Transforming Metastatic Breast Cancer Management Harnessing the Power of Antibody-Drug Conjugate Therapies

Bibliography and Suggested Reading

Abelman RO, Spring L, Fell GG, et al. Sequential use of antibody-drug conjugate after antibody-drug conjugate for patients with metastatic breast cancer: ADC after ADC (A3) study. Abstract 1022. Presented at: 2023 ASCO Annual Meeting; June 2–6, 2023; Chicago, Illinois.

Adams E, Wildiers H, Neven P, Punie K. Sacituzumab govitecan and trastuzumab deruxtecan: two new antibody-drug conjugates in the breast cancer treatment landscape. *ESMO Open*. 2021;6(4):100204.

Adamson BJS, Cohen AB, Estevez M, et al. Affordable Care Act (ACA) Medicaid expansion impact on racial disparities in time to cancer treatment. *J Clin Oncol.* 2019;37(18_suppl):LBA1.

American Academy of Family Physicians (AAFP). Center for Diversity and Health Equity. AAFP website. https://www.aafp.org/family-physician/patient-care/the-everyone-project/aafp-center-for-diversity-and-health-equity.html. Accessed May 2024.

American Cancer Society. Breast cancer facts and figures. American Cancer Society website. https://www.cancer.org/research/cancer-facts-statistics/breast-cancer-facts-figures.html. Accessed May 2024.

Bardia A, Barrios CH, Dent R, Hu X. Trastuzumab deruxtecan (T-DXd; DS-8201) vs investigator's choice of chemotherapy in patients with hormone receptor-positive (HR+), HER2 low metastatic breast cancer whose disease has progressed on endocrine therapy in the metastatic setting: A randomized, global phase 3 trial (DESTINY-Breast06). *Cancer Res.* 2021;81(4_Suppl):OT-03-09.

Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. *N Engl J Med.* 2021;384(16):1529–1541.

Bardia A, Jhaveri K, Im S, et al. Datopotamab deruxtecan (Dato-DXd) vs chemotherapy in previously-treated inoperable or metastatic hormone receptor-positive, HER2-negative (HR+/HER2–) breast cancer (BC): primary results from the randomised phase III TROPION-Breast01 trial. Abstract LBA11. Presented at: ESMO Congress 2023; October 23, 2023; Madrid, Spain.

Bardia A, Mayer IA, Diamond JR, et al. Efficacy and safety of anti-Trop-2 antibody drug conjugate sacituzumab govitecan (IMMU-132) in heavily pretreated patients with metastatic triple-negative breast cancer. *J Clin Oncol*. 2017;35(19):2141–2148.

Bardia A, Tolaney SM, Loirat D, et al. ASCENT: a randomized phase III study of sacituzumab govitecan (SG) vs treatment of physician's choice (TPC) in patients (pts) with previously treated metastatic triple-negative breast cancer (mTNBC). Abstract LBA17. Presented at ESMO Virtual Congress 2020; September 19, 2020.

Bardia A, Tolaney SM, Loirat D, et al. Sacituzumab govitecan (SG) versus treatment of physician's choice (TPC) in patients (pts) with previously treated, metastatic triple-negative breast cancer (mTNBC): Final results from the phase 3 ASCENT study. *J Clin Oncol.* 2022;40(suppl 16):1071.

Benson AB 3rd, Ajani JA, Catalano RB, et al. Recommended guidelines for the treatment of cancer treatment-induced diarrhea. *J Clin Oncol*. 2004;22(14):2918–2926.

Beyer KMM, Zhou Y, Laud PW, et al. Mortgage lending bias and breast cancer survival among older women in the United States. *J Clin Oncol*. 2021;39(25):2749–2757.

Brooks LA, Manias E, Bloomer MJ. Culturally sensitive communication in healthcare: a concept analysis. *Collegian*. 2018;26(3):383–391.



Carey LA, Loirat D, Punie K, et al. Sacituzumab govitecan as second-line treatment for metastatic triple-negative breast cancer-phase 3 ASCENT study subanalysis. *NPJ Breast Cancer*. 2022;8(1):72.

Centers for Disease Control and Prevention. Socioenvironmental maps—poverty. Last reviewed September 27, 2022. CDC website. https://www.cdc.gov/dhdsp/maps/sd_poverty.htm. Accessed May 2024.

Centers for Medicare and Medicaid Services (CMS). The accountable health communities health-related social needs screening tool. August 10, 2021. CMS website. https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf. Accessed May 2024.

