



Company overview

November 2024



QBiotics Group

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QBiotics Group: mission & overview

Harnessing the power of nature to improve lives



Australian public unlisted life sciences company

Two assets in human clinical development:

1. Tigilanol tiglate (TT) in Phase II development for multiple solid tumours
Soft tissue sarcoma (FDA Orphan Drug Designation)
Head & neck cancer
2. EBC-1013 in Phase I development for wound healing



Tigilanol tiglate (veterinary formulation): STELFONTA[®] commercially approved to treat canine mast cell tumours

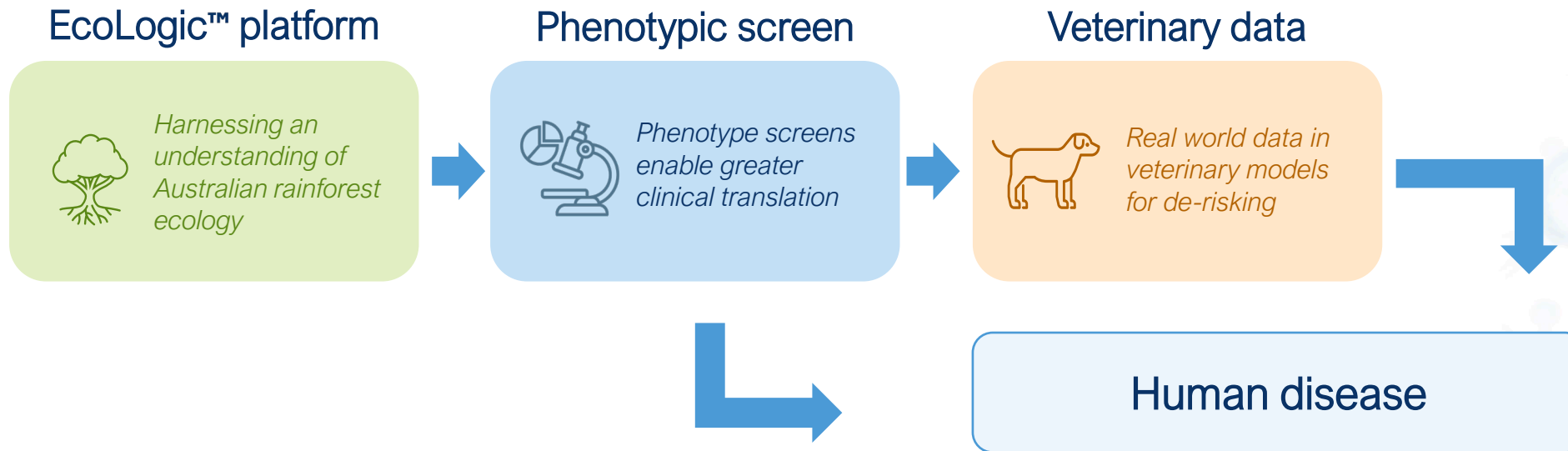


Discovery programmes in antibiotics and anti-inflammatories



Three key pillars drive scientific discovery from nature & development of novel drug candidates

~45% of all marketed pharmaceuticals are based on small molecules discovered from nature



Nature has remarkable chemical diversity unmatched by synthetic chemistry

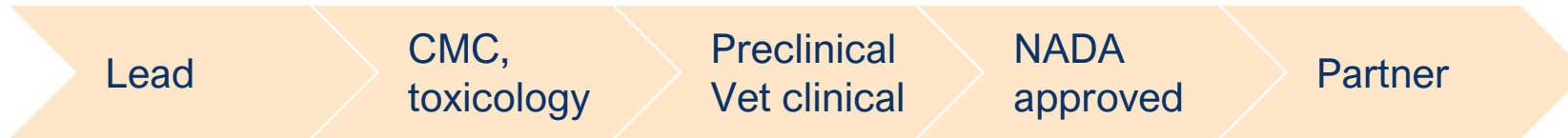
Mainstream discovery programmes rely on limited number of validated disease targets

Our platform provides greater opportunity for discovery of novel molecular structures and new modes of action

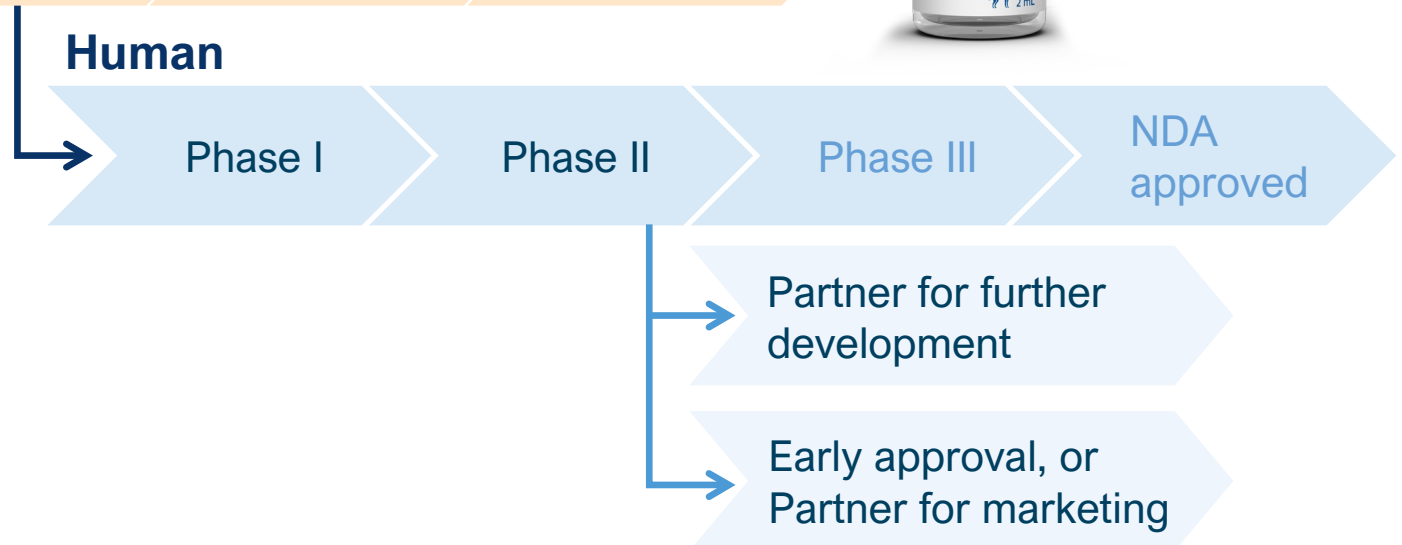
QBiotics' innovative approach to business

Veterinary to human validation- derisks our human programmes

Veterinary



Human



‘Real world’ veterinary data informs & de-risks human clinical development, >20,000 dogs treated globally

Efficacy, safety, dosing and administration can be tested across a range of species

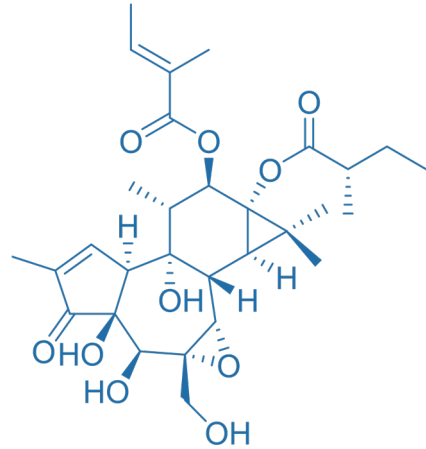
Robust clinical pipeline in human disease, supported by validation in veterinary programmes

Human disease programmes									
Drug candidate	Therapeutic area	Indication	Discovery	Preclinical	Phase I	Phase II	Phase IIb/III	Approval	Programme updates
Tigilinol tiglate	Oncology	Soft tissue sarcoma (STS)					FDA: Orphan Drug Designation granted		QB46C-H07: Phase IIa Preliminary data: ESMO & CTOS 2024 Full results in Q1 CY2025
		Head & neck cancers (H&NC)							QB46C-H08: Phase IIa Recruiting
EBC-1013	Wound healing	Venous leg ulcers							QB1013C-H201- Phase I Recruiting
Several leads	Novel antibiotics								Lead optimization
	Anti-inflammatory								Lead optimization

