NEW ZEALAND DATA SHEET

1. PRODUCT NAME

TRODELVY® (Sacituzumab govitecan), 180 mg, powder for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose vial of TRODELVY delivers 180 mg sacituzumab govitecan.

Reconstitution with 20 mL of 0.9% Sodium Chloride Injection, USP, results in a concentration of 10 mg/mL with a pH of 6.5 (see Section 4.2 *Dose and Method of Administration*). The product is for use in one patient on one occasion only. Discard any unused portion.

Part of Sacituzumab govitecan is produced in genetically engineered mammalian (murine myeloma) cells.

For the full list of excipients, see Section 6.1 *List of excipients*.

3. PHARMACEUTICAL FORM

Powder for injection.

TRODELVY is an off-white to yellowish lyophilised powder. Following reconstitution, the solution is clear and yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Metastatic triple-negative breast cancer

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

HR+/HER2- metastatic breast cancer

TRODELVY is indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy (including a CDK4/6 inhibitor) and at least two additional systemic therapies in the locally advanced or metastatic setting.

4.2 Dose and method of administration

Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite SN-38.

Pre-medication

Prior to each dose of TRODELVY, pre-medication for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting (CINV) is recommended.

- Prevention of infusion reactions: give antipyretics, H1 and H2 blockers prior to infusion; corticosteroids may be used for patients who had prior infusion reactions.
- Prevention of CINV: give a two or three drug antiemetic combination regimen (e.g. dexamethasone with either a 5-HT3 receptor antagonist or an NK1 receptor antagonist, as well as other drugs as indicated).

Prophylaxis for Neutropenia

Primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) is recommended starting in the first cycle in patients at increased risk of febrile neutropenia (see Section 4.4 *Special Warnings and Precautions for Use*).

Dosage

The recommended dose of TRODELVY is 10 mg/kg administered as an intravenous (IV) infusion once weekly on Days 1 and 8 of 21-day treatment cycles.

Do not administer TRODELVY at doses greater than 10 mg/kg.

Duration of treatment

Continue treatment until disease progression or unacceptable toxicity.

Dosage adjustment for adverse events

Infusion-related reactions

Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction. Permanently discontinue TRODELVY for life-threatening infusion-related reactions (see Section 4.4 *Special warnings and precautions for use*).

Dose modifications for adverse reactions

Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of TRODELVY as described in Table1. Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

Table 1: Dose modifications for adverse reactions.

Adverse reaction	Occurrence	Dose modification
Severe neutropenia (see Section 4.4 *Special warnings and precautions for use*)		
Grade 4 neutropenia ≥7 days or less if clinically indicated, OR Grade 3-4 febrile neutropenia OR Grade 3-4 neutropenia which requires a 2 to 3 week dose delay for recovery to ≤Grade 1	First	Administer granulocyte-colony stimulating factor (G-CSF) as soon as clinically indicated
	Second	25% dose reduction; administer G-CSF as soon as clinically indicated
	Third	50% dose reduction; administer G-CSF as soon as clinically indicated
	Fourth	Discontinue treatment; administer G-CSF as soon as clinically indicated
Grade 3-4 neutropenia which requires a dose delay longer than 3 weeks for recovery to ≤Grade 1	First	Discontinue treatment; administer G-CSF as soon as clinically indicated
Severe toxicities other than neutropenia		
Grade 4 non-haematological toxicity of any duration, OR Any Grade 3 nausea OR Any Grade 3-4 vomiting or diarrhoea due to treatment that is not controlled with antiemetics and anti-diarrhoeal agents (see Section 4.4 *Special warnings and precautions for use*), OR Other Grade 3 non-haematological toxicity persisting >48 hours despite optimal medical management, OR Any Grade 3-4 toxicity (other than neutropenia), which requires a 2 or 3 week dose delay for recovery to ≤Grade 1	First	25% dose reduction
	Second	50% dose reduction
	Third	Discontinue treatment
Any Grade 3-4 toxicity (other than neutropenia), which does not recover to ≤Grade 1 within 3 weeks	First	Discontinue treatment

Special populations

Paediatric population

The safety and effectiveness of TRODELVY in paediatric patients have not been established.

Elderly

No dose adjustment is necessary in older patients (see Section 4.4 *Special warnings and precautions for use*).

Renal impairment

No dose adjustment is necessary in patients with mild or moderate renal impairment. TRODELVY has not been studied in patients with severe renal impairment, or end-stage renal disease (CL_{cr} <15 mL/min)(see Section 5.2 *Pharmacokinetic properties*).

Hepatic impairment

No dose adjustment is necessary in patients with mild hepatic impairment (bilirubin ≤ULN and AST >ULN, or bilirubin >1.0 to ≤1.5 ULN and AST of any level.). The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established, and hepatic UGT1A1 activity could be decreased in such patients. No recommendations can be made for the starting dose in these patients (see Section 4.4 *Special warnings and precautions for use*).

Method of administration

Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus.

TRODELVY is a cytotoxic drug. Follow applicable special handling and disposal procedures. The product is for use in one patient on one occasion only. Discard any unused portion.

Only 0.9% Sodium Chloride Injection, USP, should be used for reconstitution and dilution as the stability of the reconstituted product has not been determined with other infusion-based solutions.

For instructions on reconstitution and dilution of the medicine before administration, see Section 6.6 *Special precautions for disposal and other handling*.

Use the diluted solution in the infusion bag immediately. If not used immediately, the infusion bag containing TRODELVY solution can be stored refrigerated at 2°C to 8°C for up to 24 hours. After refrigeration, administer diluted solution at room temperature up to 25°C within 8 hours (including infusion time).

Do not freeze or shake. Protect from light.

Administration

- Administer TRODELVY as an intravenous infusion. Protect infusion bag from light. The infusion bag should be covered during administration to the patient until dosing is complete. It is not necessary to cover the infusion tubing or to use light protective tubing during the infusion.
- An infusion pump may be used.
- Do not mix TRODELVY, or administer as an infusion, with other medicinal products.
- Upon completion of the infusion, flush the intravenous line with 20 mL 0.9% Sodium Chloride Injection, USP.

First infusion: Administer infusion over 3 hours.

Subsequent infusions: Administer infusion over 1 to 2 hours if prior infusions were tolerated.

Observe patients during the infusion and for at least 30 minutes after each infusion for signs or symptoms of infusion-related reactions (see Section 4.4 *Special warnings and precautions for use*).

4.3 Contraindications

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY (see Section 4.4 *Special warnings and precautions for use*).

4.4 Special warnings and precautions for use

Neutropenia

TRODELVY can cause severe or life-threatening neutropenia. Fatal infections in the setting of neutropenia have been observed in clinical trials with TRODELVY, primarily in the first two cycles of treatment. Primary prophylaxis with G-CSF is recommended starting in the first cycle of treatment in patients at increased risk of febrile neutropenia, e.g., older patients (in particular aged 65 years and older), patients with previous neutropenia, poor performance status, organ dysfunction (including renal, liver or cardiovascular dysfunction), or multiple comorbid conditions. Monitor absolute neutrophil count (ANC) during treatment.

Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Dose modifications may be required due to neutropenia or febrile neutropenia. Treat neutropenia with G-CSF and consider adding G-CSF prophylaxis in subsequent cycles as clinically indicated (see Section 4.2 *Dose and method of administration*).

Neutropenia occurred in 68% (465/688) of patients treated with TRODELVY, including Grade 3-4 neutropenia in 51% of patients. Neutropenia was the reason for dose reduction in 12% (65/688) of patients. Neutropenic colitis was observed in 1% (7/688) of patients.

Febrile neutropenia occurred in 6% (42/688) of patients treated with TRODELVY.

The median time to first onset of neutropenia (including febrile neutropenia) was 16 days and has occurred earlier in some patient populations (see Section 4.4 *Special precautions and warnings for use - Use in patients with reduced UGT1A1 activity*).

Diarrhoea

TRODELVY can cause severe diarrhoea. Withhold TRODELVY for Grade 3-4 diarrhoea at the time of scheduled treatment administration and resume when resolved to ≤Grade 1 (see Section 4.2 *Dose and method of administration*).

At the onset of diarrhoea, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhoea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhoea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated.

Patients who exhibit an excessive cholinergic response to treatment with TRODELVY (e.g., abdominal cramping, diarrhoea, salivation, etc.) can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Diarrhoea occurred in 63% (430/688) of all patients treated with TRODELVY. Grade 3 diarrhoea occurred in 10% (71/688) of all patients treated with TRODELVY. Three of 688 patients (<1%) discontinued treatment because of diarrhoea. Diarrhoea in some cases was observed to have led to dehydration and subsequent acute kidney injury.

Hypersensitivity

TRODELVY can cause severe and life-threatening hypersensitivity. Severe signs and symptoms include cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Anaphylactic reactions have been observed in clinical trials with TRODELVY (see Section 4.3 *Contraindications*).

Hypersensitivity reactions within 24 hours of dosing occurred in 33% (227/688) of patients treated with TRODELVY. Grade 3 and above hypersensitivity occurred in 2% (12/688) of patients treated with TRODELVY. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.1% (1/688).

Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY infusion and for at least 30 minutes after completion of each infusion (see Section 4.2 *Dose and method of administration*). Medication to treat such reactions, as well as emergency equipment, should be available for immediate use.

Nausea and vomiting

TRODELVY is emetogenic. Nausea occurred in 63% of all patients treated with TRODELVY and was grade 3-4 severity in 4% of patients. Vomiting occurred in 34% of all patients treated with TRODELVY and was Grade 3-4 severity in 3% of patients.

Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK-1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV).

Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment administration and resume with additional supportive measures when resolved to ≤Grade 1 (see Section 4.2 *Dose and method of administration*).

Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Use in patients with reduced UGT1A1 activity

Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are potentially at increased risk for neutropenia, febrile neutropenia, and anaemia and may be at increased risk for other adverse reactions when treated with TRODELVY.

The incidence of Grade 3-4 neutropenia was 60.6% (43/71) in patients homozygous for the UGT1A1*28 allele, 52.9% (144/272) in patients heterozygous for the UGT1A1*28 allele, and 49.1% (140/285) in patients homozygous for the wild-type allele. The incidence of Grade 3-4 febrile neutropenia was 14.1% (10/71) in patients homozygous for the UGT1A1*28 allele, 5.9% (16/272) in patients heterozygous for the UGT1A1*28 allele, and 4.6% (13/285) in patients

homozygous for the wild-type allele. The incidence of Grade 3-4 anaemia was 15.5% (11/71) in patients homozygous for the UGT1A1*28 allele, 7.4% (20/272) in patients heterozygous for the UGT1A1*28 allele, and 8.1% (23/285) in patients homozygous for the wild-type allele.

Compared to patients homozygous for the wild-type allele, earlier median onset of neutropenia and anaemia was observed in patients homozygous for the UGT1A1*28 allele and in patients heterozygous for the UGT1A1*28 allele.

Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate UGT1A1 reduced function (see Section 4.2 *Dose and method of administration*).

Embryo-fetal toxicity

Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant person. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells (see Section 5.1 *Pharmacodynamic properties*). Advise patients who are pregnant, and females of reproductive potential, of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose (see Section 4.6 *Fertility, pregnancy and lactation*).

Use in hepatic impairment

No adjustment to the starting dose is required when administering TRODELVY to patients with mild hepatic impairment.

The exposure of TRODELVY in patients with mild hepatic impairment (bilirubin ≤ULN and AST >ULN, or bilirubin >1.0 to ≤1.5 ULN and AST of any level; n=257) was similar to patients with normal hepatic function (bilirubin and AST ≤ULN; n=526).

The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established. TRODELVY has not been tested in patients with any of the following: serum bilirubin >1.5 ULN, patients with AST or ALT > 3 ULN in the absence of liver metastases, or patients with AST or ALT > 5 ULN in the presence of liver metastases.

The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established. No recommendations can be made for the starting dose in these patients.

Use in the elderly

Of the 366 patients with TNBC treated with TRODELVY, 19% of patients were 65 years and older and 3% were 75 years and older. No overall differences in safety and effectiveness were observed between patients ≥ 65 years of age and younger patients.

Of the 322 patients with HR+/HER2- breast cancer treated with TRODELVY, 26% of patients were 65 years and older and 6% were 75 years and older. No overall differences in effectiveness were observed between patients ≥ 65 years of age and younger patients. There was a higher

discontinuation rate due to adverse reactions in patients aged 65 years or older (14%) compared with younger patients (3%).

Paediatric use

Safety and effectiveness of TRODELVY have not been established in paediatric patients.

Effects on laboratory tests

No data available.

4.5 Interaction with other medicines and other forms of interaction

No formal drug-drug interaction studies were conducted with sacituzumab govitecan or its components.

UGT1A1 inhibitors
Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38 (see Section 4.4 *Special warnings and precautions for use* and Section 5.2 *Pharmacokinetic properties*). Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 inducers
Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers (see Section 4.4 *Special warnings and precautions for use* and Section 5.2 *Pharmacokinetic properties*). Avoid administering UGT1A1 inducers with TRODELVY.

4.6 Fertility, pregnancy and lactation

Effects on fertility

Fertility studies with sacituzumab govitecan have not been conducted. Based on findings in animals, TRODELVY may impair fertility in females of reproductive potential.

In a repeat-dose toxicity study in cynomolgus monkeys, intravenous administration of sacituzumab govitecan resulted in endometrial atrophy, uterine haemorrhage, increased follicular atresia of the ovary, and atrophy of vaginal epithelial cells at doses ≥60 mg/kg (1.9 times the recommended human dose of 10 mg/kg based on body surface area; and >29 times the plasma exposure to free SN-38, based on clinical AUC at the recommended human dose).

Use in pregnancy – Pregnancy Category D

Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant person. There are no available clinical data on the use of TRODELVY in pregnancy to inform the associated risk. TRODELVY contains a genotoxic component, SN-38, and is toxic to rapidly dividing cells (see Section 5.1 *Pharmacodynamic properties*).

Verify the pregnancy status of females of reproductive potential prior to the initiation of TRODELVY.

Advise patients who are pregnant, and females of reproductive potential, of the potential risk to a fetus.

Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Because of the potential for genotoxicity, advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

Animal data

There were no reproductive and developmental toxicology studies conducted with sacituzumab govitecan.

Use in lactation

There is no information regarding the presence of sacituzumab govitecan or SN-38 in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration. The effects of reported adverse reactions such as fatigue and asthenia are unknown, therefore, caution is advised when driving or operating machines.

4.8 Undesirable effects

The following adverse reactions are discussed in greater detail in Section 4.4 *Special warnings and precautions for use*:

- Neutropenia
- Diarrhoea
- Hypersensitivity
- Nausea and vomiting.

Adverse effects across clinical trials

The data described in Section 4.4 *Special warnings and precautions for use* reflect exposure to TRODELVY as a single agent at the recommended dose for the treatment of metastatic TNBC and HR+/HER2- breast cancer, in 688 patients across three studies: IMMU-132-01, IMMU-132-05 (ASCENT) and IMMU-132-09 (TROPiCS-02). The median duration of treatment in this pooled safety population was 4.63 months, and the most common (>20%) adverse reactions were neutropenia, nausea, diarrhoea, fatigue, alopecia, anaemia, constipation, vomiting, decreased appetite and abdominal pain.

Adverse effects in ASCENT (TNBC)

The ASCENT study (IMMU-132-05, NCT02574455) was an international, randomised, active-controlled, open-label trial in patients with mTNBC who had previously received a taxane and at least two prior therapies. Patients were randomised (1:1) to receive either TRODELVY (n=258) or physician's choice of single agent chemotherapy (n=224) until disease progression or unacceptable toxicity (see Section 5.1 *Pharmacodynamic properties - Clinical trials*).

All patients received standard prophylaxis and treatment for chemotherapy-induced nausea and vomiting (CINV) with a 2- or 3-drug combination regimen, and take-home medications for CINV and diarrhoea.

The median duration of treatment was 4.4 months for TRODELVY (range: 0 to 23 months) and 1.3 months for single agent chemotherapy (range: 0 to 15 months).

Serious adverse reactions occurred in 27% of patients receiving TRODELVY. The most common (>1%) serious adverse reactions in the TRODELVY group were neutropenia (7%), diarrhoea (3%), and pneumonia (3%). Fatal adverse reactions occurred in 0.8% of patients who received TRODELVY, including respiratory failure (0.4%). Adverse reactions leading to permanent discontinuation of TRODELVY occurred in 5% of patients. The most common adverse reactions leading to permanent discontinuation were pneumonia (0.8%) and fatigue (0.8%).

Adverse reactions leading to a dose reduction of TRODELVY occurred in 22% of patients. The most frequent (≥4%) adverse reactions leading to a dose reduction were neutropenia (11%) and diarrhoea (5%).

Adverse reactions leading to a treatment interruption of TRODELVY occurred in 63% of patients. The most frequent (≥5%) adverse reactions leading to a treatment interruption were neutropenia (47%), diarrhoea (5%), respiratory infection (5%) and leukopenia (5%).

Granulocyte-colony stimulating factor (G-CSF) was used in 47 of patients who received TRODELVY.

Tables 2 and 3 summarise the most common adverse reactions and haematological laboratory abnormalities, respectively, in the ASCENT study.

Table 2: Most common adverse events in the ASCENT study (≥10% in either arm)

	TRODELVY (n=258)		Single Agent Chemotherapy* (n=224)	
Adverse event	**All Grade %**	**Grade 3-4 %**	**All Grade %**	**Grade 3-4 %**
Blood and lymphatic system disorders				
Neutropenia [i.]	64	52	44	34
Anaemia[ii]	40	9	28	6
Leukopenia[iii]	17	10	12	6
Lymphopenia[iv]	10	2	6	2
Gastrointestinal disorders				
Diarrhoea	65	11	17	1
Nausea	62	3	30	0.4
Vomiting	33	2	16	1
Constipation	37	0.4	23	0
Abdominal pain	21	3	8	1
Stomatitis[v]	17	2	13	1
General disorders and administration site conditions				
Fatigue[vi]	65	6	50	10
Pyrexia	15	0.4	14	2
Infections and infestation				
Urinary tract infection	13	0.4	8	0.4
Upper respiratory tract infection	12	0	3	0
Investigations				
Alanine aminotransferase increased	10	1	10	1
Metabolism and nutrition disorders				
Decreased appetite	28	2	21	1
Hypokalaemia	16	3	13	0.4
Hypomagnesaemia	12	0	6	0
Musculoskeletal and connective tissue disorders				
Back pain	16	1	14	2
Arthralgia	12	0.4	7	0
Nervous system disorders				
Headache	18	0.8	13	0.4
Dizziness	10	0	7	0
Psychiatric disorders				
Insomnia	11	0	5	0
Respiratory, thoracic and mediastinal disorders				

	TRODELVY (n=258)		Single Agent Chemotherapy* (n=224)	
Adverse event	**All Grade %**	**Grade 3-4 %**	**All Grade %**	**Grade 3-4 %**
Cough	24	0	18	0.4
Skin and subcutaneous tissue disorders				
Alopecia	47	0	16	0
Rash	12	0.4	5	0.4
Pruritus	10	0	3	0

*Chemotherapy consisted of one of the following single-agents: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (except if patient had ≥Grade 2 neuropathy, n=52).

Graded per NCI CTCAE v.5.0.

[i] Including neutropenia and neutrophil count decreased
[ii] Including anaemia, haemoglobin decreased, and red blood cell count decreased
[iii] Including leukopenia and white blood cell count decreased
[iv] Including lymphopenia and lymphocyte count decreased
[v] Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation
[vi] Including fatigue and asthenia

Table 3: Most common haematological laboratory abnormalities in ASCENT (≥10% in either arm)

Laboratory abnormality	TRODELVY (n=258)		Chemotherapy (n=224)	
	All Grade (%)	**Grade 3-4 (%)**	**All Grade (%)**	**Grade 3-4 (%)**
Decreased haemoglobin	94	9	84	6
Decreased leukocytes	88	41	70	25
Decreased neutrophils	78	49	60	36
Decreased lymphocytes	78	31	68	24
Decreased platelets	22	1	32	3

Adverse effects in TROPiCS-02 (HR+/HER2-)

The TROPiCS-02 study (IMMU-132-09) was an international, randomised, open-label trial in patients with unresectable locally advanced or metastatic HR-positive, HER2-negative (IHC 0, IHC1+, or IHC 2+/ISH-) breast cancer whose disease has progressed after the following in any setting: a CDK 4/6 inhibitor, endocrine therapy, and a taxane; patients received at least two prior chemotherapies in the metastatic setting (one of which could be in the neoadjuvant or adjuvant setting if progression or recurrence occurred within 12 months). Patients were randomised (1:1) to receive either TRODELVY or Single Agent Chemotherapy (SAC) until disease progression or unacceptable toxicity (see Section 5.1 *Pharmacodynamic properties - Clinical trials*).

The median duration of treatment was 4.11 months for TRODELVY and 2.33 months for the SAC group overall.