Chen L, Li CI. Racial disparities in breast cancer diagnosis and treatment by hormone receptor and HER2 status. *Cancer Epidemiol Biomarkers Prev.* 2015;24(11):1666–1672.

Crown A, Fazeli S, Kurian A, et al. Disparities in breast cancer care: current state of access to screening, genetic testing, oncofertility, and reconstruction. Published March 28, 2023. *J Am Coll Surgeons* website. https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/press-releases/2023/significant-disparities-in-breast-cancer-care-persist-but-surgeons-can-drive-change/. Accessed May 2024.

Dent R, Cescon DW, Bachelot T, et al. TROPION-Breast02: phase 3, open-label, randomized study of first-line datopotamab deruxtecan versus chemotherapy in patients with locally recurrent inoperable or metastatic TNBC who are not candidates for anti–PD-(L)1 therapy. Abstract OT1-03-05. Presented at: 2022 San Antonio Breast Cancer Symposium; December 5, 2022; San Antonio, Texas.

Diéas V, Deluche E, Lusque A, et al. DAISY: Trastuzumab deruxtecan for advanced breast cancer patients, regardless of HER2 status: a phase II study with biomarkers analysis. Abstract PD8-02. Presented at: 2021 San Antonio Breast Cancer Symposium; December 9, 2021; San Antonio, Texas.

Dietze EC, Chavez TA, Seewaldt VL. Obesity and triple-negative breast cancer: disparities, controversies, and biology. *Am J Pathol.* 2018;188(2):280–290.

EU Clinical Trials Register. A randomized, open-label, phase 3 study of sacituzumab govitecan versus treatment of physician's choice in patients with previously untreated, locally advanced, inoperable or metastatic triple-negative breast cancer. Start date October 31, 2022. EUCTR website. Identifier: 2021-005743-79. https://www.clinicaltrialsregister.eu/ctr-search/search?query=2021-005743-79. Accessed May 2024.

European Society for Medical Oncology (ESMO). ESMO-MCBS scorecards. ESMO website. https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards. Accessed May 2024.

Fenton MA, Tarantino P, Graff SL. Sequencing Antibody Drug Conjugates in Breast Cancer: Exploring Future Roles. *Curr Oncol.* 2023;30(12):10211–10223.

Foulkes WD, Smith IE, Reis-Filho JS. Triple-negative breast cancer. N Engl J Med. 2010;363(20):1938–1948.

Giaquinto AN, Sung H, Miller KD, et al. Breast cancer statistics, 2022. CA A Cancer J Clin. 2022;72:524–541.

Goldenberg DM, Cardillo TM, Govindan SV, et al. Trop-2 is a novel target for solid cancer therapy with sacituzumab govitecan (IMMU-132), an antibody-drug conjugate (ADC). *Oncotarget*. 2015;6:22496–22512.

Hossain F, Danos D, Prakash O, et al. Neighborhood social determinants of triple negative breast cancer. *Front Public Health*. 2019;7:18.

Howard FM, Olopade OI. Epidemiology of triple-negative breast cancer: a review. Cancer J. 2021;27(1):8–16.

Hurvitz SA, Bardia A, Punie K, et al. Sacituzumab govitecan (SG) efficacy in patients with metastatic triple-negative breast cancer (mTNBC) by HER2 immunohistochemistry (IHC) status: findings from the phase 3 ASCENT study. Abstract 168P. Presented at: ESMO Breast Cancer Congress 2022; May 4, 2022; Berlin, Germany.



Hurvitz S, Tolaney SM, Punie K, et al. Biomarker evaluation in the phase 3 ASCENT study of sacituzumab govitecan versus chemotherapy in patients with metastatic triple-negative breast cancer. Abstract GS3-06. Presented at: 2020 San Antonio Breast Cancer Symposium Virtual Meeting; December 8–11, 2020.

James, D. Deltra James: breast cancer patient and patient advocate. Interview by Creative Educational Concepts. May 2, 2024.

Koster KL, Huober J, Joerger M. New antibody-drug conjugates (ADCs) in breast cancer-an overview of ADCs recently approved and in later stages of development. *Explor Target Antitumor Ther*. 2022;3(1):27–36.

Levit LA, Byatt L, Lyss AP, et al. Closing the rural cancer care gap: three institutional approaches. *JCO Oncol Pract*. 2020;16(7):422–430.

