MELIOR PHARMACEUTICALS ANNOUNCES POSITIVE RESULTS IN PHASE 2B STUDY WITH TOLIMIDONE FOR TYPE 2 DIABETES

- **Tolimidone treatment significantly reduced HbA1c compared to placebo**
- **Company makes strategic decision to move tolimidone into NASH development**

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May 14, 2019 Exton, PA – Melior Pharmaceuticals I, Inc (Melior) announced today that its novel first-in-class insulin sensitizer, tolimidone, has demonstrated significant reduction of HbA1c compared to placebo in a recently completed Phase 2b study involving patients with Type 2 diabetes mellitus (T2DM) in an analysis of all subjects who completed the full course of treatment. Tolimidone continued to demonstrate an excellent safety profile consistent with previous clinical studies.

In this study, patients on metformin therapy with an HbA1c level >7.0% at screening, were randomized to one of three doses of MLR 1023 (25, 50 or 100 mg) or placebo administered once daily for 12 weeks with continued metformin therapy. The study randomized 433 subjects from 61 clinical sites in the U.S. and Korea.

This study follows a positive Phase 2A proof-of-concept study that was completed in 2017 in which statistically significant glucose lowering was achieved for both glucose parameters (fasting plasma glucose and area-under-the curve in a mixed meal tolerance test). In addition, positive trends were seen in lipid parameters and body weight in that 4-week study.

While this latest study confirms the ability of tolimidone to lower fasting glucose and improve glucose tolerance over a 12-week treatment regimen in T2DM, the company also uncovered evidence of errors in the clinical trial supplies, thereby indicating that the treatment effect may have been attenuated by the occurrence of dosing mix-ups. The full extent of these mistakes and the source of their origin are under investigation.

Prior to completing the Phase 2B study in T2DM, the company made a strategic decision to extend clinical development activities with tolimidone into nonalcoholic steatohepatitis (NASH). NASH, a liver condition that currently has no approved treatment, is expected to be the leading cause of liver transplants by 2020, and has a projected market value of $30 billion. The decision to pursue NASH is based on a series of robust preclinical studies showing the multiple benefits of tolimidone in NASH animal models. There is also further support by independent investigators who have shown the role of tolimidone in affecting physiological processes in addition to its role as an insulin sensitizer. Melior has filed new patents related to the use of tolimidone in NASH where it expects to receive much longer market exclusivity compared to diabetes that relies upon older patents. Melior is currently preparing to initiate a Phase 2 clinical trial with tolimidone in NASH.

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"It is indeed unfortunate that these errors in clinical trial supplies have impaired the value of this important study" said Andrew Reaume, CEO of Melior. "Nonetheless, it is noteworthy that the drug signal emerges through the supply mix-ups and firmly establishes tolimidone as the first of a new generation of insulin sensitizers. This, coupled with our growing understanding of the additional therapeutic benefits to the liver makes us very enthusiastic about tolimidone's opportunity in NASH."

About Tolimidone

Tolimidone works by activating the enzyme lyn kinase, which has several actions that improve metabolic disease including: 1) attenuating insulin resistance, 2) improving dyslipidemia and 3) reducing obesity. More recent preclinical studies have shown that lyn kinase activation has beneficial effects in liver including antifibrotic activity and promoting liver repair (hepatocellular regeneration). In addition to tolimidone, Melior has an active medicinal chemistry program that has identified potential second-generation lyn activators.

About Melior

Melior Discovery and its sister company, Melior Pharmaceuticals I, are leaders in pharmaceutical drug repositioning using the unique *thera*TRACE® 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 *thera*TRACE® 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 and www.meliorpharma.com.

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