U.S. FDA Grants Full Approval of REZUROCK(TM) (belumosudil) for the Treatment of Patients with Chronic Graft-Versus-Host Disease (cGVHD)

On 16th of July 2021, -BioNova Pharmaceuticals Ltd. (**BioNova**) partner Kadmon Holdings, Inc. (**Kadmon**) announced that REZUROCK was approved by the US FDA 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. The FDA granted Breakthrough Therapy designation and Priority Review for REZUROCK and reviewed the New Drug Application (NDA) under the Real-Time Oncology Review (RTOR) pilot program. The FDA approved this NDA six weeks ahead of the Prescription Drug User Fee Act (PDUFA) goal date of August 30, 2021. REZUROCK is the first and only FDA-approved small molecule inhibitor of ROCK2, a signaling pathway that modulates inflammatory responses and fibrotic processes. BioNova subsidiary BK Pharmaceuticals Limited (Hong Kong) holds the commercial right of REZUROCK in China.

"REZUROCK represents a new treatment paradigm for thousands of cGVHD patients, including those with difficult-to-treat manifestations like fibrosis," said Corey Cutler, MD, MPH, FRCPC, Associate Professor of Medicine at Harvard Medical School and Medical Director, Adult Stem Cell Transplantation Program at the Dana-Farber Cancer Institute. "REZUROCK has shown robust and durable responses across the spectrum of cGVHD and is safe and well tolerated, allowing patients to stay on therapy and achieve meaningful benefit from treatment."

The FDA approval of REZUROCK is based on safety and efficacy results from ROCKstar (KD025-213), a randomized, open-label, multicenter pivotal trial of REZUROCK in patients with cGVHD who had received two to five prior lines of systemic therapy. There were 65 patients treated with REZUROCK 200 mg taken orally QD. The median time from cGVHD diagnosis was 25.3 months and 48% of patients had four or more organs involved. Patients had cycled through a median of 3 prior lines of systemic therapy and 78% were refractory to their last therapy. REZUROCK 200 mg QD achieved an Overall Response Rate (ORR) of 75% through Cycle 7 Day 1 of treatment (95% Confidence Interval (CI): 63, 85), with 6% achieving a complete response and 69% achieving a partial response. The median time to first response was 1.8 months. Sixty-two percent (62%) of responders did not require new systemic therapy for at least 12 months following response. The median duration of treatment was 10.4 months.

In November 2019, BioNova formed a strategic partnership with Kadmon to exclusively develop and commercialize BN101 (REZUROCK) for the treatment of graft-versus-host disease (GVHD) in the People's Republic of China. The joint venture, BK Pharmaceuticals Limited, is domiciled in Hong Kong with shared oversight between Kadmon and BioNova.

"While hematopoietic stem cell transplant remains a curative treatment option for patients with certain hematologic malignancies, GVHD presents a major post-transplant complication and can compromise long-term outcomes. REZUROCK US approval offers a novel treatment option to cGVHD patients with high unmet medical need," said Ye Hua, M.D., MPH, Founder and CEO of BioNova. "We are working diligently with the NMPA and the hematology/transplant medical society on REZUROCK China development and hope to bring this highly anticipated treatment to Chinese cGVHD patients expeditiously."

About cGVHD

cGVHD is a complication that can occur following allogeneic stem cell transplantation, resulting in significant morbidity and mortality. In cGVHD patients, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus, and gastrointestinal tract. The number of allogenic stem cell transplant has been rising at a rate of 20-30% each year since 2008 in China, and the totally number of patients who received allogenic stem cell transplant exceeded 10,000

in 2020. About 40-70% of the post-transplant patients will develop cGVHD.

About BioNova

BioNova Pharmaceuticals Ltd. is a biopharmaceutical company dedicated to the development and commercialization of innovative medicines for the treatment of diseases with high unmet medical needs.

BioNova focuses on building a robust pipeline through internal R&D programs, collaborations with global partners, and selective license and acquisitions. With a highly capable research and development team, efficient operating model, and substantial funding, BioNova is committed to delivering high quality innovative medicines to the patients in China and globally.

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