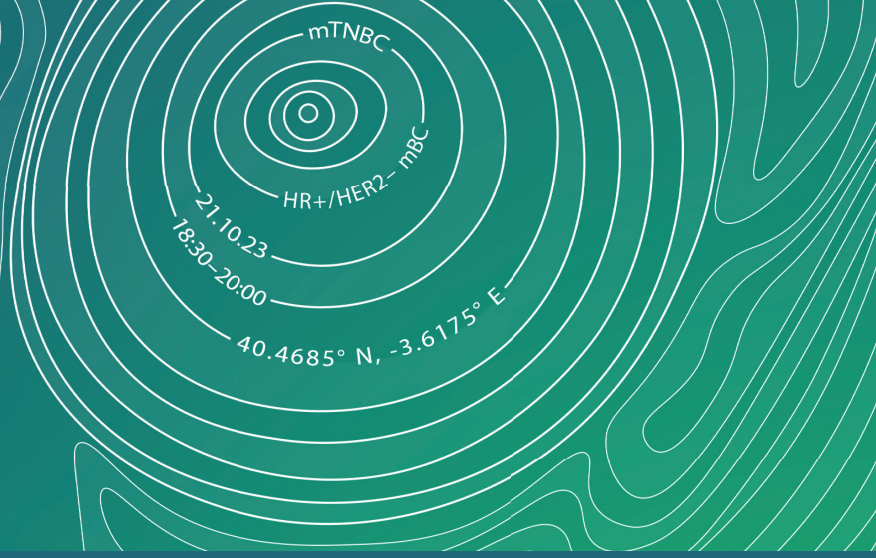
ESMO 2023 Industry Satellite Symposium

Lines of progress:

Continuing to improve outcomes in metastatic breast cancer

Saturday 21 October 2023 | 18:30–20:00 CEST
León Auditorium, Hall 7, IFEMA MADRID, Madrid, Spain



Agenda

18:30–20:00 CEST

18:30–18:45 **Welcome and introduction – Metastatic Breast Cancer: A journey of progress through innovation**		**Dr Eva Ciruelos (Chair)** *Assistant Physician, Medical Oncology Service and Coordinator of the Breast and Gynecological Cancer Unit, Hospital 12 de Octubre; Breast Cancer Unit Coordinator, HM Hospitales and Associate Professor, Department of Medicine, Universidad Complutense de Madrid, Madrid, Spain*
18:45–19:10 **Expanding possibilities in HR+/HER2– mBC**		**Prof. Hope Rugo** *Professor of Medicine, Hematology and Oncology Division, Helen Diller Family Comprehensive Cancer Center, and Director of Breast Oncology and Clinical Trials Education, UCSF, San Francisco, USA*
19:10–19:35 **Improving outcomes for patients with metastatic TNBC**		**Prof. Dr Andreas Schneeweiss** *Head of the Gynecological Oncology Section, National Center for Tumor Diseases, and Fellow of the German Cancer Research Center, Heidelberg, Germany*
19:35–19:55 **Audience Q&A**		**All speakers facilitated by the Chair**
19:55–20:00 **Closing remarks**		**Chair**

HR+/HER2– mBC, hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer; mBC, metastatic breast cancer; mTNBC, metastatic triple-negative breast cancer; Q&A, questions and answers.

This promotional symposium is sponsored and organised by Gilead Sciences, Inc. and will include discussion of licensed products. It is intended for healthcare professionals only.

TRODELVY▼ as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease.

TRODELVY as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the advanced setting.
N.B. HR+/HER2– mBC INDICACIÓN AÚN NO FINANCIADA EN ESPAÑA. N.B. HR+/HER2– mBC indication does not have marketing authorisation in the UK.

TRODELVY special warnings and precautions include traceability, severe or life-threatening neutropenia, severe diarrhoea, hypersensitivity, nausea and vomiting, use in patients with reduced UGT1A1 activity, embryo-foetal toxicity, and sodium.

