**Tolero Pharmaceuticals Presents Preclinical Data on CDK9 Inhibitor Alvocidib and its Prodrug, TP-1287, at AACR 2017**

*Preclinical Data supports the potential role of CDK9-mediated targeting of MCL-1 in treatment of therapy-resistant cancers*

SALT LAKE CITY, April 5, 2017 --Tolero Pharmaceuticals, Inc., a clinical-stage company developing treatments for serious hematological diseases, presented preclinical data on alvocidib, an investigational inhibitor of cyclin-dependent kinase 9 (CDK9), in Phase II development for relapsed/refractory acute myeloid leukemia (AML) and its prodrug, TP-1287. The findings were presented during the American Association for Cancer Research (AACR) Annual Meeting, April 1-5, in Washington, D.C.

Preclinical data presented in the poster titled **"TP-1287, an oral prodrug of the cyclin-dependent kinase-9 inhibitor alvocidib"** demonstrated the potential activity of an oral, bioavailable version of alvocidib, TP-1287, compared to intravenous alvocidib. In this study, TP-1287 demonstrated anti-tumor activity in the MV4-11 AML mouse xenograft model and as much as 61.7% inhibition of the pharmacodynamic biomarker MCL-1 in a xenograft model.

Preclinical findings presented in the poster titled **"Alvocidib potentiates the activity of venetoclax in preclinical models of multiple myeloma"** suggested that the MCL-1-lowering agent and CDK9 inhibitor, alvocidib, may address intrinsic venetoclax resistance in multiple myeloma (MM) patients. Venetoclax is a small molecule BCL-2 inhibitor being developed by AbbVie and Genentech, a member of the Roche Group, for hematological cancers. Inhibition of expression of the anti-apoptotic protein MCL-1 was demonstrated in MM cell lines for up to 96 hours. Activity of venetoclax was potentiated with the addition of alvocidib and resulted in a > 500-fold decrease of the half maximal inhibitory concentration (IC50) in venetoclax-resistant OPM-2 cells.

"We believe that these findings further validate the potential of alvocidib," **said David J. Bearss, Ph.D., Chief Executive Officer of Tolero Pharmaceuticals.** "Identifying alvocidib's ability to downregulate MCL-1, which plays a central role in cell survival, was key to understanding its potential activity in AML. In addition, these data have opened alternative avenues for expanding research of alvocidib in treating other cancers, including addressing chemotherapeutic resistance in multiple myeloma."

**Steven Weitman, M.D., Chief Medical Officer of Tolero Pharmaceuticals added:** "The data presented provide supportive evidence for alvocidib's potential in the treatment of hematological cancers. Today there remains an unmet need for altering the progressive course of therapy-resistant cancers. We look forward to the clinical development of alvocidib and hope that we can bring a treatment to improve survival and quality of life for people suffering from therapy-resistant malignancies."

**About Alvocidib**

Alvocidib is an investigational agent which is a small molecule inhibitor of cyclin-dependent kinase 9

(CDK9). It is currently in development as part of combination therapy for frontline and relapsed/refractory AML. CDK9 is a protein critical to the regulation of gene expression, including the MCL-1 gene and other important genes involved in cancer. Given the potential role CDK9 de-regulation plays in expression of cancer-associated genes related to cell division and proliferation, CDK9 is an attractive target for the treatment of various cancers.

**About TP-0184**

TP-0184 is a small molecule inhibitor of activin-like kinase 2 (ALK2), also known as a bone morphogenetic protein (BMP) receptor. ALK2 activation leads to high levels of hepcidin, a peptide liver hormone that functions as a master regulator of serum iron levels, particularly in response to inflammation. Anemia of chronic disease (ACD) is a condition where chronic infection, immune activation or cancer lead to high levels of hepcidin via Interleukin-6 production, which reduces iron levels in the blood to low levels. Inhibiting ALK2 with TP-0184 is a potential approach to treating ACD by reducing hepcidin expression and restoring blood iron levels to normal.

**About Tolero**

Tolero Pharmaceuticals is a clinical-stage biopharmaceutical company researching and developing treatments to improve and extend the lives of patients with oncological and hematological diseases. Our diverse pipeline targets important biological drivers of blood disorders to treat leukemias, anemia, and solid tumors, as well as targets of drug resistance and transcriptional control. Tolero is based in the United States and is wholly owned by Sumitomo Dainippon Pharma Co., Ltd., a pharmaceutical company based in Japan.

Additional information about the company and its product pipeline can be found at www.toleropharma.com.

**Disclaimer Regarding Forward-Looking Statements**

The forward-looking statements in this press release are based on management's assumptions and beliefs in light of information presently available, and involve both known and unknown risks and uncertainties. Any forward-looking statements set forth in this press release are made only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

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