Serious adverse reactions occurred in 28% of patients receiving TRODELVY. Serious adverse reactions in >1% of patients receiving TRODELVY included diarrhoea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia and vomiting (each 2%). Fatal adverse reactions occurred in 2% of patients who received TRODELVY, including arrhythmia, pneumonia, COVID-19 pneumonia, septic shock, nervous system disorder, and pulmonary embolism (each 0.4%),

Adverse reactions leading to permanent discontinuation of TRODELVY occurred in 6% of patients. The most common adverse reactions leading to permanent discontinuation were neutropenia, asthenia, and general physical health deterioration (each 0.7%).

Adverse reactions leading to a dose reduction of TRODELVY occurred in 34% of patients. The most frequent (≥3%) adverse reactions leading to a dose reduction were neutropenia (16%), diarrhoea (8%), and febrile neutropenia and fatigue (each 3%).

Adverse reactions leading to a treatment interruption of TRODELVY occurred in 66% of patients. The most frequent (≥3%) adverse reactions leading to a treatment interruption were neutropenia (50%), leukopenia, anaemia and diarrhoea (each 3%).

Tables 4 and 5 summarise the most common adverse reactions and haematological laboratory abnormalities, respectively, in the TROPiCS-02 study.

Table 4: Most common treatment-emergent adverse events in the TROPiCS-02 study (≥10% of patients)

	TRODELVY (n=268)		**SAC (n=249)**	
Adverse event	**All Grade %**	**Grade 3 or Higher %**	**All Grade %**	**Grade 3 or higher%**
Blood and lymphatic system disorders				
Neutropenia[i]	71	52	55	39
Anaemia[ii]	37	8	28	4
Leukopenia[iii]	14	9	10	6
Lymphopenia[iv]	12	4	12	4
Gastrointestinal disorders				
Diarrhoea	62	10	23	1
Nausea	59	1	35	3
Constipation	35	0.4	25	0
Vomiting	24	1	16	2
Abdominal pain[v]	27	4	18	1
Dyspepsia[vi]	12	0	6	0
General disorders and administration site conditions				

	TRODELVY (n=268)		SAC (n=249)	
Adverse event	**All Grade %**	**Grade 3 or Higher %**	**All Grade %**	**Grade 3 or higher%**
Fatigue[vii]	60	8	51	5
Immune system disorders				
Hypersensivity[viii]	27	2	19	0.8
Metabolism and nutrition disorders				
Decreased appetite	21	2	21	0.8
Hypokalaemia	11	2	4	0.4
Musculoskeletal and connective tissue disorders				
Arthralgia	15	0.4	12	0.4
Back pain	13	2	13	2
Nervous system disorders				
Headache	16	0.4	15	0.8
Respiratory, thoracic and mediastinal disorders				
Dyspnoea[ix]	20	2	17	5
Cough	12	0	7	0.4
Skin and subcutaneous tissue disorders				
Alopecia	48	0	19	0
Pruritus	12	0.4	2	0

*Single agent chemotherapy included one of the following single-agents: eribulin (n=130), vinorelbine (n=63), gemcitabine (n=56), or capecitabine (n=22).
Graded per NCI CTCAE v.5.0.
i. Including neutropenia; neutrophil count decreased.
ii. Including anemia; haemoglobin decreased; red blood cell count decreased.
iii. Including leukopenia; white blood cell count decreased.
iv. Including lymphopenia; lymphocyte count decreased.
v. Including Abdominal pain and Abdominal pain upper
vi. Including dyspepsia, gastrooesophageal reflux disease.
vii. Including fatigue, asthenia.
viii. Hypersensitivity events reported up to the end of the day after treatment was administered. Includes events coded to the following preferred terms: Cough; dyspnoea; rash; pruritus; stomatitis; hypotension; rash maculopapular; flushing; erythema; infusion related reaction; rhinitis allergic; dermatitis acneiform; eczema; conjunctivitis; generalised oedema; rash pruritic; oedema; urticaria; blister; cheilitis; contrast media allergy; dermatitis; dermatitis exfoliative generalised; drug hypersensitivity; eye oedema; sneezing; mouth ulceration; periorbital oedema; rash erythematous.
ix. Including dyspnoea; dyspnoea exertional.

Other clinically significant adverse reactions in TROPiCS-02 (⩽10%) include: pain (5%), rhinorrhea (5%), hypocalcemia (3%), nasal congestion (3%), skin hyperpigmentation (3%), colitis or neutropenic colitis (2%), hyponatremia (2%), pneumonia (2%), proteinuria (1%), enteritis (0.4%).

Table 5: Most Common Haematological Laboratory Abnormalities in TROPiCS (≥5% of patients)

Laboratory abnormality	TRODELVY (n=268)		SAC (n=249)	
	All Grade (%)	Grade 3 or Higher (%)	All Grade (%)	Grade 3 or Higher (%)
Decreased haemoglobin	73	8	59	5
Decreased leukocytes	89	38	73	26
Decreased neutrophils	83	53	68	40
Decreased lymphocytes	66	21	47	14

Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralising antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies may be misleading.

Across clinical studies in patients treated with TRODELVY, 9 (1.1%) of 785 patients developed antibodies to sacituzumab govitecan; 6 of these patients (0.8% of all patients treated with TRODELVY) had neutralizing antibodies against sacituzumab govitecan. There are insufficient data to determine the impact of immunogenicity on sacituzumab govitecan efficacy, safety, or pharmacokinetics.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/}

4.9 Overdose

Signs and Symptoms:

There is no information on overdose in human clinical trials. In a clinical trial, planned doses of up to 18 mg/kg (approximately 1.8 times the maximum recommended dose of 10 mg/kg) of TRODELVY were administered. In these patients, a higher incidence of severe neutropenia was observed.

Management/treatment:

Patients who experience overdose should have immediate interruption of their infusion and be closely monitored.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

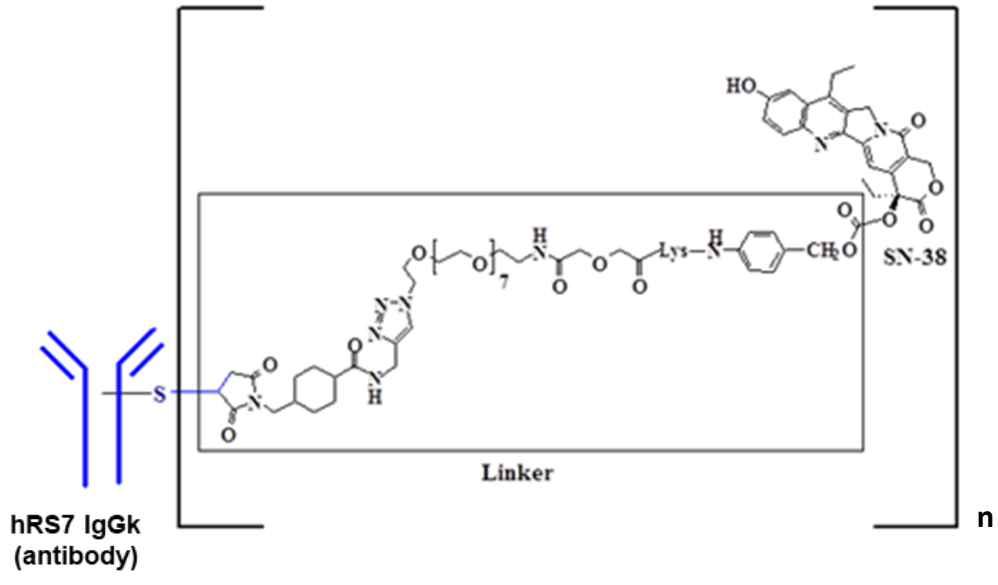
TRODELVY exposure-response relationships and a pharmacodynamic time-course for efficacy have not been fully characterised.