Veterinary programmes							
Drug/ drug candidate	Therapeutic area	Indication	Clinical			Approval	Programme updates
STELFONTA®	Oncology	Canine: mast cell tumours					Marketed EU, USA, UK, AU
Tigilinol tiglate		Canine: soft tissue sarcoma, oral melanoma					Recruiting
		Equine: sarcoid, melanoma					Sarcoids reporting, melanoma recruiting
EBC-1013	Wound healing	Equine & canine: acute & chronic wounds					Recruiting

Tigilanol tiglate in oncology

Tigilanol tiglate: a novel epoxytigliane with potential to treat a wide range of solid tumours



Molecular structure



Mode of action (MoA)

- Unique & multifactorial:
 - Rapid tumour destruction
 - Vascular disruption
 - Immunogenic cell death
 - Anti-tumour immunity



Efficacy & safety

- Tumour responses observed in Phase I studies across 9 tumour types
- Promising CR/PR tumour responses in Phase II STS
- Minimal scarring
- Well-tolerated safety profile



Regulatory & commercial

- FDA has granted Orphan Drug Designation in STS
- Commercial supply established
 - ✓ low COGs
 - ✓ high stability
- Approved product for canine mast cell tumours: STELFONTA®



Significant market opportunity

- Potential across multiple solid tumours, including internally & externally located tumours
- Potential for use in combination with a range of existing therapies:
 - Checkpoint inhibitors
 - Conventional chemotherapies
 - Surgery
 - Radiation therapy
- Solid tumours represent a large unmet need

Tigilanol tiglate: Mode of action

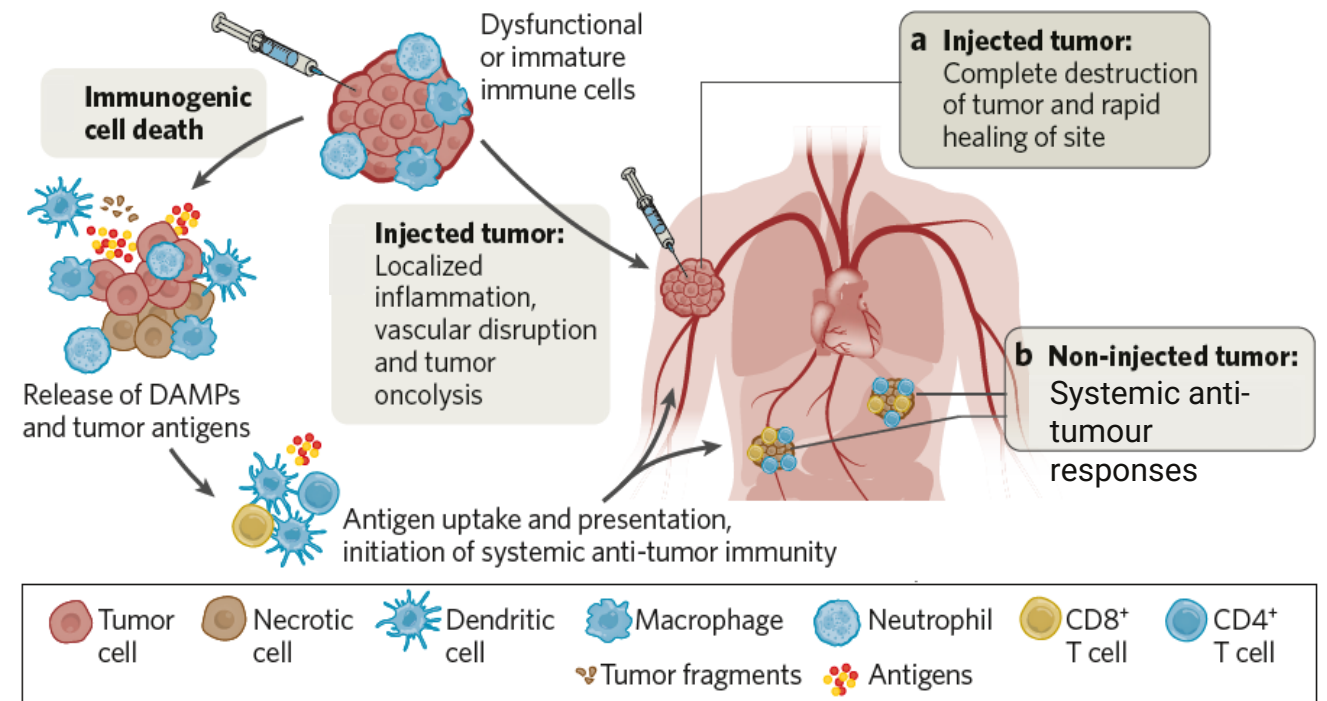


Tigilanol tiglate's multifactorial mode of action provides strong differentiation



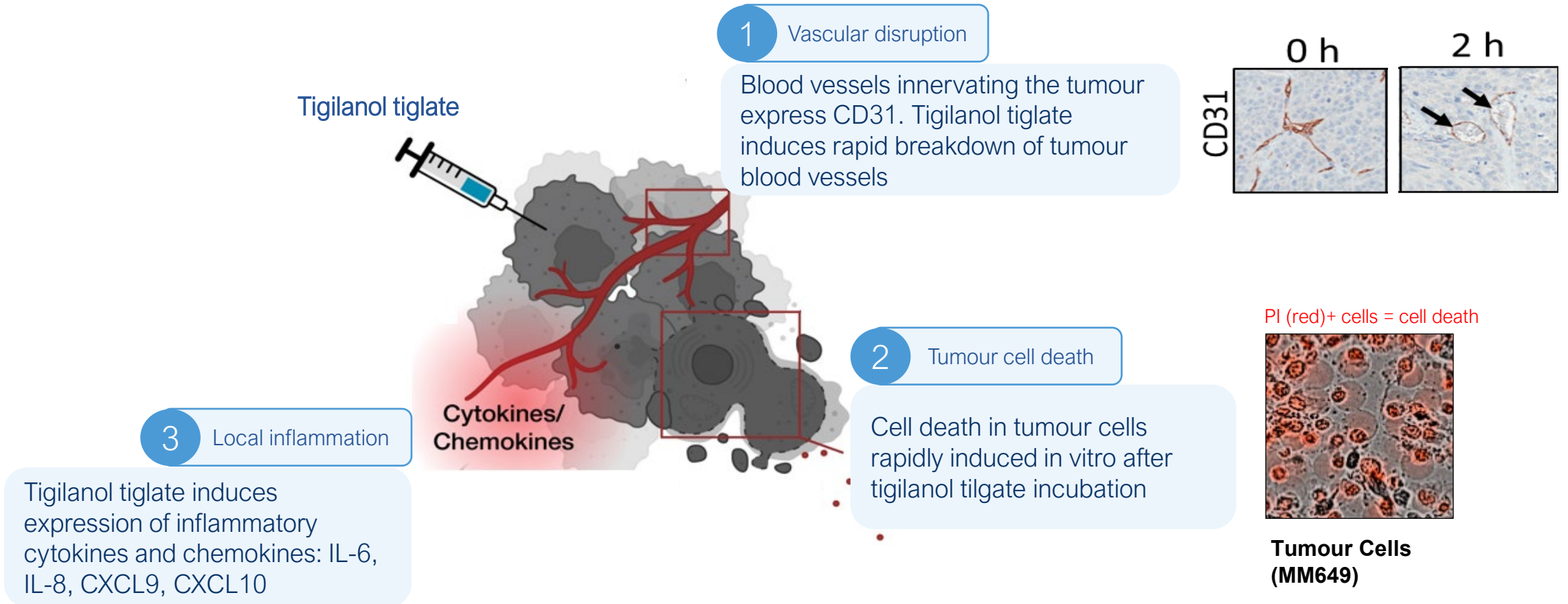
Tigilanol tiglate is a Protein Kinase C activator, but can also affect other targets¹

- A. Local response: Tigilanol tiglate induces rapid tumour destruction by vascular disruption, tumour cell oncolysis and inflammation within 5-7 days, followed by rapid healing of site.
- B. Systemic response: Tumour cell death induces immunogenic cell death and systemic anti-tumour immunity.

