SEATTLE, WA, UNITED STATES, October 16, 2024 /EINPresswire.com/ -- Qilu Puget Sound Biotherapeutic Corp. (Sound Biologics), a pioneering biotechnology company focused on next-generation antibody therapies, today announced the accelerated approval of its lead product, PSB205, by the National Medical Products Administration (NMPA) in China.

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>
> *Wei Yan*

This milestone marks the first-ever approval of a MabPair™ product for the treatment of recurrent or metastatic cervical cancer.

PSB205, also known as QL1706, is a novel bifunctional therapy combining anti-PD-1 (Iparomlimab) and anti-CTLA-4 (Tuvonralimab) antibodies, designed and produced together from a single cell line using Sound Biologics' proprietary MabPair™ technology.

Unlike conventional dual targeting immunotherapy, which often results in heightened toxicity, PSB205 offers a uniquely balanced approach. By fine-tuning the exposure levels of both antibodies per treatment, PSB205 delivers robust anti-tumor responses while significantly reducing the risk of severe immune related side effects.

"We are thrilled to offer a new, more effective option for cervical cancer patients in China," said Wei Yan, CEO of Sound Biologics. "The approval of PSB205 highlights the groundbreaking potential of MabPair™ technology, providing enhanced efficacy with better tolerability. We look forward to additional data in ongoing trials in other types of solid tumors."

Clinical Results Show Promise for Advanced Cervical Cancer

Cervical cancer remains one of the leading malignancies among women, with approximately 100,000 new cases and 30,000 deaths annually in China alone. PSB205 addresses the urgent need for more effective treatments for patients who have failed first-line therapies.

The pivotal Phase II DUBHE-C-206 clinical trial conducted by Qilu Pharma in China, involving 148

patients with recurrent or metastatic cervical cancer, demonstrated impressive results.

Key findings included:

- Overall Response Rate (ORR): 33.3%
- Disease Control Rate (DCR): 65.3%
- Median Progression-Free Survival (PFS): 5.4 months
- Median Overall Survival (OS): 17.1 months

Additionally, safety data showed that 43.9% of patients experienced immune-related adverse events (irAEs), with 14% developing grade 3 or higher irAEs, underscoring PSB205's superior tolerability profile.

MabPair™ Technology: A Game-Changer in Delivering Dual Targeting Immunotherapy

MabPair™ products like PSB205 offer distinct advantages over conventional bispecific antibodies. By producing two independently engineered monoclonal antibodies from a single cell line to form one product, Sound Biologics ensures optimized target coverage, effector functions, pharmacokinetics, and enhanced therapeutic efficacy of the treatment. This breakthrough has the potential to redefine combination immunotherapy, offering a more natural antibody structure with better stability and reduced toxicity.

PSB205 is currently being evaluated in multiple ongoing Phase III trials across various tumor types, with over 2,000 patients treated to date.

About Sound Biologics
Sound Biologics is a leading biotechnology company dedicated to the discovery and development of innovative immune therapies. Leveraging its proprietary MabPair™ platform, the company is revolutionizing the antibody combination treatment with products that offer superior efficacy, flexibility, safety and reduced cost. For more information, visit www.soundbiologics.com.

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