Mechanism of action

Sacituzumab govitecan is a Trop-2-directed antibody-drug conjugate. Sacituzumab is a humanised antibody that recognises Trop-2. The small molecule, SN-38, is a topoisomerase I inhibitor, which is covalently attached to the antibody by a linker. Pharmacology data suggest that sacituzumab govitecan binds to Trop-2-expressing cancer cells and is internalised with the subsequent release of SN-38 via hydrolysis of the linker. SN-38 interacts with topoisomerase I and prevents re-ligation of topoisomerase I-induced single strand breaks. The resulting DNA damage leads to apoptosis and cell death. Sacituzumab govitecan decreased tumour growth in mouse xenograft models of triple-negative breast cancer.

Physicochemical Properties

Chemical structure



Sacituzumab govitecan is a Trop-2 directed antibody and topoisomerase inhibitor conjugate, composed of the following three components:

- the humanised monoclonal antibody, hRS7 IgG1κ (also called sacituzumab), which binds to Trop-2 (the trophoblast cell-surface antigen-2);
- the drug SN-38, a topoisomerase inhibitor;
- a hydrolysable linker (called CL2A), which links the humanised monoclonal antibody to SN-38.

The recombinant monoclonal antibody is produced by mammalian (murine myeloma) cells, while the small molecule components SN-38 and CL2A are produced by chemical synthesis. Sacituzumab govitecan contains on average 7 to 8 molecules of SN-38 per antibody molecule. Sacituzumab govitecan has a molecular weight of approximately 160 kilodaltons.

CAS number

1491917-83-9

Cardiac electrophysiology

The effect of TRODELVY on the QTc interval was assessed in a PK-ECG substudy (n=17) of the Phase 3 ASCENT study (Study IMMU-132-05). The maximum mean change from baseline was 9.7 msec (with a two-sided 90% confidence interval upper bound of 16.8 msec) at the recommended dose. A positive exposure-response relationship was observed between QTc increases and SN-38 concentrations.

Clinical trials

Locally Advanced or Metastatic Triple-Negative Breast Cancer (ASCENT)

The ASCENT study (IMMU-132-05; NCT02574455) was an international Phase 3, multicentre, open-label, randomised study conducted in 529 patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who had relapsed after at least two prior chemotherapies (one of which could be in the neoadjuvant or adjuvant setting provided progression occurred within 12 months of adjuvant therapy). All patients had received previous taxane treatment in either the adjuvant, neoadjuvant, or advanced setting unless there was a contraindication or intolerance to taxanes during or at the end of the first taxane cycle. Poly-ADP ribose polymerase (PARP) inhibitors were allowed as one of the two prior chemotherapies for patients with a documented germline BRCA1/BRCA2 mutation.

Patients with previously-treated, stable brain metastases were allowed to enrol (up to a pre-defined maximum of 15% of the trial population). Patients with known or suspected brain metastases were required to have a brain MRI (magnetic resonance imaging) prior to enrolment. Patients with known Gilbert's disease or bone-only disease were excluded.

Patients were randomised 1:1 to receive TRODELVY 10 mg/kg as an intravenous infusion on Days 1 and 8 of a 21-day cycle (n=267) or physician's choice of single agent chemotherapy (n=262). Single agent chemotherapy was selected by the investigator before randomisation from one of the following single-agent regimens: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (except if patient had ≥Grade 2 neuropathy, n=52).

Patients were treated until disease progression or unacceptable toxicity. The primary efficacy endpoint was progression-free survival (PFS) in patients without brain metastases at baseline (the BM-neg subgroup) as measured by blinded, independent, centralised review (BICR) using

Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria. Secondary efficacy endpoints included PFS for the full population (all randomised patients, with and without brain metastases) and overall survival (OS).

The full population (n=529) was 99.6% female; 79% White; 12% Black/African American; and had a median age of 54 years (range: 27–82 years), with 81% younger than 65 years. All patients had an ECOG performance status of 0 (43%) or 1 (57%). Forty-two percent of patients had hepatic metastases; 8% were BRCA1/BRCA2 mutational status positive, and 70% were TNBC at diagnosis. Baseline brain metastases were present in 12% of patients (n=61; 32 in the TRODELVY arm and 29 in the single agent chemotherapy arm). The median number of prior systemic therapies was 4, and for 29% of patients this included an anti-PD-(L)1 agent. Thirteen percent of patients in the TRODELVY group in the full population received only 1 prior line of systemic therapy in the metastatic setting.

Efficacy results for ASCENT are summarised in Table 6, Figure 1, and Figure 2.

Table 6: Efficacy results from the ASCENT study

	All randomised patients		**BM-neg subgroup**	
	TRODELVY n=267	**Single agent chemotherapy n=262**	**TRODELVY n=235**	**Single agent chemotherapy n=233**
Progression-Free Survival (PFS) per BICR				
Disease progression or death, n (%)	190 (71%)	171 (65%)	166 (71%)	150 (64%)
Median PFS in months (95% CI)	4.8 (4.1, 5.8)	1.7 (1.5, 2.5)	5.6 (4.3, 6.3)	1.7 (1.5, 2.6)
Hazard ratio (95% CI)	0.43 (0.35, 0.54)		0.41 (0.32, 0.52)	
p-value*	<0.0001		<0.0001	
Overall Survival (OS)				
Deaths, n (%)	179 (67%)	206 (79%)	155 (66%)	185 (79%)
Median OS in months (95% CI)	11.8 (10.5, 13.8)	6.9 (5.9, 7.7)	12.1 (10.7, 14.0)	6.7 (5.8, 7.7)
Hazard ratio (95% CI)	0.51 (0.41, 0.62)		0.48 (0.38, 0.59)	
p-value*	<0.0001		<0.0001	

CI = Confidence Interval. PFS is defined as the time from the date of randomisation to the date of the first radiological disease progression or death due to any cause, whichever comes first.

* Stratified log-rank test adjusted for stratification factors: number of prior chemotherapies, presence of known brain metastases at study entry, and region.

