



BioNova Announces Submission of New Drug Application for Belumosudil for the Treatment of Chronic Graft-Versus-Host Disease in China

Shanghai and Hong Kong, PRC, Nov. 22, 2021 - 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 joint venture subsidiary BK Pharmaceuticals Limited, today announced that it has filed a New Drug Application (NDA) for belumosudil for the treatment of chronic graft-versus-host disease (cGVHD) to the China National Medical Products Administration (NMPA). In 2019, BioNova and Kadmon Holdings, Inc., which has been subsequently acquired by Sanofi SA (NYSE: SNY), entered into a strategic partnership to form a joint venture, BK Pharmaceuticals Limited, to develop and commercialize belumosudil for GVHD in China.

Belumosudil, marked in the United States under the brand name REZUROCK™, is a first-in-class, orally available, selective small molecule inhibitor of ROCK2 (Rho-associated coiled-coil kinase 2), a molecular target involved in multiple autoimmune, fibrotic and neurodegenerative diseases. Belumosudil was granted Breakthrough Therapy Designation by both the U.S. Food and Drug Administration (FDA) and NMPA for the treatment of cGVHD in 2018 and 2020, respectively. In July 2021, the U.S. FDA granted REZUROCK full approval for the treatment of adult and pediatric patients 12 years and older with cGVHD after failure of at least two prior lines of systemic therapy.

“This NDA submission represents an exciting milestone to BioNova and marks a significant step towards addressing the current unmet medical need in post-transplant patients living with cGVHD.” said Ye Hua, M.D., Founder and CEO of BioNova. “The first NDA filing has transformed BioNova from an essentially R&D biotech to a commercial-stage biopharma. We continue to work diligently with NMPA during the review process and hope to bring belumosudil across the finish line in a timely manner.”

“We are very pleased with this significant progress made in such a short time frame.” Remarked Bryan Huang, Ph.D., CEO of BK Pharmaceuticals Limited. “Over the last two years, the BioNova team has demonstrated high professional integrity, rigorous and efficient execution. We continue to work to prepare for the potential commercial launch of belumosudil in China.”

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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