• Name:
Toshio Shimizu, M.D., PhD.

• Current Position:
Head of Physicians (Early Phase 1 Drug Development Unit)
Department of Experimental Therapeutics
National Cancer Center Hospital Japan

• Country: Japan

• Educational Background:
M.D. (Kindai University Faculty of Medicine, Osaka Japan 1999)
PhD. (Kindai University Graduate School of Medicine, Osaka Japan 2005)
Visiting Research Scholar (Jan 2010 – Mar 2012)
The University of Texas at Austin, College of Pharmacy, Austin, TX, United States
Phase 1 Clinical Fellow (Jan 2010 – Mar 2012)
START (South Texas Accelerated Research Therapeutics) San Antonio, TX, United States

• Professional Experience:
Dr. Toshio Shimizu is a Head of Physicians at Department of Experimental Therapeutics (O ncology Early Phase 1 Drug Development Unit), National Cancer Center Hospital, Tokyo Jap an. Dr. Shimizu's research interests include the Early Phase 1 Drug Development and clinical pharmacology/trials for the development of new anticancer agents as well as molecular gene tic targets for cancer therapy. Dr. Shimizu is a Board Certified Senior Member of the Medic al Oncology by Japanese Society of Medical Oncology (JSMO) and a Fellow of the Japanes e Society of Internal Medicine (FJSIM). Dr. Shimizu is alumnus of Department of Medical Oncology, Faculty of Medicine, Kindai University in Osaka, Japan where he graduated and t hereafter, performed his residency in internal medicine and fellowship/staff physician/Assistant Professor in Medical Oncology supervised by Prof. Kazuhiko Nakagawa and Prof. Masahir o Fukuoka. He then performed a more advanced clinical fellowship in early phase 1 drug development at START (South Texas Accelerated Research Therapeutics) in San Antonio, Te xas USA which operates one of the world's largest early phase 1 drug development cancer r esearch programs supervised by Anthony W. Tolcher, M.D., FRCPC. He is currently the prin cipal investigator/ co-investigator of over 35-40 early phase 1 clinical trials of novel anticanc er agents including many immuno-oncology trials for patients with advanced cancer. He has been a member of the Joint Scientific Committee Review Member for Phase 1 trials in Hon g Kong, The Consortium on Harmonization of Institutional Requirements for Clinical Researc h (CHAIR) and serves as a scientific reviewer for phase 1 trials in HKSAR (Hong Kong Sp ecial Administrative Region of the People's Republic of China). Dr. Shimizu has authored and co-authored over 30 peer-reviewed publications of original cancer research in internationally r espected scientific journals including the Clinical Cancer Research. Dr. Shimizu is also the r ecipient of the ASCO 2011 Merit Award (Oral Presentation at Clinical Science Symposium) at American Society of Clinical Oncology (ASCO) 47th Annual Meeting, Chicago, IL, USA, June 2011. Since September 2017, the Asian Oncology Early Phase 1 Consortium (AsiaOn e) has officially been formed across key early phase new drug development institutions (p hase 1 centers) in Japan, China (HKSAR), Korea, Taiwan and Singapore. Dr. Shimizu is on e of the core investigator who is currently leading AsiaOne platform.

• Professional Organizations:

- ASCO (American Society of Clinical Oncology) Active Member
- AACR (American Association for Cancer Research) Active Member
- Scientific Committee Review Member for Phase 1 trials in HKSAR (Hong Kong Special Administrative Region of the People's Republic of China) of the Consortium on Harmonization of Institutional Requirements for Clinical Research (CHAIR)
- Board Certified Senior Member of JSMO (Japanese Society of Medical Oncology)
- Diplomate, Subspecialty Board of Medical Oncology of JSMO (Japanese Society of Medical Oncology)
- General Clinical Oncologist by Japanese Board of Cancer Therapy (JBCT)
- Fellow of the Japanese Society of Internal Medicine (JSIM)
- Board Certified Member of the Japanese Society of Internal Medicine (JSIM)

• Main Scientific Publications: (selected)

Shimizu T, Yonesaka K, Hayashi H, Iwasa T, Haratani K, Yamada H, Ohwada S, Kamiyama E, Nakagawa K. Phase 1 study of new formulation of patritumab (U3-1287) Process 2, a fully human anti-HER3 monoclonal antibody in combination with erlotinib in Japanese patients with advanced non-small cell lung cancer ***Cancer Chemother Pharmacol.*** 79(3):489-95, 2017

Shimizu T, Fukuoka K, Takeda M, Iwasa T, Yoshida T, Horobin J, Keegan M, Vaickus L, Chavan A, Padval M, Nakagawa K. A first-in-Asian phase 1 study to evaluate safety, pharmacokinetics and clinical activity of VS-6063, a focal adhesion kinase (FAK) inhibitor in Japanese patients with advanced solid tumors ***Cancer Chemother Pharmacol.*** 77(5):997-1003, 2016

Shimizu T, Seto T, Hirai F, Takenoyama M, Nosaki K, Tsurutani J, Kaneda H, Iwasa T, Kawakami H, Noguchi K, Shimamoto K, Nakagawa K. Phase 1 study of pembrolizumab (MK-3475; anti-PD-1 monoclonal antibody) in Japanese patients with advanced solid tumors ***Invest New Drugs.*** 34(3):347-54, 2016

Shimizu T, LoRusso PM, Papadopoulos KP, Patnaik A, Beeram M, Smith LS, Rasco DW, Mays TA, Chambers G, Ma A, Wang J, Laliberte R, Voi M, Tolcher AW. Phase I First-in-Human Study of CUDC-101, a Multitargeted Inhibitor of HDACs, EGFR, and HER2 in Patients with Advanced Solid Tumors. ***Clin Cancer Res*** 20(19):5032-40.2014

Shimizu T, Tolcher AW, Papadopoulos K, Rasco DW, Beeram M, Smith LS, Smetzer L, Mays T, Kaiser B, Arvalez C, Cavazos A, Mangold G, Patnaik A. The clinical effect of the dual-targeting strategy involving PI3K/AKT/mTOR and RAS/MEK/ERK pathways in first-in-human phase I study. ***Clin Cancer Res*** 18(8):2316-25.2012

Shimizu T, Okamoto I, Tamura K, Satoh T, Miyazaki M, Akashi Y, Ozaki T, Fukuoka M, Nakagawa K. Phase I clinical and pharmacokinetic study of the glucose-conjugated cytotoxic agent D-19575 (glufosfamide) in patients with solid tumors. ***Cancer Chemother Pharmacol.*** 65(2):243-50.2010

Shimizu T, Yamamoto N, Yamada Y, Fujisaka Y, Yamada K, Fujiwara Y, Takayama K, Tokudome T, Klimovsky J, Tamura T. Phase I clinical and pharmacokinetic study of 3-weekly, 3-hour infusion of ixabepilone (BMS-247550), an epothilone B analog, in Japanese patients with refractory solid tumors. ***Cancer Chemother Pharmacol.*** 61(5):751-8.2008