Figure 1: Kaplan-Meier plot of PFS by BICR (all randomised patients) in ASCENT

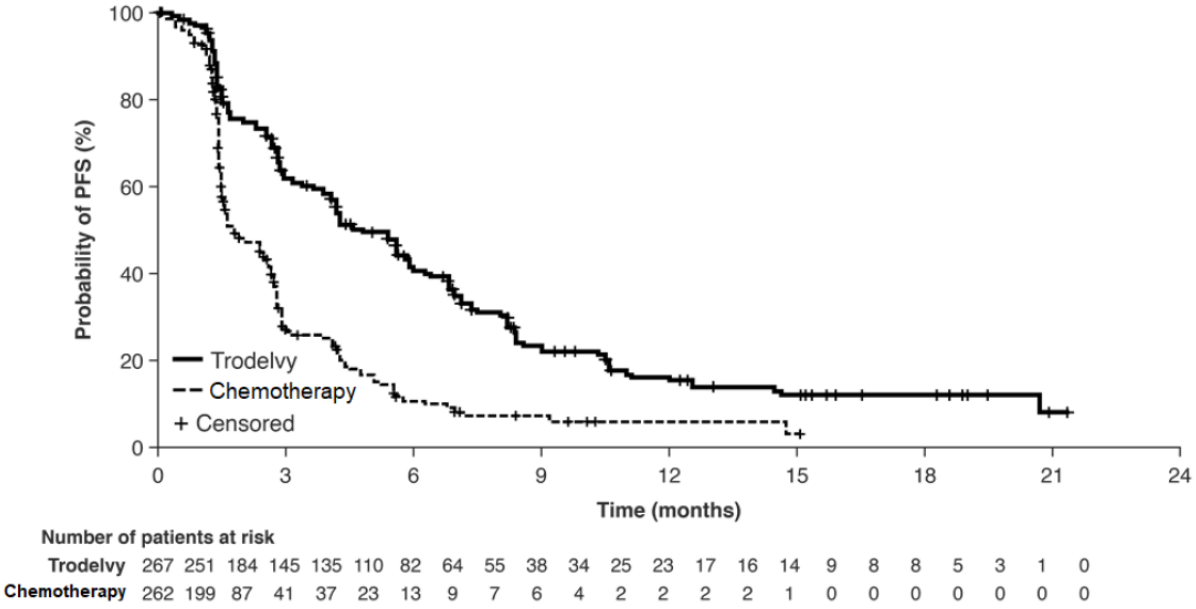
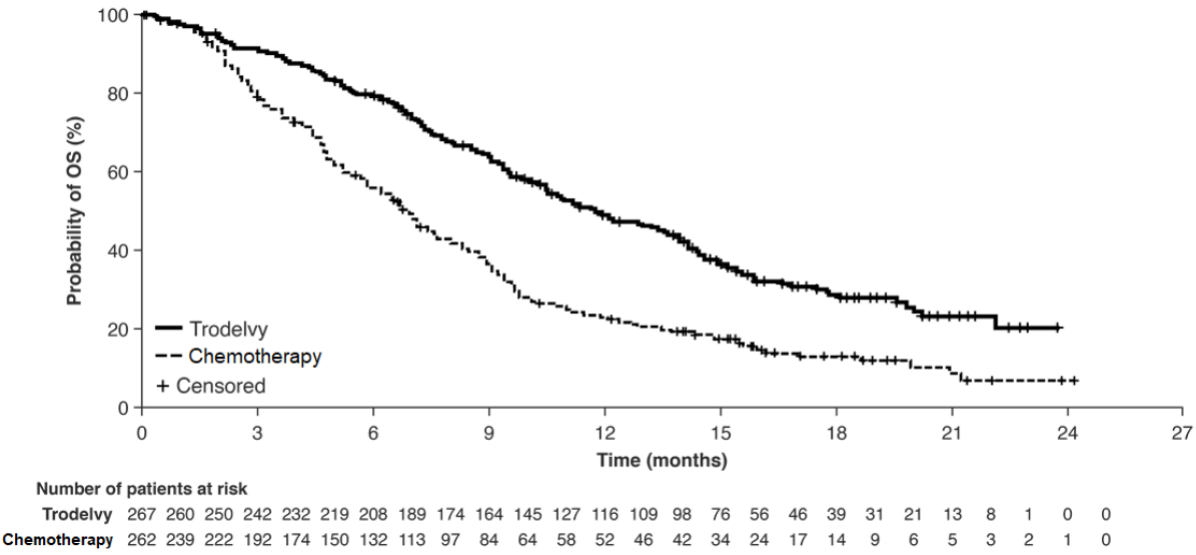


Figure 2: Kaplan-Meier plot of OS (all randomised patients) in ASCENT



Efficacy results for the subgroup of patients who had received only 1 prior line of systemic therapy in the metastatic setting (in addition to having disease recurrence or progression within 12 months of neoadjuvant/adjuvant systemic therapy) were consistent with those who had received at least two prior lines in the metastatic setting.

An exploratory analysis of PFS in 61 patients with previously treated, stable brain metastases showed a stratified HR of 0.65 (95% CI: 0.35, 1.22). The median PFS in the TRODELVY arm was 2.8 months (95% CI: 1.5, 3.9) and the median PFS with single agent chemotherapy was 1.6 months (95% CI: 1.3, 2.9). Exploratory OS analysis in the same population showed a stratified HR of 0.87

(95% CI: 0.47, 1.63). The median OS in the TRODELVY arm was 6.8 months (95% CI: 4.7, 14.1) and the median OS with single agent chemotherapy was 7.5 months (95% CI: 4.7, 11.1).

Locally Advanced or Metastatic HR-Positive, HER2-Negative Breast Cancer (TROPiCS-02)

The efficacy of TRODELVY was evaluated in a multicentre, open-label, randomised study TROPiCS-02 (IMMU-132-09) conducted in 543 patients with unresectable locally advanced or metastatic HR-positive, HER2-negative (IHC 0, IHC1+, or IHC 2+/ISH-) breast cancer whose disease has progressed after the following in any setting: a CDK 4/6 inhibitor, endocrine therapy, and a taxane; patients received at least two prior chemotherapies in the metastatic setting (one of which could be in the neoadjuvant or adjuvant setting if progression or recurrence occurred within 12 months).

Patients were randomised (1:1) to receive TRODELVY 10 mg/kg as an intravenous infusion on Days 1 and 8 of a 21-day cycle (n=272) or SAC (n=271). SAC was determined by the investigator before randomisation from one of the following single-agent regimens: eribulin (n=130), vinorelbine (n=63), gemcitabine (n=56), or capecitabine (n=22). Randomisation was stratified based on prior chemotherapy regimens for metastatic disease (2 vs. 3-4), visceral metastasis (yes vs. no), and endocrine therapy in the metastatic setting for at least 6 months (yes vs. no).

Patients were treated until disease progression or unacceptable toxicity. Administration of TRODELVY was permitted beyond RECIST-defined disease progression if the patient was clinically stable and considered by the investigator to be deriving clinical benefit. The primary efficacy outcome measure was PFS as determined by BICR per RECIST v1.1. Additional efficacy outcome measures were OS, ORR by BICR, and DOR by BICR.

The median age of the study population was 56 years (range: 27-86 years), and 26% of patients were 65 years or over. Almost all patients were female (99%). The majority of patients were White (67%); 4% were Black, 3% were Asian, and 26% were of unknown race. Patients received a median of 7 (range: 3 to 17) prior systemic regimens in any setting and 3 (range: 0 to 8) prior systemic chemotherapy regimens in the metastatic setting. Approximately 42% of patients had 2 prior chemotherapy regimens for metastatic disease compared to 58% of patients who had 3 to 4 prior chemotherapy regimens. Patients had an ECOG performance status of 0 (44%) or 1 (56%). Ninety-five percent of patients had visceral metastases. Most patients received endocrine therapy in the metastatic setting for ≥6 months (86%).

