Expanded Access Policy of Belite Bio, Inc

Belite Bio, Inc. is dedicated to advancing novel therapeutics targeting retinal degenerative eye diseases with significant unmet medical need, such as atrophic age-related macular degeneration (AMD), commonly known as Geographic Atrophy (GA) and Stargardt disease (STGD1). Our lead candidate Tinlarebant, developed from our RBP4 intellectual property portfolio, is a novel oral therapy which is intended to reduce the accumulation of toxins in the eye that cause STGD1 and contribute to GA.

Belite Bio believes the safest and most effective way of providing access to Tinlarebant is through participation in our ongoing clinical trials. In a trial setting, patients benefit from direct care through regular monitoring and comprehensive follow-up by healthcare professionals. Therefore, Belite Bio encourages patients to speak with their treating physicians about participating in a clinical trial. For more information on the current clinical trials sponsored by Belite Bio, please visit the "Clinical Trials" page on our website at https://belitebio.com/ or visit www.clinicaltrials.gov.

Belite Bio recognizes the importance of utilizing the applicable regulatory pathways for providing access to our investigational therapy when patients with serious or life-threatening conditions have exhausted all treatment options and are not eligible to participate in a clinical trial. Expanded access, also called compassionate use, is a potential pathway for a patient to gain access to an investigational therapy that has not yet been approved by U.S. Food and Drug Administration or another regulatory authority.

Currently, Belite Bio is unable to provide Tinlarebant on an expanded access basis due to limited supplies of the investigational drug but is hopeful to establish an expanded access program for eligible patients in the future. All requests for expanded access must come from a patient's treating physician and will be evaluated and responded to on a case-by-case basis. We will continue to assess our capacity to facilitate expanded access and should the program become available, the associated policy will be updated. The posting of the policy by Belite Bio shall not serve as a guarantee of access to any specific investigational therapy for any individual patient.