Sacituzumab Govitecan

Indication

Locally advanced or metastatic triple negative breast cancer after 2 cycles of systemic therapy, at least one of which must have been in the advanced / metastatic setting

Regimen details

Sacituzumab Govitecan 10mg/kg in 0.9% Saline. Give on day 1 and day 8

Final concentration should be **1.1 mg/mL** to **3.4 mg/mL** (the total volume should not exceed 500 mL).
For patients whose body weight exceeds 170 kg, divide the total dosage of TRODELVY equally between two 500 mL infusion bags and infuse sequentially via slow infusion.

Cycle frequency

21 days

Number of cycles

Until disease progression or unacceptable toxicity

Administration

Administered over 3 hours for 1st infusion and patients must be observed for 30 mins after the infusion. If well tolerated subsequent infusions can be given over 1-2 hours but patients still need observing for 30 mins afterwards

Pre-medication

IV Chlorphenamine, IV Ranitidine (or other H_2 antagonist) and Paracetamol

Emetogenicity

Pre-chemo IV dexamethasone and IV ondansetron.
TTO of ondansetron, dexamethasone and as required metoclopramide. Aprepitant to be added if problems with nausea

Additional supportive medication

Loperamide

Extravasation

Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days
Bone profile	14 days
Magnesium	14 days
Glucose	14 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST) Bone profile and Magnesium

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	**Limit**
Neutrophil count	Day 1 - > 1.5 x 10^9/L Day 8 - > 1.0 x 10^9/L
Platelet count	> 100 x 10^9/L
Creatinine clearance	≥ 60 mL/min
Bilirubin	< 1.5 x ULN
AST or ALT	< 3 x ULN (or <5 times ULN for patients with liver mets)

Dose modifications

Grade 4 neutropenia for >7 days, or grade 3 febrile neutropenia (neuts <1.0 and fever >38.5) or Grade 3-4 neutropenia which delays dosing 2 or 3 weeks to recover to grade 1

-1st episode – 25% dose reduction and administer GCSF
-2nd episode – 50% dose reduction
-3rd episode – Discontinue treatment

Grade 3-4 neutropenia which delays dosing beyond 3 weeks for recovery to grade 1 – Discontinue treatment

Non-haematological toxicities

Grade 4 non-haematological or non-neutropenic haematological toxicity that recovers to grade 1 within 3 weeks, OR Any grade 3-4 nausea, vomiting or diarrhoea that isn't controlled with antiemetics or ant-diarrheal agents, OR Other Grade 3-4 non-haematological toxicities persisting >48hrs despite optimal medical management

-1st episode – 25% dose reduction
-2nd episode – 50% dose reduction
-3rd episode – Discontinue treatment

Any grade 3-4 non-neutropenic haematological toxicity, grade 3 nausea, or Grade 3-4 vomiting which doesn't recover to grade 1 within 3 weeks – Discontinue treatment

Adverse effects –

For full details consult product literature/ reference texts

Fatigue
Nausea and vomiting
Diarrhoea
Neutropenia / Febrile neutropenia
Anaemia
Hypersensitivity
Hypomagnesaemia
Insomnia
Mucositis
Alopecia (approx 50%)

Significant drug interactions

Lancashire & South Cumbria Cancer Network
Systemic Anticancer Treatment Protocol

– for full details consult product literature/ reference texts

Inhibitors of UGTIA1 (ie Propofol, Ketoconazole, EGFR tyrosine kinase inhibitors) can increase exposure and therefore toxicity
Inducers of UGTIA1 (ie carbamezapine, phenytoin, rifampicin, protease inhibitors) should be used with caution as they may reduce exposure to the active drug
Inhibitors of CYP3A are not anticipated to impact exposure

Additional comments

Initially consultation every 3 weeks can be extended if patient tolerating well after some time on treatment

References

THIS PROTOCOL HAS BEEN DIRECTED BY DR MOON, MEDICAL ONCOLOGIST

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

Date: September 2023
Review: September 2025
VERSION: 3