TRODELVY demonstrated a statistically significant improvement in PFS by BICR and OS versus SAC. The improvement in PFS by BICR and OS was generally consistent across pre-specified subgroups. Efficacy results are summarised in Table 7 and Figures 3 and 4.

Table 7: Efficacy results from TROPiCS-02 study

	TRODELVY **N=272**	**SAC** **N=271**
Progression-Free Survival by BICR[1]		
Median PFS in months (95% CI)	5.5 (4.2, 7.0)	4.0 (3.1, 4.4)
Hazard ratio (95% CI)	0.661 (0.529, 0.826)	
p-value[2]	0.0003	
PFS rate at 12 months, % (95% CI)	21.3 (15.2, 28.1)	7.1 (2.8, 13.9)
Overall Survival[3]		
Median OS in months (95% CI)	14.4 (13.0, 15.7)	11.2 (10.1, 12.7)
Hazard ratio (95% CI)	0.789 (0.646, 0.964)	
p-value[2]	0.0200	
Objective Response Rate by BICR[3]		
Number of responders (%)	57 (21.0%)	38 (14.0%)
Odds ratio (95% CI)	1.625 (1.034, 2.555)	
p-value	0.0348	
Duration of Response by BICR[3]		
Median DOR in months (95% CI)	8.1 (6.7, 9.1)	5.6 (3.8, 7.9)

[1] PFS is defined as the time from the date of randomisation to the date of the first radiological disease progression or death due to any cause, whichever comes first (data cut-off 3 January 2022).

[2] Stratified log-rank test adjusted for stratification factors: prior chemotherapy regimens for metastatic disease (2 vs. 3-4), visceral metastasis (yes vs. no), and endocrine therapy in the metastatic setting for at least 6 months (yes vs. no).

[3] Based on second interim OS analysis (conducted when 390 OS event were observed; data cut-off 1 July 2022).

BICR = Blinded Independent Central Review; CI = Confidence Interval

Figure 3: Kaplan-Meier Plot of PFS by BICR in TROPiCS-02

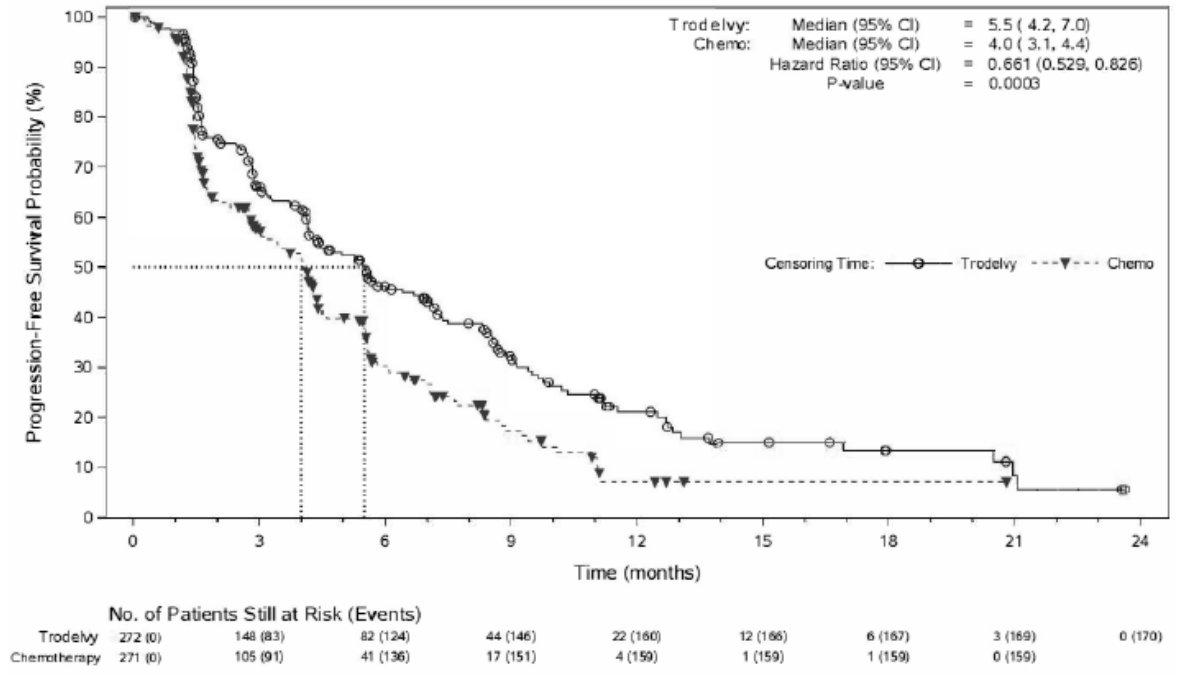
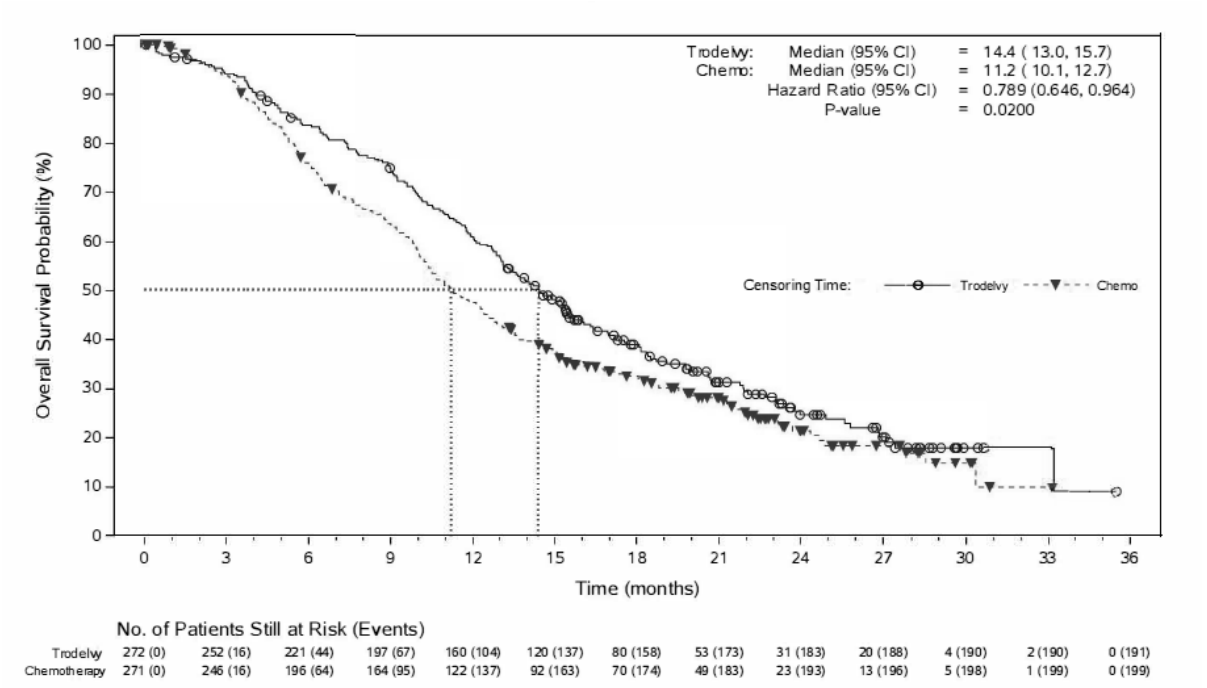


Figure 4: Kaplan-Meier Plot of OS in TROPiCS-02



5.2 Pharmacokinetic properties

The serum pharmacokinetics of sacituzumab govitecan and SN-38 were evaluated in the ASCENT study in a population of mTNBC patients who received sacituzumab govitecan as a single agent at a dose of 10 mg/kg. The pharmacokinetic parameters of sacituzumab govitecan and free SN-38 are presented in Table 8.