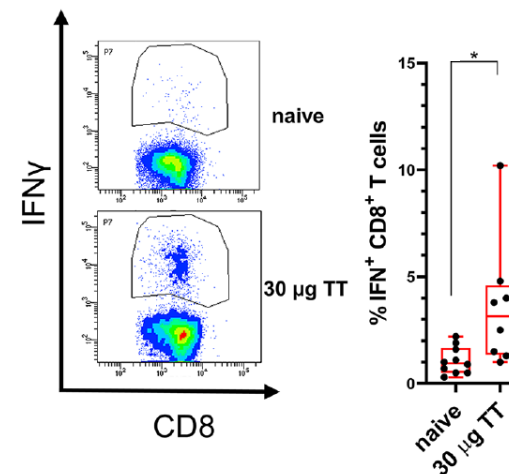
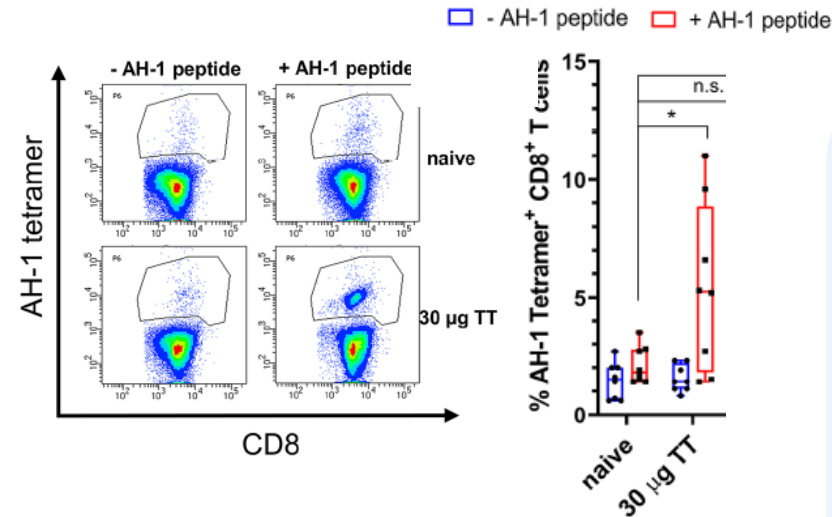
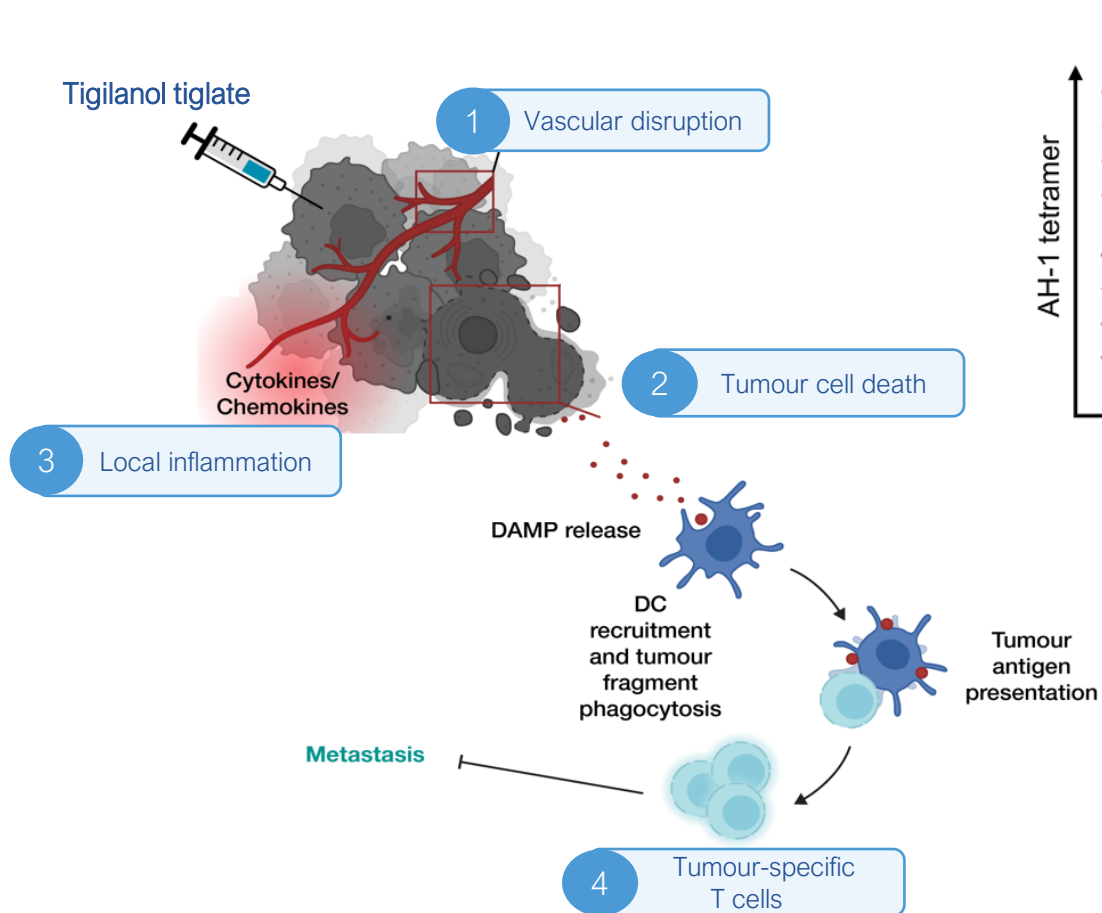


¹ Other targets of TT under investigation, Boyle *et al.* 2014. *PLoS One.* 9(10):e108887; Cullen *et al.* 2021. *Scientific Reports* 11(1):1-4

Injected tumour responses: tumour cell death, tumour vasculature disruption & inflammation



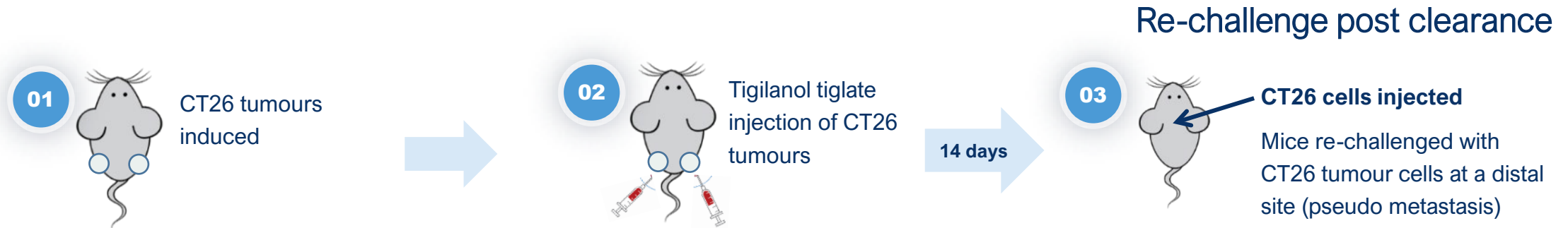
CD8⁺ T cells play a role in tigilanol tiglate induced anti-tumour responses in vivo



