



## **MELIOR PHARMACEUTICALS ANNOUNCES POSITIVE PHASE 2A RESULTS IN TYPE 2 DIABETES STUDY**

**-MLR-1023 represents a new class of anti-diabetic agent-  
- In addition to positive effects on primary diabetic parameters other beneficial changes to  
metabolic disease were observed -**

June 13, 2016 Exton, PA – Melior Pharmaceuticals I, Inc. and Bukwang Pharmaceuticals Co, Ltd (Korea) announced today that they have achieved positive results in their Phase 2a proof-of-concept study to evaluate MLR-1023 in subjects with Type 2 diabetes. The study met its primary endpoint (lowering of post-prandial plasma glucose as evaluated in a mixed meal tolerance test) as well as several secondary endpoints including the lowering of fasting plasma glucose at a statistically significant level as per protocol design. The study also revealed positive effects towards lipid levels and body weight. The results were presented on June 12th at the 76<sup>th</sup> Sessions of the American Diabetes Association in New Orleans, LA.

The 4-week protocol, conducted in partnership between the two companies enrolled 130 subjects across 19 clinical sites in the US and Korea.

Highlights of the results include:

- Statistically significant reduction in area-under-the-curve (AUC) in a mixed meal tolerance test was achieved at the low dose (100 mg) both in the once-per-day treatment group (-86.5 mg\*hr / dL) and the two-times-per-day treatment group (-91.5 mg\*hr /dL)
- Statistically significant reduction of fasting plasma glucose (FPG) was achieved after 28 days of treatment in the 100 mg, once-per-day treatment group (-38.5 mg/dL)
- Additional statistically significant results were found for AUC and FPG in other active dose groups and visits
- In general, drug effects were in favor of active doses of MLR-1023 even if they were not statistically significant
- Positive trends were seen in all lipid parameters with statistically significant lowering of triglycerides
- At the most effective doses for glucose lowering statistically significant lowering of body weight was observed in the US subjects (-0.58 kg)
- The treatment was generally well-tolerated

“The MLR-1023 compound, by showing a reduction of glucose and favorable effects on weight in the early phase studies, may address unmet clinical needs and warrants further evaluation in Phase II studies,” says Dr. William Cefalu, Professor at Louisiana State University’s Pennington Biomedical Research Center who was an investigator on the trial.

“We are very pleased with the reception of these results by the diabetes research community,” said Andrew Reaume, CEO of Melior Pharmaceuticals I. “It serves to underscore the significance



of this potentially important, and desperately needed new category of anti-diabetic agent.”

MLR-1023 is an oral insulin signal potentiating agent in development for the treatment of Type 2 diabetes. It improves glycemic control by directly and selectively activating the Lyn tyrosine kinase enzyme, which has been shown to modulate insulin-signaling pathways independently of PPAR-related interactions. Preclinical studies showed that MLR-1023 has the potential to lower blood glucose levels more effectively than existing therapies while also lowering weight without altering food intake.

Melior has licensed MLR-1023 to Bukwang for the development and commercialization in Asian countries excluding Japan.

### **About Melior**

Melior Discovery and Melior Pharmaceuticals, its sister company, are leaders in pharmaceutical drug repositioning using the unique *theraTRACE*® platform comprised of multiplexed *in vivo* disease models. Melior is using these capabilities to build an internal pipeline of development candidates and also partners with pharmaceutical and biopharmaceutical companies to apply the *theraTRACE*® platform and its in-depth *in vivo* pharmacology expertise to their development candidates. Melior Discovery and Melior Pharmaceuticals are privately held and located in Exton, PA. For more information, visit [www.meliordiscovery.com](http://www.meliordiscovery.com).

### **About Bukwang Pharmaceutical Company, Ltd.**

Bukwang Pharm. Co., Ltd. is a leading Korean pharmaceutical company listed on the Korean Stock Exchange [KRX:003000]. The company has been in business for over 50 years. Sales are primarily derived from products licensed from Europe, the United States and Japan. The company is currently investing significant resources in R&D to create a robust pipeline of preclinical and clinical agents for the treatment of oncology, gastrointestinal disorders, CNS disorders and metabolic diseases.

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