

BioNova Announces 乐舒克® (Belumosudil Mesylate Tablets) Approval by China NMPA for the Treatment of Patients with Chronic Graft-Versus-Host Disease (cGVHD)

- 乐舒克® (Belumosudil Mesylate Tablets) is approved for the treatment of patients 12 years and older with cGVHD who have an inadequate response to corticosteroids or other systemic treatments.
- This approval is the first and only targeted therapy approved for this indication in China.

Shanghai, China and Summit, NJ, August 1 2023 - BioNova Pharmaceuticals Limited (BioNova), a company dedicated to the discovery, development and commercialization of innovative medicines for the treatment of diseases with unmet medical needs, together with its subsidiary BK Pharmaceuticals Limited (BK Pharma), is pleased to announce that 乐舒克® (Belumosudil Mesylate Tablets) has been approved by the China National Medical Products Administration (NMPA) for the treatment of patients with cGVHD who have an inadequate response to corticosteroids or other systemic treatments.

This is the first targeted therapy approved for this indication in China and marks a significant milestone in the medical community, as cGVHD is a life-threatening condition with limited treatment options. Belumosudil has been approved in other countries including the U.S., Great Britain, Canada, Australia and Israel, and marked under the tradename Rezurock/Rholistiq.

"Today's NMPA approval of 乐舒克® (Belumosudil Mesylate Tablets) marks a momentous achievement for BioNova and, more importantly, for cGVHD patients suffering from this devastating condition and for their families. Ahead of the approval, 乐舒克® (Belumosudil Mesylate Tablets) has already been listed as the recommended second-line therapy for cGVHD in the 2023 Chinese Society of Clinical Oncology (CSCO) guidelines, which is a testimony of the recognition and anticipation of this new drug in the hematology and transplantation medical society. Our dedicated team has worked tirelessly along with participating clinical centers to bring this innovative treatment to fruition, and this approval is a testament to their unwavering commitment to improving patient lives. We are immensely proud of their efforts and grateful to the patients and healthcare providers who participated in the clinical trials." said Ye Hua, M.D., Founder and CEO of BioNova.

"The approval of 乐舒克® (Belumosudil Mesylate Tablets) is a significant milestone for BioNova, building a solid foundation for our long-term strategy to build a renowned biotech company focusing on developing transformative therapies in areas with critical unmet medical needs. As we move forward, we anticipate 乐舒克® (Belumosudil Mesylate Tablets) success to positively impact our growth trajectory, reinforcing our position as a pioneering force in the biopharmaceutical industry. This milestone strengthens our resolve to continue investing in research and innovation, ultimately benefitting patients and shareholders alike," commented Bryan Huang, Ph.D., CFO and Chief Strategy Officer of BioNova, acting CEO of BK Pharma.

With 乐舒克® (Belumosudil Mesylate Tablets) NDA approval for cGVHD treatment, BioNova aims to initiate immediate commercialization efforts, ensuring broad accessibility to patients in need. The company remains committed to further unfolding potential novel treatment for challenging medical conditions, aiming to translate innovative science to medical solutions that improve patients' lives globally.

About cGVHD

cGVHD is a serious complication that can occur after allogeneic hematopoietic stem-cell

transplant, where the transplanted cells attack the recipient's tissues, leading to devastating morbidity and mortality.

About 乐舒克®(Belumosudil Mesylate Tablets)

乐舒克®(Belumosudil Mesylate Tablets) is the first and only approved therapy in China targeting Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response and fibrotic processes.

About BioNova

BioNova Pharmaceuticals Limited is a privately held clinical-stage biopharmaceutical company dedicated to the development and commercialization of innovative medicines for cancer and other life-threatening diseases with high unmet medical needs. Headquartered in Shanghai, BioNova is a fast-growing company of which robust pipeline is built upon internal R&D programs, collaborations with and acquisitions from partners of cutting-edge technology. With a highly capable and experienced team in combination with substantial funding, BioNova is committed to delivering high-quality innovative medicines to patients in China and globally.

For further information, please refer to <https://www.bionovapharma.com>.

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