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**Apricoxib Prolongs Time-to-Progression and Overall Survival
in Biomarker-Selected NSCLC Patients**

First report of Phase II APRiCOT-L study results presented at ASCO

Chicago and San Diego – June 6, 2011 – Tragara Pharmaceuticals, Inc. announced today that apricoxib (**Capoxigem**[®], TG01) in combination with erlotinib demonstrated significant and consistent clinical benefit over erlotinib alone in a clinically relevant subset of biomarker-selected patients with non-small cell lung cancer (NSCLC) who had previously failed a platinum-containing regimen for advanced disease. Complete data from the study, APRiCOT-L, were presented for the first time during the annual meeting of the American Society for Clinical Oncology (ASCO) in Chicago. Apricoxib is Tragara's novel, oral, once-daily COX-2 inhibitor in development for the treatment of a variety of cancers.

In the trial “**APRiCOT-L: A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase 2 Study of the Efficacy and Safety of Apricoxib in Combination with Erlotinib in Non-Small Cell Lung Cancer Patients**” (Abstract #7528, Poster #17), combination therapy with apricoxib and erlotinib demonstrated significant benefits over erlotinib and placebo in the subset of patients ≤65 years-of-age including:

- 71% improvement in disease control rate;
- 93% improvement in median progression-free survival; and
- 205% improvement in median overall survival.

“APRiCOT-L results demonstrating clinical benefit are the first reported for a study that employed modulation of a functional biomarker to prospectively select patients for treatment with a COX-2 inhibitor,” stated Barbara Gitlitz, MD, Associate Professor of Clinical Medicine, USC/Norris Comprehensive Cancer Center Keck School of Medicine. “The benefits seen in TTP and OS are impressive and apricoxib is a promising new agent advancing into Phase III development.”

The study, a Phase II randomized, double-blind, multi-center, placebo-controlled trial, evaluated time-to-progression as the primary endpoint in 120 patients at oncology centers in the United States. In the APRiCOT-L study, Tragara utilized a functional biomarker known as PGEM (a urinary metabolite of PGE₂, the pro-inflammatory product of COX-2 activity) to select patients for inclusion into the trial in order to identify the patient population with the best chance of benefitting from apricoxib therapy. The patient selection process included an open-label five-day apricoxib run-in period where baseline and day five urine samples were collected from patients.



Patients with a 50% or greater PGEM decrease from baseline were eligible for randomization if all other eligibility criteria were met.

Time-to-progression was not statistically significantly different than erlotinib alone for the overall population. Safety profiles of the two arms were similar. The most common adverse events reported were of the skin and gastrointestinal tract, similar to the reported toxicity profile of erlotinib alone. Most events were mild to moderate.

“We are very pleased with the efficacy and safety outcomes of APRiCOT-L and the operational ease of employing the patient selection strategy,” said Sara Zaknoen, M.D., chief medical officer, Tragara Pharmaceuticals, Inc. “We believe that apricoxib represents an important new potential treatment for patients with NSCLC and look forward to moving into Phase III.”

Capoxigem has been shown to potently inhibit COX-2-derived PGE₂ production, reversing the PGE₂-dependent epithelial-mesenchymal transition (EMT) process and the associated progression and metastasis of solid tumors. Reversal of EMT has important implications for the treatment of NSCLC using COX-2 inhibitors in combination with other agents.

Apricoxib is being studied in another Phase II clinical trial evaluating its use in combination with chemotherapy as second-line therapy for NSCLC. This trial utilizes a patient selection methodology similar to APRiCOT-L. Additionally, the company completed enrollment in late 2010 in a Phase II randomized trial of apricoxib in combination with erlotinib and gemcitabine for the first-line treatment of patients with pancreatic cancer.

About Capoxigem[®] (apricoxib, TG01)

Capoxigem (apricoxib, TG01) is an oral, once-daily selective COX-2 inhibitor. It is being evaluated for the treatment of cancer. Capoxigem affects a number of different oncogenic signaling pathways, including the HIF-1, VEGF, VEGF-R and PDGF systems for angiogenesis; the EGFR, HER2/neu, Bcr/Abl for growth control and differentiation; the intrinsic and extrinsic pathways for apoptosis; and the integrin and metalloproteinase systems for tissue invasion and metastasis. Capoxigem also potently inhibits COX-2-derived PGE₂ production, reversing the PGE₂-dependent epithelial-mesenchymal transition (EMT) process and the associated progression and metastasis of solid tumors. In pre-clinical cancer models, Capoxigem has shown superiority to compounds with similar mechanisms of action and synergy in combination with cisplatin, trastuzumab, and pemetrexed.

Capoxigem added to erlotinib therapy in a clinically relevant subset of biomarker-selected patients with advanced refractory non-small cell lung cancer significantly prolonged time to progression, progression-free survival and overall survival in a Phase II proof-of-concept study (APRiCOT-L). In clinical studies to date, Capoxigem has been well tolerated with a manageable side effect profile.



In addition to the APriCOT-L study, a Phase II study of Capoxigem in pancreatic cancer recently completed enrollment and an investigator initiated study of Capoxigem in NSCLC in combination with chemotherapy is currently underway in the United States.

Apricoxib is also being evaluated for the treatment of inflammation-related pain. In inflammation-related pain, Capoxigem modulates the cyclooxygenase pathway, reducing the production of inflammatory prostaglandins. A large Phase IIa Proof-of-Concept and dose finding study in inflammation-related pain has been completed in the United States. Superiority to placebo and an active comparator was demonstrated; safety was comparable to the active comparator.

About Tragara

Tragara Pharmaceuticals, Inc. is a privately held pharmaceutical company based in San Diego, CA. 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[®] (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). TG02 is currently in phase I clinical development. The Company is also developing a "theranostic" product: ProGEM[™], 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.

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