Tigilanol tiglate induces tumour-specific CD8⁺ T cells

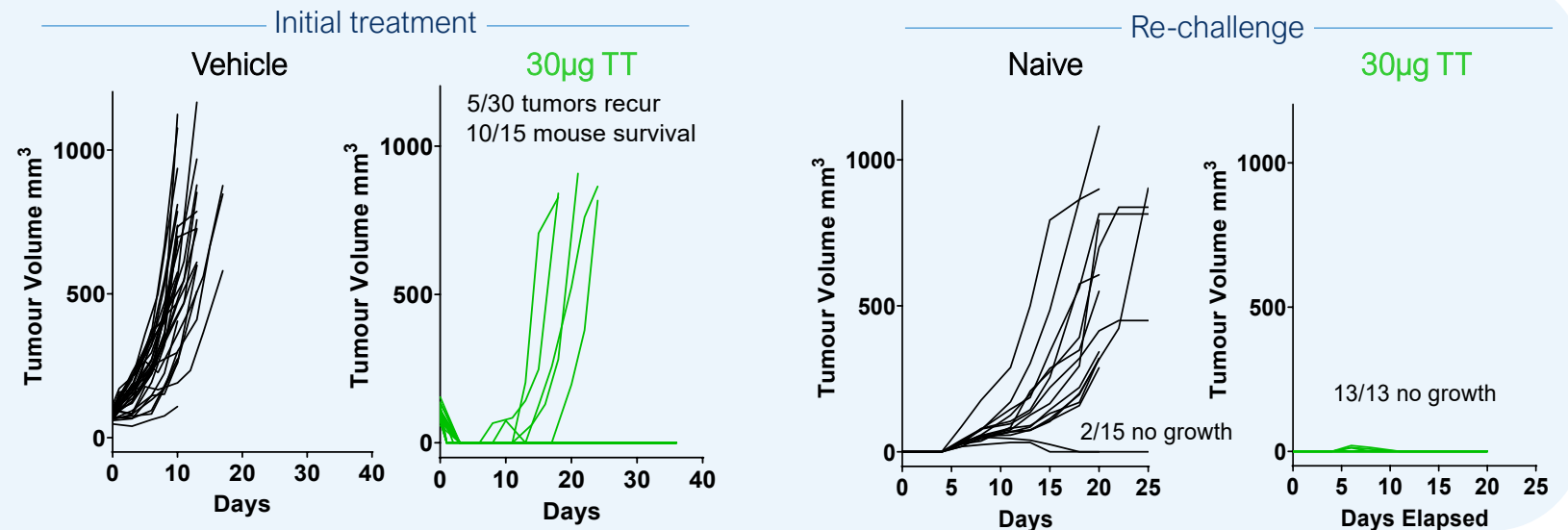
Tigilanol tiglate induces functional CD8⁺ T cell responses in re-challenged mice

Tigilanol tiglate induced anti-tumour T cells protect against distal and recurrent tumour growth



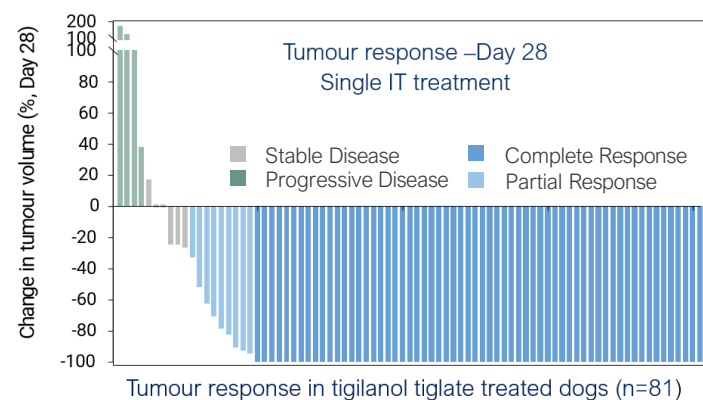
Induction of T cell responses is required for protection against distal tumour growth and recurrence

Tigilanol tiglate protects against distal tumour growth



STELFONTA[®] (tigilanol tiglate): monotherapy validation in veterinary setting

Significant datasets in canine mast cell tumour (MCT) with impressive efficacy



- 75% CR with a single IT treatment ($p < 0.0001$ vs sham control)¹
- Objective tumour response rate (CR/PR) of 80%
- 87% CR with second treatment for partial responders
- No tumour recurrence in 93% of evaluable cases at 84 days and 89% at 12 months.

Successfully commercialised across key markets



Pretreatment



Day 1: Tumour haemorrhagic necrosis



Day 7: Complete Response



Day 28: Site healed

Approved as a first-line, alternative to surgery, veterinary pharmaceutical treatment for canine MCT.

- >20,000 dogs treated to date
- Global supply chain, marketing and distribution network with partner Virbac
- Regulatory, CMC and commercial validation

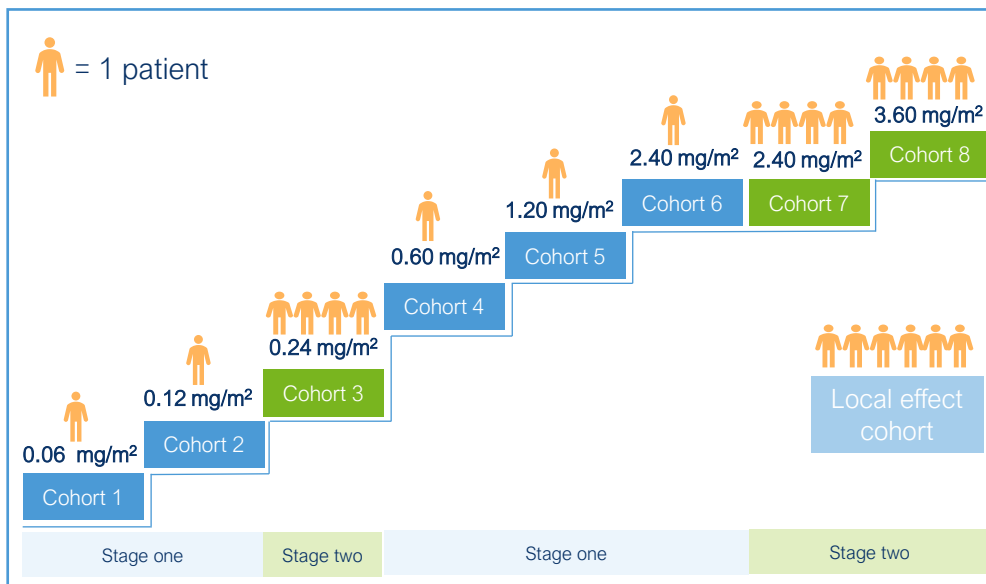
¹ QBiotech Study Report PN1894. RECIST v1.1 applied to injected tumour. Published by De Ridder T. et al (2020). 2 Jones et al., 2021
CMC: chemistry, manufacturing and controls, CR: complete response, IT: intratumoural, PR: partial response

Tigilanol tiglate: Human clinical studies



Phase I trial enrolled patients across 9 tumour types in escalating dose study

Adult, ECOG : 0-2, life expectancy >12 weeks, measurable disease

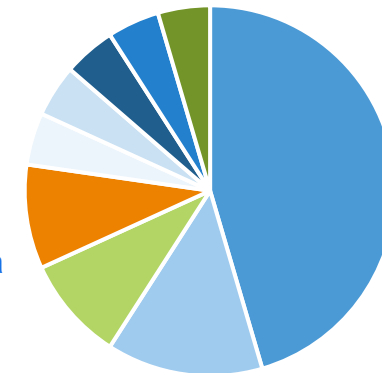


Primary endpoint: establish safety, tolerability and maximum tolerated dose (MTD)

Secondary endpoints: Preliminary efficacy and pharmacokinetics

Characteristics of 22 patients: range of cutaneous, subcutaneous and nodal tumours

- SCC
- Melanoma
- BCC
- AC Breast
- AF
- AC Colorectal
- Angiosarcoma
- ACC
- AMF



