Jangik I. Lee, Pharm.D., Ph.D.

Professor

- Address

• E-mail: jangik.lee@snu.ac.kr
• Web Site: https://www.snupharm.ac.kr/korean/about/about8_view.asp?key=212
• Tel: +82-2-3668-7474
• Fax: +82-504-209-3497

- Education

• PhD, University of Pittsburgh (2001)
• PharmD, University of Minnesota (1996)
• MS, Seoul National University (1986)
• BSPharm, Seoul National University (1984)

- Work Experiences

•2015. 9 - present: Professor, College of Pharmacy, Seoul National University, Seoul, Korea
•2012. 3 - 2015. 8.: Professor, College of Pharmacy, Yonsei University, Incheon, Korea
• 2011. 2 - 2012. 2: Scientific Investigator, Food and Drug Administration, Silver Spring, MD, U.S.A.
•2001. 8 - 2011. 2: Clinical Pharmacology Reviewer/Team Leader, Food and Drug Administration, Silver Spring, MD, U.S.A.
•1986. 1 - 1992. 8: Clinical Researcher/Team Leader, Lucky R&D Center, Daejeon, Korea

- Awards

FDA Outstanding Service Award, Food and Drug Administration, Rockville, MD, U.S.A. (2004)

- Selected Publication

•Pharmacokinetic characteristics of vactosertib in patients with advanced solid tumors in a first-in-human phase 1 study. *Investigational New Drugs* 2019
•Association of genetic polymorphisms of CYP2E1, NAT2, GST and SLCO1B1 with the risk of anti-tuberculosis drug-induced liver injury. *BMJ Open* 2019
•Determination of a radotinib dosage regimen based on dose-response relationships for the treatment of newly diagnosed patients with chronic myeloid leukemia. *Cancer Medicine* 2018;7:1766
• Optimization of radotinib doses for the treatment of chronic myelogenous leukemia based on dose-response relationship analysis. *Leukemias & Lymphomas* 2016;57:1856

Clinical Pharmaceutical and Regulatory Sciences

Clinical Pharmaceutical Science (CPS) is a research discipline that conducts the pharmaceutical study at the interface of the benc h and bedside. CPS utilizes contemporary research approaches to generate new knowledge applicable to the disposition and activity of drugs in humans and to evaluate differences in drug response a mong individuals. CPS links clinical pharmacotherapy expertise wi th bench or mathematical approaches. CPS research projects inte grate laboratory techniques, pre-clinical models, and human-base d research to answer mechanistic questions that improve health o utcomes.

Regulatory Science (RS) is a specialized research discipline th at develops and applies scientific methods, tools, approaches and other science-based processes derived from various research disc iplines for the purpose of achieving regulatory and other policy obj ectives. RS research in the development and clinical use of pharm aceuticals is closely associated with the CPS research.

An optimization of radotinib doses in the treatment of chronic m yelogenous leukemia is an example of clinical pharmaceutical res earch based on both CPS and RS principles. The magnitude of ra dotinib dose adjusted for patient's body weight (Dose/BW) and the probability of dose-limiting toxicity (DLT) demonstrated a positive a ssociation. There exists a significant difference in the Kaplan-Meie r curves for time to first DLT between the patient subgroups of Dos e/BW <6 and ≥6 mg/kg. Hence, a two-tier weight-based dosing re gimen is recommended in a regulatory application in order to impr ove the safety profile of radotinib: 300 mg or 400 mg twice daily for patients weighing ≤65 or >65 kg, respectively.