

### FOR IMMEDIATE RELEASE

# GLIKNIK ANNOUNCES DOSING OF FIRST PATIENT IN PHASE 2 TRIAL TARGETING PREVENTION OF RECURRENCE OF HIGH-RISK ORAL CAVITY CANCER

 Trial to Assess Effectiveness and Safety of Biropepimut-S (GL-0817) in the Prevention of Recurrence of Squamous Cell Cancer of the Oral Cavity in Patients at High Risk of Recurrence after Successful Initial Treatment –

**BALTIMORE, Maryland, August 28, 2017** – Gliknik Inc. today announced that clinicians have enrolled and dosed the first of 80 patients in the company's phase 2 clinical trial assessing the efficacy and safety of biropepimut-S (GL-0817), an immunomodulatory therapeutic targeting the prevention of recurrence of squamous cell cancer of the oral cavity in patients at high risk of recurrence after surgery, chemotherapy, and radiation.

"We are pleased to enroll the first patient in this phase 2 trial of biropepimut-S, which will further our understanding of the potential role of this advanced-design cancer vaccine with immune enhancing adjuvants in high-risk oral cavity cancer," said Jeff Herpst, Senior Director of Clinical Development at Gliknik.

High-risk oral cavity cancer is associated with a recurrence rate of approximately 70% within three years of the time of surgical resection despite adjuvant chemoradiotherapy. Unfortunately, only a small percent of patients respond to the clinical options currently available for physicians to use in treating such patients who recur.

"With recurrent oral cavity cancer being so difficult to treat, now is an opportune time to assess how useful and safe biropepimut-S may be in protecting individuals from recurrence of highrisk oral cavity cancer," said David Block, CEO of Gliknik. "The goal of the study is to see if we can activate the individual's immune system to eliminate residual cancer cells that cannot be seen by current imaging methods, thereby avoiding clinical recurrence. We are finding that physicians and patients are interested in clinical trials addressing this significant unmet medical need."



## **About Biropepimut-S**

Designed in part by an inventor of PD-L1 antibodies for cancer, biropepimut-S (GL-0817) is a highly engineered peptide cancer vaccine designed to train the patient's immune system against multiple important epitopes within MAGE-A3, a protein commonly expressed in many human cancers while not expressed by normal tissues. Biropepimut-S was specifically designed to have superior penetration into cells of the immune system, bypassing protein degradation pathways. These improvements over first-generation products are intended to increase the likelihood of immune response. Biropepimut-S has elicited epitope-specific T-cell responses in the majority of patients in previous clinical trials. Biropepimut-S has received Orphan Drug designation from the U.S. Food and Drug Administration for MAGE-A3 expressing head and neck squamous cell cancer.

## **About the Phase 2 Trial**

This randomized, double-blind, placebo-controlled trial is being conducted in HLA-A2 positive patients at 45 sites in the U.S., Germany, Hungary, Poland, Serbia, Spain, and Ukraine. Following standard post-operative chemoradiotherapy for high-risk disease, study participants will be assigned vaccination with either biropepimut-S and low-dose cyclophosphamide or placebo controls with the vaccine adjuvants Leukine® (sargramostim, Sanofi) and Hiltonol® (poly-ICLC, Oncovir) for 10 vaccinations over a two-year period. More information is available at https://clinicaltrials.gov/ct2/show/NCT02873819

## **About Gliknik**

Gliknik is a clinical-stage biopharmaceutical company with expertise in modulation of the immune system to fight disease. The company's programs are designed to address unmet needs in tumor immunology and autoimmune diseases. Our mission at Gliknik is to discover and develop truly innovative biologics for people living with cancer and immune disorders. Learn more at www.gliknik.com.

This press release contains "forward-looking statements" concerning the development and commercialization of Gliknik products, the potential benefits and attributes of such products, and Gliknik's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Gliknik undertakes no obligation to update any forward-looking statements for any reason.

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