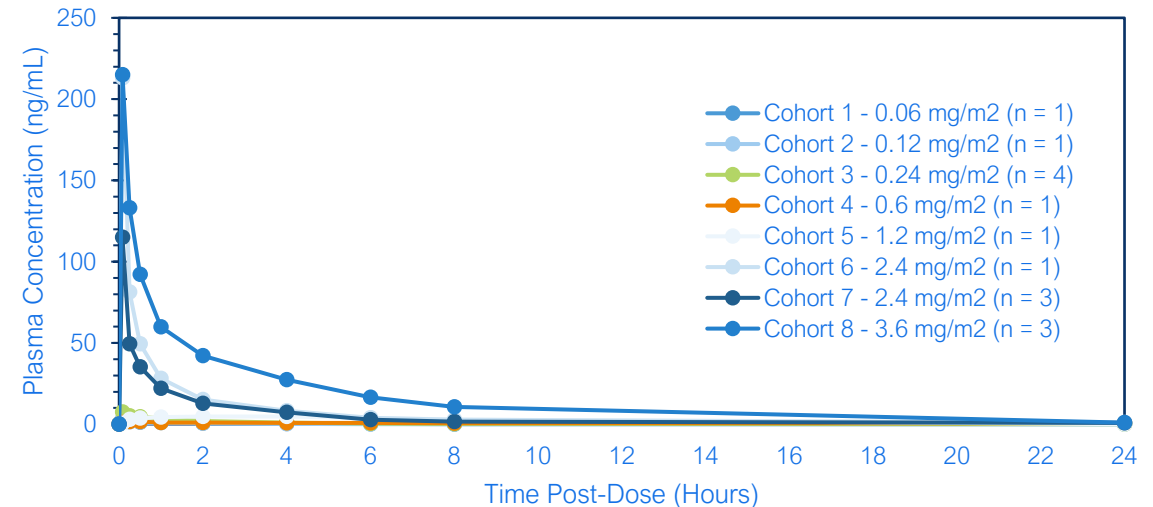
Stage of tumour	# (%) of patients
Stage I	2 (9%)
Stage II	5 (23%)
Stage III	4 (18%)
Stage IV	7 (32%)
Unknown	4 (18%)

Well-tolerated safety profile, intratumoural injection limits systemic exposure

96% of adverse events (AE's) were mild to moderate

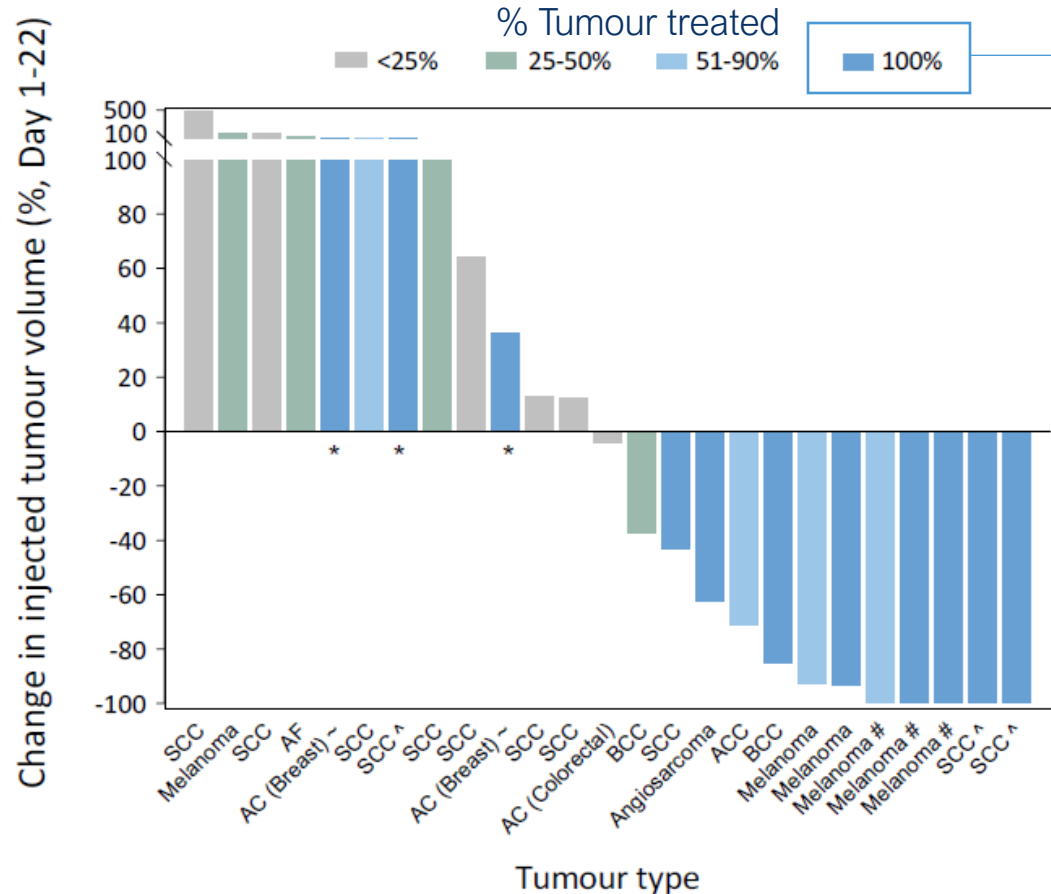
- Total AEs were generally mild (Grade 1 and 2), related to the local action of tigilanol tiglate (e.g., local pain, swelling, necrosis, oedema)
- No deaths. No Grade 5 AEs
- Most common TEAEs were injection site pain and injection site reactions (n=74). Grade 2 in five patients, Grade 3 in two patients

Pharmacokinetics: tigilanol tiglate has minimal systemic exposure and rapid clearance



- Plasma concentrations rapidly decline within 2-4 hrs post injection
- C_{max} 237ng/ml- 8.16mg received: dose dependent and dose proportional
- T_{max} 15 minutes- negligible at 24 hrs
- MTD not declared at max dose of 3.6mg/m²

Strong monotherapy results from single injection of tigilanol tiglate across different tumour types



Tumour responses in all 9 tumour types
20 of 22 patients had tumour responses: 4 CR, 3PR, 13 SD

Table represents tumour responses from 6 patients

Response at full treatment rate (100% tumour treated)	%
Complete tumour response (CR)	50%
Local tumour control (CR/PR/SD)	100%

Patient Dose: tigilanol tiglate dose escalation based on body surface area

Tumour dose: 0.5 mg tigilanol tiglate/ 0.5 cm³ of tumour volume

Responses in metastatic melanoma including abscopal responses in distal tumours

Case study 2: Metastatic melanoma



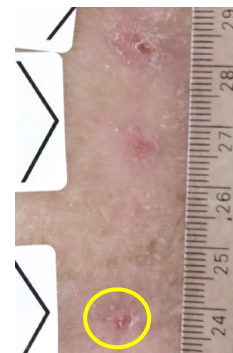
Pre-treatment



Day 1: 30 mins:
tumour necrosis



Day 8: Non-injected,
4th tumour regresses



Day 35: CR in the non-
injected tumour

Single IT injection

- Into top 3 tumours - 4th tumour (circled) not treated
- Abscopal response in lung & sternum tumours reported