Lisberg AE, Sands J, Shimizu T, et al. Dose escalation and expansion from the phase I study of DS-1062, a trophoblast cellsurface antigen 2 (TROP2) antibody drug conjugate (ADC), in patients (pts) with advanced non-small cell lung cancer (NSCLC). Abstract 9619. Presented at: 2020 ASCO Virtual Scientific Program; May 29–21, 2020.

Miglietta F, Griguolo G, Bottosso M, et al. Evolution of HER2-low expression from primary to recurrent breast cancer. *NPJ* Breast Cancer. 2021;7(1):137.

Modi S, Jacot W, Iwata YH, et al. Trastuzumab deruxtecan (T-DXd) versus treatment of physician's choice (TPC) in patients (pts) with HER2-low unresectable and/or metastatic breast cancer (mBC): updated survival results of the randomized, phase III DESTINY-Breast04 study. Abstract 3760. Presented at: ESMO Congress 2023; October 21, 2023; Madrid, Spain.

Modi S, Jacot W, Yamashita T, et al. Trastuzumab deruxtecan in previously treated HER2-low advanced breast cancer. *N* Engl J Med. 2022;387(1):9–20

Modi S, Jacot W, Yamashita T, et al. Trastuzumab deruxtecan (T-DXd) versus treatment of physician's choice (TPC) in patients (pts) with HER2-low unresectable and/or metastatic breast cancer (mBC): results of DESTINY-Breast04, a randomized, phase 3 study. Abstract LBA3. Presented at: 2022 ASCO Annual Meeting; June 3–7, 2022; Chicago, Illinois.

Nagayama A, Ellisen LW, Chabner B, Bardia A. Antibody-drug conjugates for the treatment of solid tumors: clinical experience and latest developments. *Target Oncol*. 2017;12(6):719–739.

National Association of Community Health Centers (NACHC). Protocol for responding to and assessing patients' assets, risks and experiences (PRAPARE) toolkit. December 3, 2022. NACHC website. https://prapare.org/knowledge-center/category/prapare-implementation-and-action-toolkit/. Accessed May 2024.

National Cancer Institute. Genetics of breast and gynecologic cancers (PDQ)—health professional version. Last updated April 4, 2024. National Cancer Institute website. https://www.cancer.gov/types/breast/hp/breast-ovarian-genetics-pdq#_2723_toc. Accessed May 2024.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: breast cancer. Version 2.2.24; March 11, 2024. NCCN website. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed May 2024.

Nelson RS, Seligson ND, Bottiglieri S, et al. UGT1A1 Guided Cancer Therapy: Review of the Evidence and Considerations for Clinical Implementation. *Cancers (Basel)*. 2021;13(7):1566.

Newman LA. Breast cancer disparities: socioeconomic factors versus biology. Ann Surg Oncol. 2017;24(10):2869–2875.

Ocean AJ, Starodub AN, Bardia A, et al. Sacituzumab govitecan (IMMU-132), an anti-Trop-2-SN-38 antibody-drug conjugate for the treatment of diverse epithelial cancers: safety and pharmacokinetics. *Cancer.* 2017;123:3843–3854.

O'Connor JM, Sedghi T, Dhodapkar M, et al. Factors associated with cancer disparities among low-, medium-, and high-income U.S. counties. *JAMA Netw Open*. 2018;1(6):e183146.

Ogitani Y, Aida T, Hagihara K, et al. DS-8201a, a novel HER2-targeting ADC with a novel DNA topoisomerase I inhibitor, demonstrates a promising antitumor efficacy with differentiation from T-DM1. *Clin Cancer Res.* 2016;22(20):5097–5108.

Parisi C, Mahjoubi L, Gazzah A, Barlesi F. TROP-2 directed antibody-drug conjugates (ADCs): the revolution of smart drug delivery in advanced non-small cell lung cancer (NSCLC). *Cancer Treat Rev.* 2023;118:102572.



Patel MI, Lopez AM, Blackstock W, et al. Cancer disparities and health equity: a policy statement from the American Society of Clinical Oncology. *J Clin Oncol*. 2020;38(29):3439–3448.

Penner LA, Dovidio JF, Hagiwara N, et al. An analysis of race-related attitudes and beliefs in Black cancer patients: implications for health care disparities. *J Health Care Poor Underserved*. 2016;27(3):1503–1520.

Penner LA, Harper FWK, Dovidio JF, et al. The impact of Black cancer patients' race-related beliefs and attitudes on racially-discordant oncology interactions: a field study. *Soc Sci Med*. 2017;191:99–108.