▼ This medicinal product is subject to additional monitoring. The Prescribing Information and adverse reporting information for TRODELVY can be found at the end of this document. Please see the Summary of Product Characteristics for full details on managing adverse reactions.

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or via the Yellow Card app (download from the Apple App Store or Google Play Store). Adverse events should also be reported to Gilead: safety_fc@gilead.com or +44 (0) 1223 897500

The authorised presentation for TRODELVY differs between the EU/EEA and UK SmPCs. Please always refer to your local prescribing information. This promotional piece has been produced and funded by Gilead. It is intended for healthcare professionals and the intended recipient only.

GILEAD | Oncology

EU PRESCRIBING INFORMATION – Consult Summary of Product Characteristics (SmPC) before prescribing.
Trodelvy®▼ (sacituzumab govitecan) 200 mg powder for concentrate for solution for infusion.
INDICATION: Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease. Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting.
DOSAGE/ADMINISTRATION: Intravenous infusion only. Should be administered in an environment where full resuscitation facilities are available. Premedication for prevention of infusion reactions and chemotherapy-induced nausea and vomiting (CINV) is recommended. Initial infusion administered over 3 hours, patients should be observed for at least 30 minutes after initial dose for signs/symptoms of infusion-related reactions. Subsequent infusions administered over 1 to 2 hours, if prior infusions were tolerated. Adults: 10 mg/kg administered once weekly on Days 1 and 8 of 21-day treatment cycles. Elderly: No dose adjustment is required in patients ≥ 65 years old. Data from sacituzumab govitecan in patients ≥ 75 years are limited. Hepatic impairment: Mild - No adjustment to starting dose required. Safety not established in moderate/severe - not recommended. Renal impairment: Mild or moderate - No adjustment to starting dose required. Severe or end-stage renal impairment - not studied. Paediatric (< 18 years): Safety and efficacy not established.
CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients.
WARNINGS/PRECAUTIONS: Refer to SmPC. Hypersensitivity: Trodelvy can cause anaphylactic reactions and severe and life-threatening hypersensitivity. Contraindicated in patients with a known hypersensitivity to Trodelvy. Inform patients of the risk of serious infusion reactions and anaphylaxis. Instruct patients to report signs or symptoms of hypersensitivity to their medical team. Neutropenia: Can cause severe or life-threatening neutropenia. Should not be administered in case of neutropenic fever. Administration of granulocyte colony-stimulating factor (G-CSF) and dose reduction are required for severe neutropenia or febrile neutropenia. Consider G-CSF for secondary prophylaxis. Diarrhoea: Can cause severe diarrhoea. Grade 3-4 diarrhoea must resolve to ≤Grade 1 before treatment, dose reduction is required. Infusion-related reactions: Pre-infusion medication for patients receiving Trodelvy is recommended. Patients should be closely observed for infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Infusion should be slowed down or interrupted, if patient develops infusion-related reaction. Should be permanently discontinued if life-threatening, infusion-related reactions occur. Nausea and vomiting: Emetogenic. Premedication with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK-1 receptor antagonist) is recommended for prevention of CINV. In case of Grade 3 nausea or Grade 3-4 vomiting treatment should only be continued with additional supportive measures when resolved to ≤Grade 1. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting. Increased risk of adverse reactions in patients with reduced UGT1A1 activity: Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk of neutropenia, febrile neutropenia, and anaemia and are at increased risk for other adverse reactions following initiation of treatment. Patients with known reduced UGT1A1 activity should be closely monitored for adverse reactions.