Case study 3: Metastatic melanoma – failed multiple surgeries



Pre-treatment



Day 2: Tumour necrosis



Day 29: Complete
response



24 months: Patient
tumour free

Single IT injection into 2 tumours in axilla

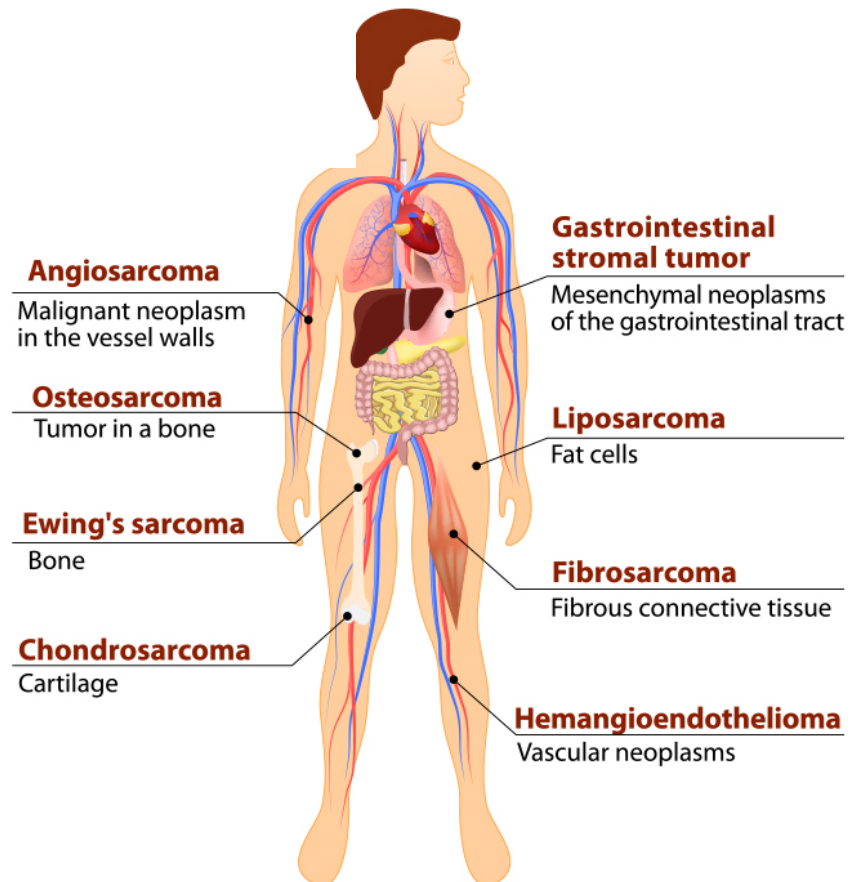
Abscopal response in:

- Nodal deposit and leg melanoma - both cleared
- Patient clinically and ultrasound clear at 33 months post-treatment

Tigilanol tiglate development in Soft Tissue Sarcomas (STS)

STS is a heterogenous cancer with high unmet need

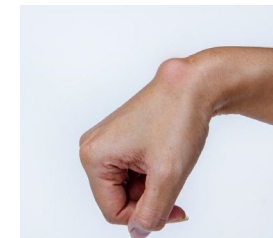
80-100 Histologically diverse subtypes



~124,573 new cases annually across 16 major markets¹



Incidence is increasing at 0.5% per year



~75% of STS cases: in the extremities such as arms and legs

Trunk wall and retroperitoneum account for 10% cases

Patient segmentation at diagnosis:

70% patients have localised/ resectable disease

- Out of these, 75% of resected progress to advanced/ unresectable disease

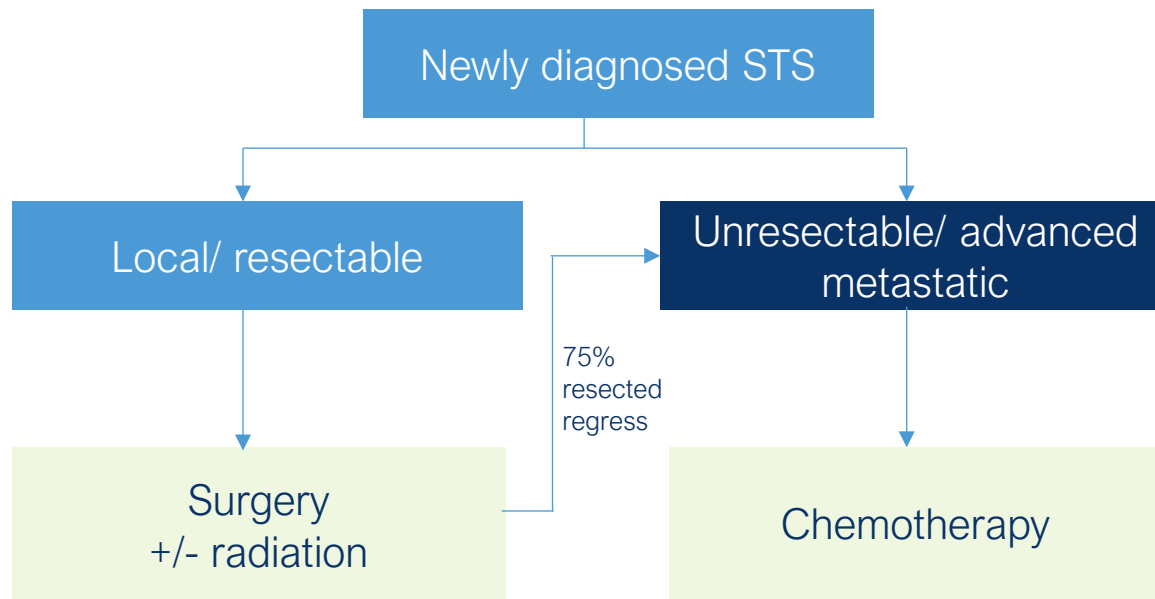
30% are initially diagnosed with unresectable, advanced metastatic disease

¹ Global Data 2022

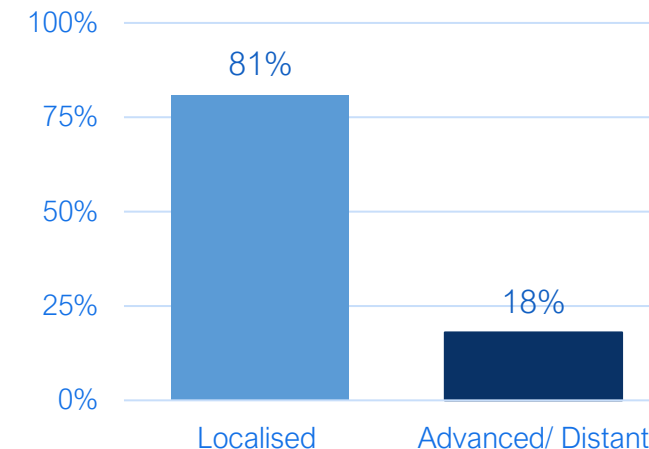
Image references: Surgical associates of North Texas, RT answers, Mayo clinic

Advanced STS cancers have few treatment options

Due to diversity of subtype, STS is a tough disease to diagnose and treat



5-year survival for STS stages¹



Chemotherapy: only few drugs approved, all with low response rates, low duration of response and severe side effects²

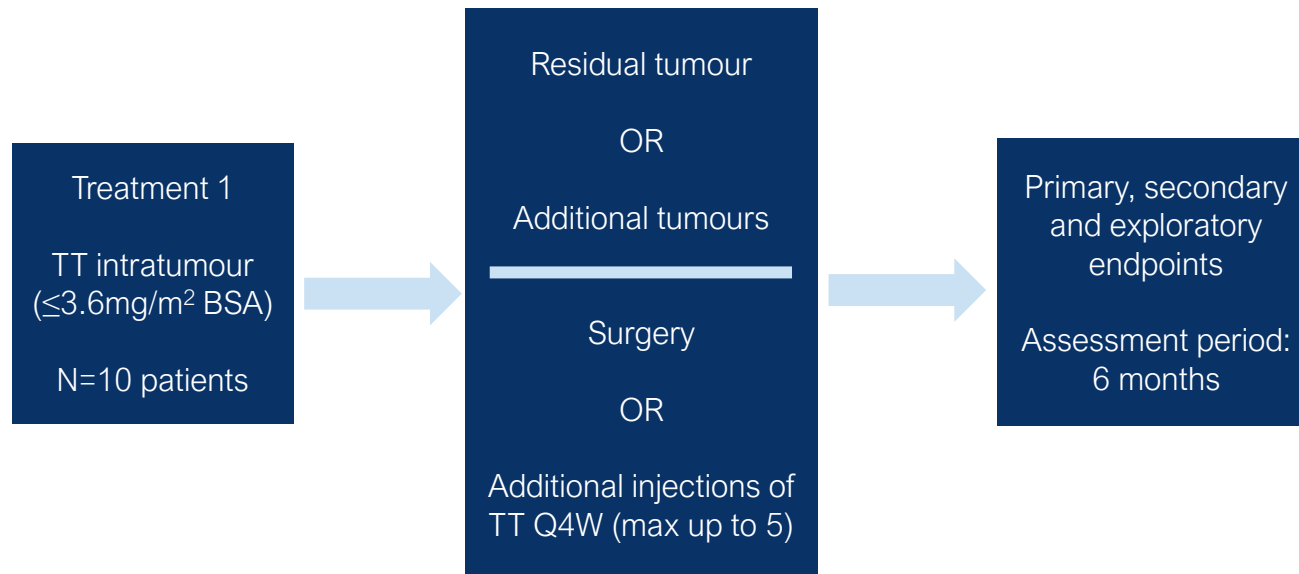
¹ SEER .cancer.gov/statfacts, ² Kasper, 2019. Challenge in finding new therapeutic avenues in soft tissue sarcoma. Clin Sarcoma Res
STS: soft tissue sarcoma