Powell CA, Modi S, Iwata H, et al. Pooled analysis of drug-related interstitial lung disease and/or pneumonitis in nine trastuzumab deruxtecan monotherapy studies. *ESMO Open*. 2022;7(4):100554.

Prakash O, Hossain F, Danos D, et al. Racial disparities in triple negative breast cancer: a review of the role of biologic and non-biologic factors. *Front Public Health*. 2020;8:576964.

Prat A, Modi S, Tsurutani J, et al. Determination of HER2-low status in tumors of patients with unresectable and/or metastatic breast cancer in DESTINY-Breast04. Abstract HER2-18. Presented at: 2022 San Antonio Breast Cancer Symposium; December 6–10, 2022; San Antonio, Texas.

Rebner M, Pai VR. Breast cancer screening recommendations: African American women are at a disadvantage. *J Breast Imaging.* 2020;2(5):416–421.

Rossi A, Fortuna MC, Caro G, et al. Chemotherapy-induced alopecia management: clinical experience and practical advice. *J Cosmet Dermatol*. 2017;16(4):537–541.

Rugo HS, Bardia A, Marmé F, et al. Overall survival (OS) results from the phase III TROPiCS-02 study of sacituzumab govitecan (SG) vs treatment of physician's choice (TPC) in patients (pts) with HR+/HER2- metastatic breast cancer (mBC). Abstract LBA76. Presented at: ESMO Congress 2022; September 9–13, 2022; Paris, France.

Rugo HS, Bardia A, Marmé F, et al. Overall survival with sacituzumab govitecan in hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic breast cancer (TROPiCS-02): a randomised, open-label, multicentre, phase 3 trial. *Lancet.* 2023;402(10411):1423–1433.

Rugo HS, Bardia A, Marmé F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol.* 2022;40(29):3365–3376.

Rugo HS, Bianchini G, Cortes J, et al. Optimizing treatment management of trastuzumab deruxtecan in clinical practice of breast cancer. *ESMO Open*. 2022;7(4):100553.

Rugo HS, Crossno CL, Gesthalter YB, et al. Real-world perspectives and practices for pneumonitis/interstitial lung disease associated with trastuzumab deruxtecan use in human epidermal growth factor receptor 2–expressing metastatic breast cancer. *JCO Oncol Pract.* 2023;19(8):539–546.

Rugo HS, Jacot W, Tokunaga E, et al. Trastuzumab deruxtecan (T-DXd) vs treatment of physician's choice (TPC) in patients (pts) with HER2-low unresectable and/or metastatic breast cancer (mBC): a detailed safety analysis of the randomized, phase 3 DESTINY-Breast04 trial. Abstract 1850. Presented at: ESMO Breast Cancer Congress 2023; May 11, 2023; Berlin, Germany.

Rugo HS, Tolaney SM, Loirat D, et al. Safety analyses from the phase 3 ASCENT trial of sacituzumab govitecan in metastatic triple-negative breast cancer. *NPJ Breast Cancer*. 2022;8(1):98.

Schettini F, Chic N, Braso-Maristany F, et al. Clinical, pathological, and gene expression features of HER2-low breast cancer. Abstract 23P. Presented at: ESMO Breast Cancer Virtual Meeting 2020; May 23–24, 2020.

Schmid P, Cortes J, Marme F, et al. Sacituzumab govitecan (SG) efficacy in hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2–) metastatic breast cancer (MBC) by HER2 immunohistochemistry (IHC) status in the phase III TROPICS-02. Abstract 214MO. Presented at: ESMO Congress 2022; September 9–13, 2022; Paris, France.

Sharma P. Biology and management of patients with triple-negative breast cancer. *Oncologist*. 2016;21(9):1050–1062.



Skay A, Kardashian A. Malignant cause of diarrhea. Proceedings of UCLA Health. 2020;4.

Spring LM, Tolaney SM, Fell G, et al. Response-guided neoadjuvant sacituzumab govitecan for localized triple-negative breast cancer: results from the NeoSTAR trial. *Ann Oncol*. 2024;35(3):293–301.

Swain SM, Nishino M, Lancaster LH, et al. Multidisciplinary clinical guidance on trastuzumab deruxtecan (T-DXd)-related interstitial lung disease/pneumonitis-Focus on proactive monitoring, diagnosis, and management. *Cancer Treat Rev*. 2022;106:102378.