SPECIAL POPULATIONS: There was a higher discontinuation rate due to adverse reactions in patients aged 65 years or older (14%) compared with younger patients (3%) with HR+/HER2- metastatic breast cancer. There was a higher incidence rate of serious adverse events in patients aged 75 years or older (67%) compared to patients aged 65 years or older (43%) and patients younger than 65 years (24%) with HR+/HER2- metastatic breast cancer.
INTERACTIONS: See SmPC for full list. UGT1A1 inhibitors: Concomitant administration with inhibitors of UGT1A1 may increase incidence of adverse reactions due to potential increase in systemic exposure to SN-38 (the small molecule moiety of sacituzumab govitecan) primarily metabolised via UGT1A1; UGT1A1 inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers.
PREGNANCY/LACTATION/FERTILITY: See SmPC for full details. Pregnancy: Trodelvy can cause teratogenicity and/or embryo-foetal lethality during pregnancy. Should not be used during pregnancy unless the clinical condition of the woman requires treatment with Trodelvy. Women of Childbearing Potential (WOCBP)/Contraception in Males and Females: WOCBP have to use effective contraception during treatment and for 6 months after the last dose. Male patients with female partners of childbearing potential have to use effective contraception during treatment and for 3 months after the last dose. The pregnancy status of women of childbearing potential should be verified prior to the initiation of Trodelvy. Breast-feeding: Should be discontinued during treatment and for 1 month after the last dose. Fertility: may be impaired in females of reproductive potential.
DRIVING/USING MACHINERY: Minor influence on ability to drive and use machines. Dizziness reported as "very common" side effect.
SIDE EFFECTS: Refer to SmPC for full list of side effects. Very common (≥ 1/10): Urinary tract infection, Upper respiratory tract infection; Neutropenia, Anaemia, Leukopenia, Lymphopenia, Decreased appetite, Hypokalaemia, Hypomagnesaemia, Insomnia, Hypersensitivity, Headache, Dizziness, Dyspnoea, Cough, Nausea, Diarrhoea, Vomiting, Constipation, Abdominal pain, Alopecia, Rash, Pruritus, Back pain, Arthralgia, Fatigue. Common (≥1/100 to <1/10): Sepsis, Pneumonia, Nasopharyngitis, Sinusitis, Bronchitis, Influenza, Oral herpes, Febrile neutropenia, Thrombocytopenia, Dehydration, Hyperglycaemia, Hypophosphatemia, Hypocalcaemia, Hyponatraemia, Anxiety, Dysgeusia, Hypotension, Rhinorrhoea, Nasal congestion, Epistaxis, Productive cough, Upper airway cough syndrome, Neutropenic colitis, Colitis, Stomatitis, Abdominal pain upper, Dyspepsia, Gastrooesophageal reflux disease, Abdominal distension, Dry skin, Rash maculopapular, Skin hyperpigmentation, Dermatitis acneiform, Musculoskeletal chest pain, Muscle spasms, Dysuria, Haematuria, Proteinuria, Pain, Chills, Weight decreased, ALP increased, aPPT prolonged LDH increased. Most frequently reported serious: Febrile neutropenia, Diarrhoea, Neutropenia, and Pneumonia.
LEGAL CATEGORY: POM. **PACK:** Type 1 colourless, clear glass 50 mL vial, elastomeric butyl stopper and sealed with an aluminum flip-off overseal. One vial per pack.
PRICE: List Price – Pack of 1 x 50mL vial = €1,031.
MARKETING AUTHORISATION NUMBER: European Union: EU/1/21/1592/001
FURTHER INFORMATION: Please contact our company for detailed information. Gilead Sciences Ireland UC, Carrigtohill, County Cork, T45 DP77, Ireland acemedinfo@gilead.com. Trodelvy is a trademark.
DATE OF PREPARATION: August 2023. IHQ-TRO-0655
▼Additional monitoring required

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or via the Yellow Card app (download from the Apple App Store or Google Play Store).

Adverse events should also be reported to Gilead to safety_FC@gilead.com or +44 (0) 1223 897500. Trodelvy is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

PRESCRIBING INFORMATION – SPAIN
Ficha técnica de Trodelvy®. Disponible en: https://ftgileadspain.com/filesRepositorio/57/FT_Trodelvy_publicidad.pdf.

GILEAD | Oncology