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***Saladax Biomedical 5-FU PCM™ Immunoassay for Chemotherapy Treatment Individualization
Promises Multiple Benefits in Treatment of Colorectal Cancer***

Bethlehem, PA., August 5, 2008 – A novel immunoassay blood test will make it easier for oncologists to accurately measure and personalize 5-fluorouracil (5-FU) dosing for patients undergoing continuous infusion chemotherapy regimens. Data from a multicenter study showed that a nanoparticle-based immunoassay from Saladax Biomedical, called 5-FU Personalized Chemotherapy Management (PCM), was validated against and performed as well as physical methods while offering advantages of automation, small sample size, and improved turn-around time for oncologists. The multicenter study evaluated the performance of the 5-FU PCM immunoassay at three sites, according to the Clinical and Laboratory Standards Institute (CLSI) protocol. Critical performance characteristics were verified: precision, cross-reactivity, interferences, LoD (limit of detection), LLoQ (lower limit of quantitation), and stability. A method comparison between a validated liquid chromatography-tandem mass spectroscopy LC-MS/MS method and the 5-FU PCM immunoassay was conducted with over 100 blood plasma samples. Evaluators found that the PCM assay was precise and gave excellent correlation with a validated LC-MS/MS. ⁱ “For many doctors, cost-effective measurement tools that could be easily integrated into their day-to-day practices simply haven’t been available”, **said Salvatore Salamone, Ph.D., CEO of Saladax Biomedical.**

Can a simple blood test improve treatment outcomes for colorectal cancer patients?

A recent clinical study demonstrated that monitoring patient’ 5-FU blood plasma levels and adjusting chemotherapy doses to achieve optimal levels of 5-FU can significantly improve response rates and minimize toxicity when compared to standard-of-care dosing based on height and weight (known as body surface area or BSA). The May issue of the *Journal of Clinical Oncology (JCO)* featured results of a Phase III randomized study of colorectal cancer patients who were dosed with 5-FU based on the current

standard, BSA, compared with patients who had doses personalized according to 5-FU blood plasma levels. The study concluded that only 25 percent of patients were in target range, while 17 percent were found to be over-dosed and 58 percent of patients were found to be under-dosed. Additionally, this study demonstrated that after 5-FU doses were adjusted to achieve appropriate plasma levels, patients experienced a doubling of response rates and improved overall survival in addition to significantly lower toxicity. ⁱⁱ "I believe the ability to personalize chemotherapy is a significant advance in the treatment of cancer and one that will lead to improved efficacy and fewer side effects for patients. Individually adjusted chemotherapy dosing, where the physician tailors dosing decisions to individual patient needs, provides great benefits to patients, a meaningful new tool for oncologists, and cost savings to the healthcare system," **stated Hakan Gadler MD, Chief Medical Officer, Saladax Biomedical.**

About Personalized Medicine

Personalized medicine denotes treatments tailored individually for patients. Recognizing that patients respond differently to treatments, it is only recently that scientific tools have become available to enable identification of individual patient or disease differences at the molecular or genetic level. These tools enable physicians to formulate individualized treatment plans more effectively. The advantages that personalized medicine may offer patients and clinicians include: ability to make more informed medical decisions, higher probability of desired outcomes thanks to better-targeted therapies, reduced probability of negative side-effects and the potential to reduce healthcare costs.

About Colorectal Cancer

Colorectal cancer is a worldwide public health problem, with more than 940,000 new cases diagnosed each year, resulting in approximately 500,000 deaths annually.ⁱⁱⁱ In the U.S., it is the third leading cause of cancer mortality, and in 2008, nearly 50,000 deaths will be attributed to this disease.ⁱⁱⁱ Its incidence rate is strongly correlated with age. Data from industrialized countries demonstrate that the incidence of colorectal cancer rises three-fold between the ages of 60 and 80 years.ⁱⁱⁱ

About Saladax

Saladax Biomedical is pioneering the development of novel, rapid, and cost-effective immunoassays that will enable routine blood-level monitoring of anti-cancer drugs to become the standard of care in treating cancer patients. With Personalized Chemotherapy Management (PCM), oncologists will be able to adjust the administered dose based on each patient's individual drug level, leading to reduced toxicity, improved outcome and lower cancer care costs. Saladax is headquartered at the business incubator of the Ben Franklin Technology Partners (BFTP) of Northeastern Pennsylvania on the campus of Lehigh University

in Bethlehem. The 5-FU PCM test will be available to U.S. clinicians later this year through a major reference laboratory.

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ⁱ A multi-center evaluation of a rapid immunoassay to quantitate 5-fluorouracil in plasma, G McMillin; C Hammett-Stabler; M Egorin; J Beumer; Y Li; G Lundell; R Harney; J Courtney; S Salamone; J Juenke; S Lepp; J Oncol Pharm Practice, Vol 14: No 2, 2008; 98-99.

ⁱⁱ Gamelin, E, Delva, R, Jacob, J, et al: "Individual fluorouracil dose adjustment based on pharmacokinetic follow-up compared with conventional dosage: Results of a multicenter randomized trial of patients with metastatic colorectal cancer." *J. Clin Oncol* 13:2099-2105, 2008.

ⁱⁱⁱ World Health Organization, "World Cancer Report." April 3, 2003, <http://www.who.int/mediacentre/news/releases/2003/pr27/en/> (April 22, 2008).