KALOBIOS EXPANDED ACCESS POLICY

KaloBios is committed to developing therapies that provide meaningful benefit to patients suffering from serious and life-threatening conditions. We currently have clinical development programs underway for KB004, with the ultimate goal of gaining FDA approval of those product candidates for certain hematologic malignancies. We understand that not all patients can participate in clinical trials and that some may seek expanded access of investigational products before they are approved. Expanded access to unapproved pharmaceutical product candidates is a complex topic that affects the needs and interests of many parties: patients, caregivers and families, and in particular those enrolled in pending clinical studies of the relevant drug; the U.S. Food and Drug Administration; treating physicians; patient advocacy and support groups; and of course the company developing the relevant drug product. After considering the many factors involved, KaloBios has adopted a policy that we will not make our products available for expanded access at this time. Here are a few of the reasons that went into our decision:

- *As a development stage company, our resources are very limited and our first obligation is to patients in our existing and planned clinical studies.* KaloBios can best serve all patients with the conditions we are studying by completing the clinical studies necessary to demonstrate safety and efficacy of our product candidates and obtaining FDA approval as soon as possible. The required clinical studies entail months and sometimes years of preparation. This effort, and the millions of dollars of related expense, would be unsuccessful without patients who are willing to enroll in these studies, often foregoing other treatment opportunities in order to participate. We are indebted to these patients and owe them our best efforts toward drug approval. Like clinical studies, expanded access programs also require substantial resources to implement and execute. In addition, patients seeking expanded access may be sicker than patients in our clinical trials or may not be responsive to prior treatments. These patients may react differently to our product candidates and may experience unexpected adverse events that, whether or not caused by the drug candidate, would require our attention. We do not believe that we could operate an expanded access program without distracting our employees from their primary function, interfering with enrollment of patients into current and future clinical studies and possibly delaying or denying the availability of approved drug to all patients.
- *At this time we do not have adequate supply of our drug products to make them available outside our clinical studies.* One aspect of planning and execution of complex, lengthy clinical studies such as ours is ensuring an adequate supply of study drug, so that patients and physicians are able to complete the studies as intended. It is essential that there is adequate supply to allow them to do so consistent with protocol timing requirements. Providing supply of drug for expanded access—along with making the difficult decisions of which patients to provide with drug, and when—could jeopardize our ability to provide drug to existing and future patients in our clinical studies.
- *Our products are complex biological products which require long lead times to produce, with significant uncertainties.* An added complexity of expanded access for monoclonal antibodies is the time, expense and uncertainties associated with manufacturing. Monoclonal antibodies like KB004 are biological products made in a highly complicated, specialized manufacturing process that takes from nine to fifteen months to complete, at substantial expense. In addition, as a small biotech company, we do not have the resources either to produce extra drug, or to build our own manufacturing facilities. As a result, we are dependent on the timing, capacity and

expertise of third party manufacturers, which presents risks to our own supply for clinical studies. We are not able to bear the additional risk and cost of producing extra drug product for expanded access purposes.

We appreciate your interest in our products and programs. Ultimately, dedicating our limited resources to the development and approval of our product candidates will provide the greatest potential for access to effective therapies.