

- **Name:** Kohei Shitara
 - **Current Position & Affiliation:** Director, Department of Gastrointestinal Oncology, National Cancer Center Hospital East
 - **Country:** Japan
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• **Educational Background:**

1996-2002: Tohoku University School of Medicine

M.D. degree awarded: April 2002

ECFMG Certificate : January 2005

• **Professional Experience:**

April 2002-March 2004: Resident at Kameda Medical Hospital

April 2004-May 2005: Senior Resident of gastroenterology at Kameda Medical Hospital

June 2005-March 2008: Staff doctor of internal medicine and medical oncology at Misawa City Hospital

April 2008-March 2012: Department of Clinical Oncology of Aichi Cancer Center Hospital

April 2012-March 2013: Staff doctor of Department of Gastroenterology and Gastrointestinal Oncology, National Cancer Center Hospital East

April 2013-March 2017: Staff doctor of Department of Experimental Therapeutics and Gastrointestinal Oncology, National Cancer Center Hospital East

March 2017-: Chief of Department of Gastrointestinal Oncology, National Cancer Center Hospital East

January 2023-: Director of Department of Gastrointestinal Oncology, National Cancer Center Hospital East

• **Professional Organizations:**

Guideline member of Japanese Gastric Cancer Association, Active member of American Society of Clinical Oncology, Active member of European Society of Medical Oncology, Japanese Society of Medical Oncology (JSMO), Members of the program committee of ASCO annual meeting 2024-2026, ESMO faculty member for Gastrointestinal Tumors, non-Colorectal faculty group for the period 2021-2025

• **Main Scientific Publications:**

1. Shitara K, Shah MA, Lordick F, Van Cutsem E, Ilson DH, Klempner SJ, Kang YK, Lonardi S, Hung YP, Yamaguchi K, Enzinger P, Nakajima T, Matsangou M, Cao Y, Li R, Moran D, Pophale R, Oh M, Ranganath R, Ajani JA, Xu RH. Zolbetuximab in Gastric or Gastroesophageal Junction Adenocarcinoma. *N Engl J Med*. 2024 Sep 26;391(12):1159-1162. doi: 10.1056/NEJMc2409512. Epub 2024 Sep 16.
2. Shitara K, Bang YJ, Iwasa S, et al. Trastuzumab deruxtecan in HER2-positive advanced gastric cancer: exploratory biomarker analysis of the randomized, phase 2 DESTINY-

