

**FOR IMMEDIATE RELEASE**

**GLIKNIK LICENSEE PFIZER RECEIVES ORPHAN DRUG DESIGNATION FROM U.S. FOOD AND DRUG ADMINISTRATION FOR DRUG CANDIDATE DIRECTED TOWARDS RARE NEUROLOGICAL DISORDER**

***- FDA grants GL-2045, a recombinant IVIG-mimetic, orphan drug status for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) –***

**BALTIMORE, MARYLAND**, August 10, 2015 – [Gliknik Inc.](#), a privately held biopharmaceutical company, today announced that its licensee Pfizer Inc. (NYSE: PFE) has received notification from the U.S. Food and Drug Administration (FDA) that its autoimmune candidate drug GL-2045, a recombinant Intravenous Immune Globulin (IVIG)-mimetic, has been granted orphan drug designation for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). [CIDP](#) is a rare neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms.

GL-2045 received the Orphan Drug designation for CIDP under the U.S. Orphan Drug Act following a review by the FDA of a package of data submitted by Pfizer. The FDA Office of Orphan Products Development grants orphan drug designation to novel drugs or biologics that treat a disease or condition affecting fewer than 200,000 patients in the U.S.

Gliknik entered into an exclusive [licensing agreement](#) with Pfizer for GL-2045 in September 2013. David Block, CEO of Gliknik, said, “This orphan drug designation is important in that it provides numerous incentives to develop GL-2045 to address an unmet need in CIDP, a rare neurological disorder.”

Several brands of the pooled human blood product IVIG have previously received orphan drug designation for CIDP. In contrast, GL-2045 is a recombinant (not blood derived) drug candidate under development. GL-2045 may eventually provide patients an alternative that is at least as



effective as IVIG but potentially more convenient and safer without the risk of blood-borne pathogens.

**About Gliknik Inc.**

Gliknik is creating new therapies for patients with immune disorders and cancer. Gliknik's expertise is in modulation of the immune system to fight disease. The company's lead clinical compound is GL-0817 for prevention of the recurrence of squamous cell cancer of the oral cavity. Learn more at [www.gliknik.com](http://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 collaboration with Pfizer. 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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