Tarantino P, Tolaney SM. Detecting and managing T-DXd-related interstitial lung disease: the five "s" rules. *JCO Oncol Pract*. 2023;19(8):526–527.

The Joint Commission. Assess health-related social needs. The Joint Commission website. https://www.jointcommission.org/our-priorities/health-care-equity/accreditation-resource-center/assess-health-relatedsocial-needs/#t=_StrategiesTab&sort=%40created%20descending. Accessed May 2024.

Tolaney SM, Bardia A, Marme F, et al. Final overall survival (OS) analysis from the phase 3 TROPiCS-02 study of sacituzumab govitecan (SG) in patients (pts) with hormone receptor–positive/HER2-negative (HR+/HER2–) metastatic breast cancer (mBC). Abstract 1003. Presented at: 2023 ASCO Annual Meeting; June 2–6, 2023; Chicago, Illinois.

Trail PA. Antibody drug conjugates as cancer therapeutics. *Antibodies.* 2013;2(1):113–129.

U.S. Department of Health and Human Services. Common terminology criteria for adverse events (CTCAE). Version 5.0; November 27, 2017. National Cancer Institute website.

https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf. Accessed May 2024.

U.S. Food and Drug Administration (FDA). FDA-approved drug: fam-trastuzumab deruxtecan-nxki. Revised November 2022. FDA website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761139s024lbl.pdf. Accessed May 2024.

U.S. Food and Drug Administration (FDA). FDA-approved drug: sacituzumab govitecan-hziy. Revised February 2023. FDA website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761115s035lbl.pdf. Accessed May 2024.

U.S. National Library of Medicine. Study of Sacituzumab Govitecan-hziy Versus Treatment of Physician's Choice in Participants With HR+/HER2- Metastatic Breast Cancer (TROPiCS-02). Last updated November 18, 2023. ClinicalTrials.gov website. Identifier: NCT03901339. https://clinicaltrials.gov/study/NCT03901339?cond=NCT03901339&rank=1. Accessed May 2024.

U.S. National Library of Medicine. Study of sacituzumab govitecan versus treatment of physician's choice in patients with hormone receptor-positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) metastatic breast cancer who have received endocrine therapy (ASCENT-07). Last updated February 28, 2024. ClinicalTrials.gov website. Identifier: NCT05840211. https://classic.clinicaltrials.gov/ct2/show/NCT05840211. Accessed May 2024.

U.S. National Library of Medicine. Study of trastuzumab deruxtecan (T-DXd) vs investigator's choice chemotherapy in HER2-low, hormone receptor positive, metastatic breast cancer (DB-06). Last updated April 12, 2024. ClinicalTrials.gov website. Identifier: NCT04494425. https://www.clinicaltrials.gov/study/NCT04494425?cond=NCT04494425&rank=1. Accessed May 2024.

U.S. National Library of Medicine. Trastuzumab Deruxtecan (DS-8201a) Versus Investigator's Choice for HER2-low Breast Cancer That Has Spread or Cannot be Surgically Removed [DESTINY-Breast04]. Last updated April 11, 2024. ClinicalTrials.gov website. Identifier: NCT03734029.

https://clinicaltrials.gov/study/NCT03734029?cond=NCT03734029&rank=1. Accessed May 2024.

U.S. National Library of Medicine. Trial of sacituzumab govitecan in participants with refractory/relapsed metastatic triple-negative breast cancer (TNBC) (ASCENT). Last updated June 15, 2022. ClinicalTrials.gov website. Identifier: NCT02574455. https://classic.clinicaltrials.gov/ct2/show/NCT02574455. Accessed May 2024.

Waks AG, Winer EP. Breast cancer treatment: a review. JAMA. 2019;321(3):288-300.



Wang F, Zheng W, Bailey CE, et al. Racial/ethnic disparities in all-cause mortality among patients diagnosed with triplenegative breast cancer. *Cancer Res.* 2021;81(4):1163–1170.

Weinstein JN, Geller A, Negussie Y, et al (eds). *Communities in Action: Pathways to Health Equity*. Washington, DC: The National Academies Press; 2017. https://www.ncbi.nlm.nih.gov/books/NBK425848/pdf/Bookshelf_NBK425848.pdf.

Wolff AC, Hammond MEH, Allison KH, et al. Human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline focused update. *Arch Pathol Lab Med.* 2018;142(11):1364–1382.

Yedjou CG, Sims JN, Miele L, et al. Health and racial disparity in breast cancer. Adv Exp Med Biol. 2019;1152:31–49.