- Gastric01 trial. *Nat Med.* 2024 Jul;30(7):1933-1942. doi: 10.1038/s41591-024-02992-x. Epub 2024 May 14.
3. Shitara K, Rha SY, Wyrwicz LS, Oshima T, Karaseva N, Osipov M, Yasui H, Yabusaki H, Afanasyev S, Park YK, Al-Batran SE, Yoshikawa T, Yanez P, Dib Bartolomeo M, Lonardi S, Tabernero J, Van Cutsem E, Janjigian YY, Oh DY, Xu J, Fang X, Shih CS, Bhagia P, Bang YJ; KEYNOTE-585 investigators. Neoadjuvant and adjuvant pembrolizumab plus chemotherapy in locally advanced gastric or gastro-oesophageal cancer (KEYNOTE-585): an interim analysis of the multicentre, double-blind, randomised phase 3 study. *Lancet Oncol.* 2024 Feb;25(2):212-224. doi: 10.1016/S1470-2045(23)00541-7.
 4. Shitara K, Lordick F, Bang YJ, Enzinger P, Ilson D, Shah MA, Van Cutsem E, Xu RH, Aprile G, Xu J, Chao J, Pazo-Cid R, Kang YK, Yang J, Moran D, Bhattacharya P, Arozullah A, Park JW, Oh M, Ajani JA. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. *Lancet.* 2023 May 20;401(10389):1655-1668. doi: 10.1016/S0140-6736(23)00620-7.
 5. Shitara K, Ajani JA, Moehler M, Garrido M, Gallardo C, Shen L, Yamaguchi K, Wyrwicz L, Skoczylas T, Bragagnoli AC, Liu T, Tehfe M, Elimova E, Bruges R, Zander T, de Azevedo S, Kowalyszyn R, Pazo-Cid R, Schenker M, Cleary JM, Yanez P, Feeney K, Karamouzis MV, Poulart V, Lei M, Xiao H, Kondo K, Li M, Janjigian YY. Nivolumab plus chemotherapy or ipilimumab in gastro-oesophageal cancer. *Nature.* 2022 Mar 23.
 6. Janjigian YY, Shitara K, Moehler M, Garrido M, Salman P, Shen L, Wyrwicz L, Yamaguchi K, Skoczylas T, Campos Bragagnoli A, Liu T, Schenker M, Yanez P, Tehfe M, Kowalyszyn R, Karamouzis MV, Bruges R, Zander T, Pazo-Cid R, Hitre E, Feeney K, Cleary JM, Poulart V, Cullen D, Lei M, Xiao H, Kondo K, Li M, Ajani JA. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. *Lancet.* 2021 Jun 4:S0140-6736(21)00797-2
 7. Shitara K, Van Cutsem E, Bang YJ, Fuchs C, Wyrwicz L, Lee KW, Kudaba I, Garrido M, Chung HC, Lee J, Castro HR, Mansoor W, Braghiroli MI, Karaseva N, Caglevic C, Villanueva L, Goekkurt E, Satake H, Enzinger P, Alsina M, Benson A, Chao J, Ko AH, Wainberg ZA, Kher U, Shah S, Kang SP, Tabernero J. Efficacy and Safety of Pembrolizumab or Pembrolizumab Plus Chemotherapy vs Chemotherapy Alone for Patients With First-line, Advanced Gastric Cancer: The KEYNOTE-062 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2020 Sep 3. doi: 10.1001/jamaoncol.2020.3370.
 8. Kawazoe A, Fukuoka S, Nakamura Y, Kuboki Y, Wakabayashi M, Nomura S, Mikamoto Y, Shima H, Fujishiro N, Higuchi T, Sato A, Kuwata T, Shitara K (corresponding). Lenvatinib plus pembrolizumab in patients with advanced gastric cancer in the first-line or second-line setting (EPOC1706): an open-label, single-arm, phase 2 trial. *Lancet Oncol.* 2020 Jun 23:S1470-2045(20)30271-0.
 9. Shitara K, Bang YJ, Iwasa S, Sugimoto N, Ryu MH, Sakai D, Chung HC, Kawakami H, Yabusaki H, Lee H, Saito K, Kawaguchi Y, Kamio T, Kojima A, Sugihara M, and Yamaguchi K. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer. *N Engl J Med.* 2020 Jun 18;382(25):2419-2430.
 10. Fukuoka S, Hara H, Takahashi N, Kojima T, Kawazoe A, Asayama M, Yoshii T, Kotani

- D, Tamura H, Mikamoto Y, Hirano N, Wakabayashi M, Nomura S, Sato A, Kuwata T, Togashi Y, Nishikawa H, Shitara K (corresponding). Regorafenib plus Nivolumab in Patients with Advanced Gastric or Colorectal Cancer: An Open-label, Dose-Escalation, and Dose-Expansion Phase 1b Trial (REGONIVO, EPOC1603). *J Clin Oncol*. 2020 Apr 28;JCO1903296.
11. Shitara K, Doi T, Dvorkin M, Mansoor W, Arkenau HT, Prokharau A, Alsina M, Ghidini M, Faustino C, Gorbunova V, Zhavrid E, Nishikawa K, Hosokawa A, Yalçın Ş, Fujitani K, Beretta GD, Cutsem EV, Winkler RE, Makris L, Ilson DH, Tabernero J. Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2018 Oct 18. pii: S1470-2045(18)30739-3.
 12. Shitara K, Özgüroğlu M, Bang YJ, Di Bartolomeo M, Mandalà M, Ryu MH, Fornaro L, Olesiński T, Caglevic C, Chung HC, Muro K, Goekkurt E, Mansoor W, McDermott RS, Shacham-Shmueli E, Chen X, Mayo C, Kang SP, Ohtsu A, Fuchs CS; KEYNOTE-061 investigators. Pembrolizumab versus paclitaxel for previously treated, advanced gastric or gastro-oesophageal junction cancer (KEYNOTE-061): a randomised, open-label, controlled, phase 3 trial. *Lancet*. 2018 Jul 14;392(10142):123-133.