Phase IIa trial in human STS completed recruitment

Single center, single arm, open label, Phase II study assessing preliminary efficacy of tigilanol tiglate in STS patients conducted at Memorial Sloan Kettering Cancer Centre

- Adults with advanced and/or metastatic STS with tumours accessible for injection with ECOG PS ≤ 2
- Lesion(s) volume measured by ultrasound (+CT or MRI)

QB46C-H07, NCT05755113



Primary endpoint

- Tumour ablation rate at 28 days

Secondary endpoints

- AE's and SAE's- safety and tolerability
- PK

Exploratory endpoints

- Immune infiltration in surgical / biopsy specimens
- PBMCs
- Local recurrence rate (up to 6 months)

Early data from trial supports strong safety profile in patients across different sarcoma types

Baseline demographics and disease characteristics:

Characteristic	Patients ¹ N=11
Sarcoma histologic type	
Leiomyosarcoma	4
Myxofibrosarcoma/ UPS	3
Myxoinflammatory fibroblastic sarcoma	1
Extraskeletal Osteosarcoma	1
Angiosarcoma	1
Sarcoma NOS	1
Clinical disease status	
Recurrent/ locally advanced	6
Distant metastases	5
Prior resections, median (range)	3 (0-9)
Prior radiation	8
Prior lines of systemic therapy, median (range)	3 (0-5)

Common adverse events: most patients with Grade 1-2 mild AEs

Adverse events (AEs)	N=11	
Grade ≥ 3 AEs	1	
AEs leading to discontinuation	0	
AEs in ≥ 2 patients	Grade 1-2	Grade 3
Injection site wound	8	0
Pain at injection site	8	0
Injection site infection	3	1
Odor at injection site	4	0
Drainage at injection site	2	0
Flushing	4	0
Fever	3	0
Bleeding	2	0

Intratumoural TT appears safe for patients with STS

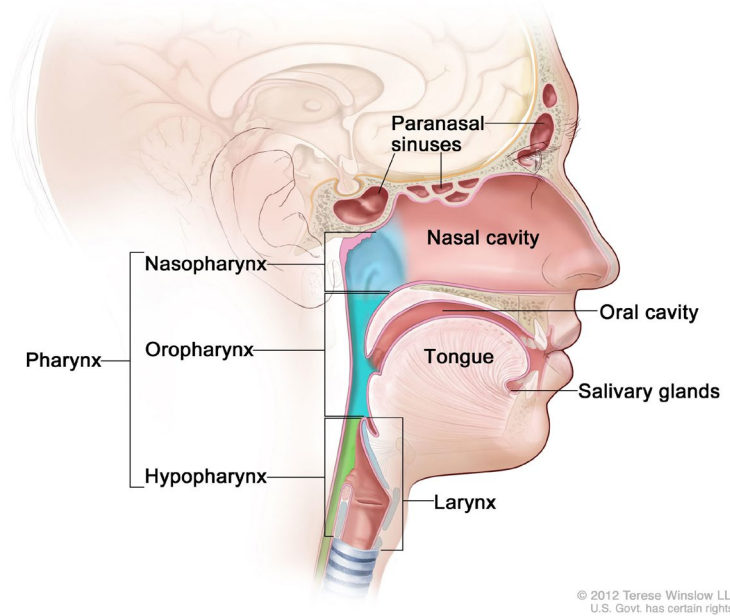
¹ 11 patients were enrolled, one was lost to follow up and was replaced

Trial ID: QB46C-H07, NCT05755113, Bartlett et al, ESMO 2024 1736P, Preliminary data presented at ESMO 2024 by principal investigator from Memorial Sloan Kettering Cancer Centre, subject to final analysis

UPS: undifferentiated pleomorphic sarcoma, NOS: not otherwise specified

Tigilanol tiglate development in Head & Neck Squamous Cell Carcinoma (HNSCC)

HNSCC is a common cancer where overall survival is a high unmet need



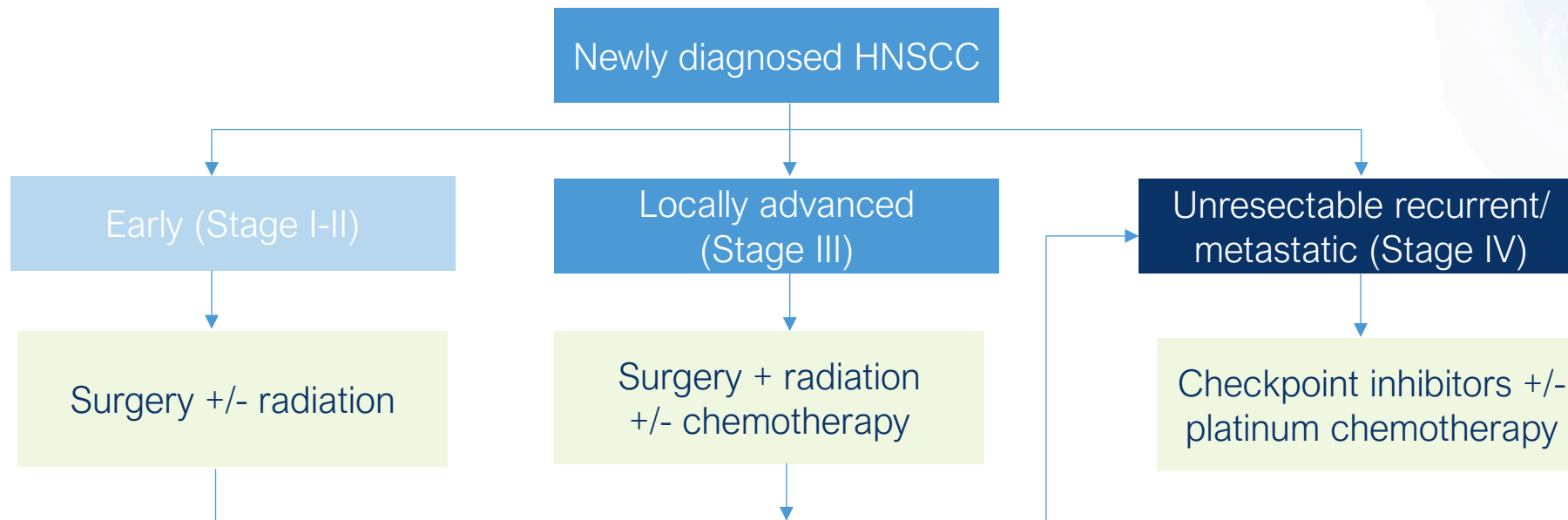
- Head and neck cancer is the 7th most common cancer
- ~ **932,000** new cases globally in 2020¹
- Extending overall survival remains a major unmet need

