

- **Name:** Toshio Shimizu
 - **Current Position & Affiliation:** Professor, Department of New Experimental Therapeutics and Director of Early-Phase 1 Drug Development Service
Kansai Medical University Hospital
 - **Country:** Japan
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• Educational Background:

Phase 1 Clinical Fellow (Jan 2010 – Mar 2012)

START (South Texas Accelerated Research Therapeutics) San Antonio, TX, USA

Supervised phase 1 training by Dr. Anthony W. Tolcher, MD. FRCPC

2010-2012 Visiting Research Scholar

The University of Texas at Austin, College of Pharmacy, Austin, TX, USA

2005 Ph.D. Kindai University Graduate School of Medicine, Osaka Japan

1999 M.D. Kindai University School of Medicine, Osaka Japan
(Japanese Government Medical License Registration)

• Professional Experience:

Professor (Nov 2024 – present)
Department of New Experimental Therapeutics
Director, Early-Phase 1 Drug Development Service
Kansai Medical University Hospital

Associate Professor (Apr 2022 – Oct 2024)
Department of Pulmonary Medicine and Medical Oncology
Wakayama Medical University Graduate School of Medicine
Wakayama Medical University Hospital, Wakayama Japan

Head of Physicians (Early Phase 1 Drug Development Service) (Apr 2016 – Mar 2022)
Department of Experimental Therapeutics
National Cancer Center Hospital, Tokyo Japan

Associate Professor (Apr 2012 – Mar 2016)
Department of Medical Oncology,
Kindai University Faculty of Medicine, Osaka Japan

Medical Oncology Fellowship-Division of Drug Development (Jun 2002 – May 2005)
National Cancer Center Hospital (NCC), Tokyo, Japan

Residency (Internal Medicine and Medical Oncology)
Kindai University Hospital, Osaka, Japan

(May 1999 – May 2002)

• Professional Organizations:

ESMO Targeted Anticancer Therapies (TAT) Scientific Committee (2022~)

Asia Pacific Oncology Drug Development Consortium (APODDC) Executive Committee

Joint Scientific Committee Review Member for Phase 1 trials in Hong Kong, HKSAR China

Councilor, Japanese Society of Medical Oncology (JSMO)

• Main Scientific Publications:

Shimizu T, Powderly J, Razak A, LoRusso P, Miller KD, Kao S, Kongpachith S, Graham M, Stoll B, Patel M, Sahtout M, Blaney M, Leibman RS, Golan T, Tolcher AW. First-in human Phase 1 Dose Escalation

Results with Livmoniplimab, an Antibody Targeting the GARP:TGFβ1 Complex, as Monotherapy and in Combination with the Anti-PD-1 Antibody Budigalimab in Patients with Advanced Solid Tumors

Frontiers in Oncology 2024 Oct 29;14:1376551. doi: 10.3389/fonc.2024.1376551. eCollection 2024

Shimizu T, Sands J, Yoh K, Spira A, Garon EB, Kitazono S, Johnson ML, Meric-Bernstam F, Tolcher AW, Yamamoto N, Jon Greenberg, Yui Kawasaki, Hong Zebger-Gong, Kobayashi F, Phillips P, Lisberg AE, Heist RS. First-in-Human, Phase 1 Dose-Escalation and -Expansion Study of TROP2-Directed Antibody Drug Conjugate Datopotamab Deruxtecan in Non-Small Cell Lung Cancer: TROPION-PanTumor 01

J Clin Oncol 2023 41(29):4678-4687.doi: 10.1200/JCO.23.00059.

Shimizu T, Fujiwara Y, Yonemori K, Koyama T, Sato J, Tamura K, Shimomura A, Ikezawa H, Nomoto M, Furuuchi K, Nakajima R, Miura T, Yamamoto N. First-in-Human Phase I Study of MORAb-202, a Folate Receptor Alpha (FRα)-Targeting Antibody-Drug Conjugate, in Patients with FRα-positive Advanced Solid Tumours. *Clin Cancer Res* 2021 27(14):3905-3915

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 2014 20(19):5032-40.

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* 2012 18(8):2316-25.