Table 8: Summary of mean pharmacokinetic parameters (CV%) of sacituzumab govitecan and free SN-38

	Sacituzumab govitecan	**Free SN-38**
C_{max} [ng/mL]	242,000 (22%)	91 (65%)
AUC_{0-168} [ng*h/mL]	5,560,000 (24%)	2730 (41%)

C_{max}: maximum serum concentration
AUC_{0-168}: area under serum concentration curve through 168 hours

Distribution

Based on population pharmacokinetic analysis, the central volume distribution of sacituzumab govitecan is 3.58 L.

Metabolism

No metabolism studies with sacituzumab govitecan have been conducted. SN-38 (the small molecule moiety of sacituzumab govitecan) is metabolised via UGT1A1.

Excretion

The median elimination half-life ($t_{1/2}$) of sacituzumab govitecan and of free SN-38 in patients with metastatic breast cancer was 23.4 and 17.6 hours, respectively. Based on population pharmacokinetic analysis, the clearance of sacituzumab govitecan is 0.128 L/h.

Pharmacokinetics in special populations

Age and race

Pharmacokinetic analyses in patients treated with TRODELVY (n=789) did not identify an effect of age or race, and mild or moderate renal impairment on the pharmacokinetics of sacituzumab govitecan.

Renal impairment

Pharmacokinetic analyses in patients treated TRODELVY did not identify an effect of mild or moderate renal impairment on the pharmacokinetics of sacituzumab govitecan. Renal elimination is known to contribute minimally to the excretion of SN-38, the small molecule moiety of sacituzumab govitecan. There are no data on the pharmacokinetics of sacituzumab govitecan in patients with severe renal impairment, or end-stage renal disease (CrCl < 15 mL/min).

Hepatic impairment

The exposure of sacituzumab govitecan is similar in patients with mild hepatic impairment (bilirubin ≤ULN and AST >ULN, or bilirubin >1.0 to ≤1.5 ULN and AST of any level; n=257) to patients with normal hepatic function (bilirubin and AST ≤ULN; n=526).

Sacituzumab govitecan and free SN-38 exposures are unknown in patients with moderate or severe hepatic impairment.

UGT1A1 gene variants

SN-38 is metabolised via UGT1A1. Genetic variants of the UGT1A1 gene such as the UGT1A1*28 allele lead to reduced UGT1A1 enzyme activity. Individuals who are homozygous for the UGT1A1*28 allele are at increased risk for neutropenia, febrile neutropenia, and anaemia from TRODELVY (see Section 4.4 Special warnings and precautions for use). Approximately 20% of the Black or African American population, 10% of the White population, and 2% of the East Asian population are homozygous for the UGT1A1*28 allele. Decreased function alleles other than UGT1A1*28 may be present in certain populations.

5.3 Preclinical safety data

Genotoxicity

SN-38 was clastogenic in an *in vitro* mammalian cell micronucleus test in Chinese hamster ovary cells and was not mutagenic in an *in vitro* bacterial reverse mutation (Ames) assay.

Carcinogenicity

Carcinogenicity studies have not been conducted with sacituzumab govitecan.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- 2-N-morpholinoethanesulfonic acid monohydrate
- Polysorbate 80
- Trehalose dihydrate

6.2 Incompatibilities

Do not mix TRODELVY, or administer as an infusion, with other medicinal products.

For reconstitution and dilution, only 0.9% Sodium Chloride Injection, USP, should be used since the stability of the reconstituted product has not been determined with other infusion-based solutions.

6.3 Shelf life

Shelf life of unopened vials

3 years for TRODELVY infusion solution.

Shelf life of reconstituted solution

The reconstituted solution should be used immediately to prepare a diluted TRODELVY infusion solution.

Shelf life of diluted infusion solution

The diluted solution in the infusion bag should be used immediately. If not used immediately, the infusion bag containing TRODELVY solution can be stored refrigerated (2°C to 8°C) for up to 24 hours. After refrigeration, administer diluted solution at room temperature up to 25°C within 8 hours (including infusion time). Protect from light and do not freeze.

6.4 Special precautions for storage

Store at 2°C to 8°C (Refrigerate. Do not freeze). Store in carton to protect from light.

6.5 Nature and contents of container

TRODELVY is supplied in single-use clear glass vials, with a rubber stopper and crimp-sealed with an aluminium flip-off cap, in a pack size of 1 vial.

6.6 Special precautions for disposal and other handling

Reconstitution

- Calculate the required dose (mg) of TRODELVY based on the patient's body weight at the beginning of each treatment cycle (or more frequently if the patient's body weight changed by more than 10% since the previous administration) (see Section 4.2 *Dose and method of administration*).
- Allow the required number of vials to warm to room temperature.
- Using a sterile syringe, slowly inject 20 mL of 0.9% Sodium Chloride Injection, USP, into each 180 mg TRODELVY vial. The resulting concentration will be 10 mg/mL.
- Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discoloured.
- Use immediately to prepare a diluted TRODELVY infusion solution.

Dilution

- Calculate the required volume of the reconstituted TRODELVY solution needed to obtain the appropriate dose according to patient's body weight. Withdraw this amount from the vial(s) using a syringe. Discard any unused portion remaining in the vial(s).
- Adjust the volume in the infusion bag as needed with 0.9% Sodium Chloride Injection, USP, to obtain a concentration of 1.1 mg/mL to 3.4 mg/mL.
- Slowly inject the required volume of reconstituted TRODELVY solution into a polyvinyl chloride, polyolefin (polypropylene and/or polyethylene) or ethylene vinyl acetate infusion bag to minimise foaming. Do not shake the contents.

TRODELVY is a cytotoxic drug. Follow applicable special handling and disposal procedures.

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Gilead Sciences (NZ)
Tompkins Wake
Level 17, 88 Shortland Street
Auckland Central, Auckland 1010
New Zealand

Tel: 0800 443 933

9. DATE OF FIRST APPROVAL

24 July 2025

10. DATE OF REVISION OF THE TEXT

20 November 2025

SUMMARY TABLE OF CHANGES

Sections Changed	Summary of new information
4.2, 4.4	Updated with prophylaxis mitigation language (s4.2). Section updated with G-CSF primary prophylaxis mitigation language to align with changes in Section 4.2 (s4.4)