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**NEWS RELEASE**

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### **Tragara Pharmaceuticals Initiates Phase I Clinical Program for TG02**

San Diego – September 9, 2010 – Tragara Pharmaceuticals, Inc. today announced the initiation of a phase I clinical trial of TG02, a unique oral multi-kinase inhibitor, in patients with advanced/refractory hematologic malignancies. Tragara will conduct the study at multiple clinical centers in the United States. In vitro and in vivo data of TG02 have demonstrated biological activity against acute leukemias and multiple myeloma in addition to several solid tumors with unmet medical needs including triple-negative breast cancer, small-cell lung cancer, and colon cancer.

“TG02 possesses a unique and exciting spectrum of kinase inhibitory capabilities. Our preclinical experience has confirmed the utility of inhibiting these multiple pathways, and we are eager to explore this potential in the clinic,” said Thomas M. Estok, president and chief executive officer, Tragara Pharmaceuticals, Inc.

TG02 is an oral, small molecule kinase inhibitor with a distinct inhibitory spectrum. TG02 inhibits ERK5, JAK2, FLT3, as well as key cell cycle and transcriptional cyclin-dependent kinases (CDKs) in an equipotent fashion at nanomolar concentrations.

“In preclinical models of leukemia, TG02 demonstrated that the combined inhibition of CDKs and JAK2/FLT3 signaling led to enhanced antitumor activity,” said Sara Zaknoen, M.D., chief medical officer, Tragara Pharmaceuticals, Inc. “In multiple myeloma, the addition of ERK5 inhibition and the established roles of the JAK-STAT and CDK9 pathways in myeloma cell survival and drug resistance suggest that TG02 could be an exciting addition to the armamentarium for this disease.”

In this first phase I trial, TG02 will be administered to patients with advanced leukemias orally over a range of doses on two separate schedules. Patients with relapsed multiple myeloma will be enrolled onto

a separate arm. The primary objective of the phase I trial is to determine the dose-limiting toxicity, maximum-tolerated dose, and recommended phase II dose of TG02. The secondary objectives include the assessment of the pharmacokinetic profile of TG02, evaluation of exploratory biomarkers, and presence of polymorphisms of genes involved in the metabolism of TG02. Evidence of anti-tumor activity also will be assessed by objective response, progression-free survival, and overall survival.

Based upon the potential utility of inhibiting the ERK5, JAK2 and CDKs pathways, Tragara also intends to initiate a phase I study of TG02 in patients with solid tumors in the near future. “We are particularly enthusiastic about TG02’s modulation of the ERK5 pathway in solid tumors,” added Francis Burrows, Ph.D., head of oncology biology, Tragara Pharmaceuticals. “Our testing in solid tumor preclinical models, particularly in triple negative breast cancer, has generated very promising data, and we believe that TG02 will be the first compound that effectively inhibits ERK5.”

Tragara will be supported in this phase I study by Ockham, a global contract research organization headquartered in Cary, North Carolina.

### **About TG02**

TG02 is a novel orally available, small molecule that targets - equipotently - the major signaling pathways involving ERK5, JAK2, FLT3 and key cell cycle and transcriptional cyclin-dependent kinases (CDKs), with excellent pharmacological and pharmaceutical properties. These pathways affect disease progression and survival in hematologic malignancies and solid tumors.

ERK5 is a recently characterized member of the MAP kinase family, with an emerging role in multiple myeloma, where it is activated by IL-6 independently of Ras and Src. ERK5 inhibitors have potential activity in multiple myeloma, both as a single agent and in combination with other agents. Additionally, ERK5 is linked to the proliferation of breast cancer cells in vitro, is commonly overexpressed in primary breast tumors. Its overexpression is an independent negative prognostic marker for disease-free survival. FLT3 overexpression and mutations are prevalent in the acute leukemias and are promising targets for drug therapy. JAK2 is involved in the development and maturation of cells in the hematopoietic lineage. The combination of a JAK2 inhibitor and a CDK is a novel combination and may benefit patients with multiple myeloma and certain solid tumors. Cyclin-dependent kinases (CDKs) play important roles in cell-cycle control and protein regulation. By inhibiting both FLT3 and CDKs, TG02 is uniquely positioned as a “first-in-class” compound to treat hematologic malignancies.

TG02 development will initially focus on the treatment of acute hematologic malignancies, including multiple myeloma;Tragara also will explore the therapeutic potential of the compound's CDK, JAK2, and ERK5 activity in solid tumors. TG02 is currently in phase I clinical testing in patient with advanced hematologic malignancies in the United States.

In early 2010, TG02 was selected by the Multiple Myeloma Research Foundation as a winner of its Biotech Investment Award, which represents a multi-year research grant commitment to fund the early-stage drug development of novel compounds that show potential in treating multiple myeloma.

### **About Tragara**

Tragara Pharmaceuticals, Inc. is a privately held pharmaceutical company based in San Diego, Calif. The company is focused on the clinical and commercial development of proprietary medicines for the treatment of cancer and inflammation. Tragara's lead therapeutic program, Capoxigem<sup>®</sup> (apricoxib, TG01), is currently in phase II clinical development in lung and pancreatic cancers and has completed a phase IIa study in inflammation/pain. A second therapeutic program, TG02, is an oral multi-kinase inhibitor that targets the major signaling pathways involving ERK5, JAK2, Flt3 and several important cyclin-dependent kinases (CDKs). The Company is also developing a "theranostic" product: ProGEM<sup>™</sup>, a proprietary diagnostic kit for the biomarker being evaluated in the Capoxigem clinical trials. Tragara is managed by a team of entrepreneurs with both Big Pharma and Biotech experience in the development and commercialization of oncology therapeutics. Its investors include: Domain Associates, Mitsubishi International Corporation, Morganthaler Ventures, Oxford BioScience Partners and ProQuest Investments.

Tragara strives to provide much-needed therapies that will contribute to patient health through better survival and an increase in the quality of life. For more information, visit [www.tragarapharma.com](http://www.tragarapharma.com).