Opportunity

- HNSCC market ~\$US2.1B in 2020²
- CAGR of 9.8%
- Sales of \$5.2 B by 2030
- No intratumoural product is approved
- Opportunity to preserve organ function & improve cosmetic outcomes
- Combination with Standard of Care

1. Globocan 2020. 2. Global Data. 8MM includes US, 5EU (France, Germany, Italy, Spain, and the UK), Japan, and urban China
CAGR: Compounded Annual Growth Rate, Image reference: National Cancer Institute

Advanced and refractory/ metastatic HNSCC patients have few treatment options



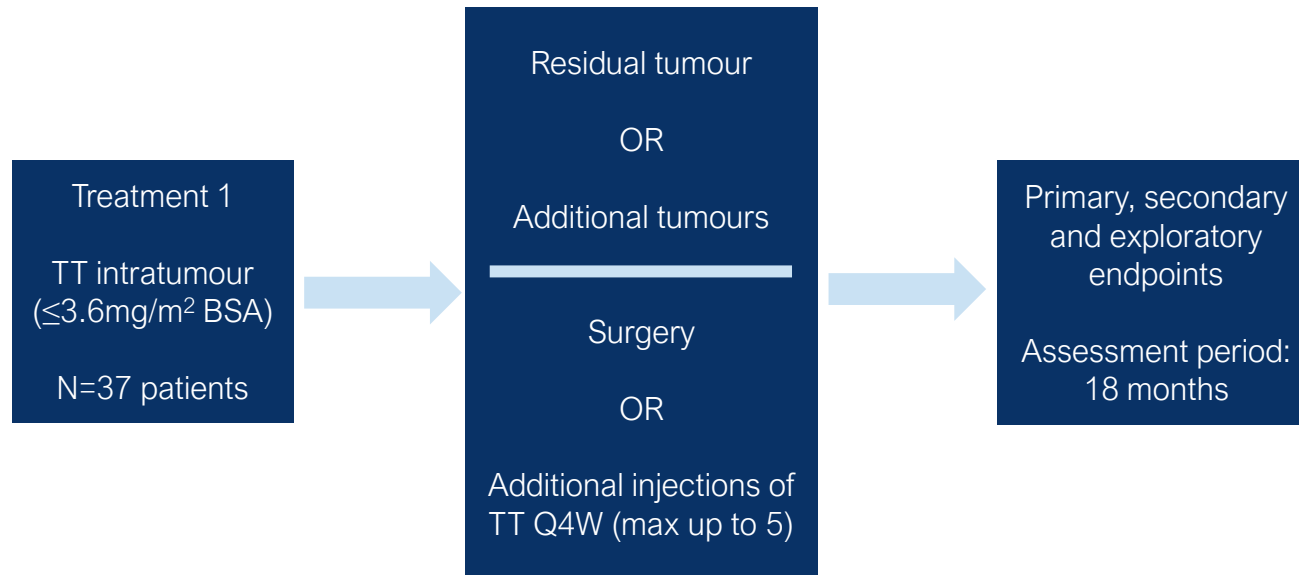
- Standard of care is surgery and chemoradiation
- Surgery is complex due to the need to preserve vital organ function
- Competitive landscape: most agents in early-stage development focused on cell signalling targeted therapies, cancer vaccines and other immuno-oncology mechanisms

Phase II open label study: recruitment underway

Multi center, single arm, open label, Phase II study assessing efficacy of tigilanol tiglate in various head and neck cancer malignancies

- Adults with advanced and/or metastatic head and neck cancer
- Lesion(s) volume measured by ultrasound (+CT or MRI)

QB46C-H08, NCT05608876



Primary endpoint

- Tumour ablation rate

Secondary endpoint

- AE's and SAE's- safety and tolerability
- Local recurrence rate
- Progression free survival (RECIST v1.1)

Exploratory

- General cancer QoL
- Head and neck QoL
- Wound healing
- ORR (RECIST v1.1 and itRECIST)
- Immune infiltration in surgical/ biopsy specimens
- PBMC's

A close-up photograph of a person's hand adjusting a microscope. The microscope is focused on a petri dish containing a blue agar culture. The background is a soft-focus laboratory setting. A large white circle is overlaid on the left side of the image, containing the title text.

EBC-1013 in wound healing

EBC-1013: Multi-faceted mode of action in wound healing



Cell signalling with multifactorial MoA affecting different stages of the wound healing process



Low competition (Pharmaceutical, not a device)



Potentially suitable for treating a wide range of chronic and acute traumatic wounds, including burns



Initial proof of concept of topical gel formulation from exploratory veterinary clinical case studies of difficult to treat wounds



First-In-Human Phase I safety trial currently recruiting in patients with venous leg ulcers

EBC-1013 for chronic and acute wounds and burns

6.5 million

US chronic wounds p.a.¹

14-29 million

globally p.a.²



Driven by ageing and increasing incidence of diabetes and obesity



Current treatments - advanced wound dressings and medical devices, only one wound healing pharmaceutical product Regranex (Becaplermin) approved in US



Significant unmet need: 10% of chronic wounds do not heal



Large failure rate; objective clinical endpoint = complete wound closure at 84 days

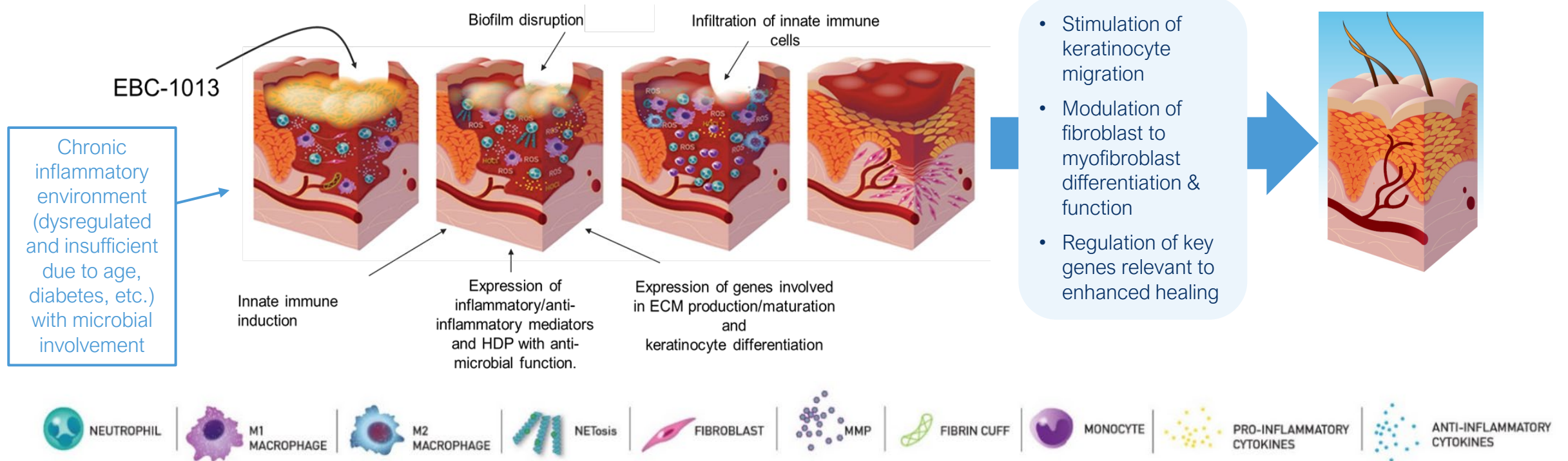
1. Hurlow et al, Defying the Recalcitrant Wound, Woundsource.com, Sponsored by ConvaTec.

2. Nussbaum et al, An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 2018 Jan;21(1):27-32.

EBC-1013 gel application has a multi-faceted mode of action in wound healing

Inflammatory and antimicrobial response

Wound resolution



Reason to believe: veterinary case studies of treatment with EBC-1013 gel show clear efficacy

Chronic non-healing wound of 5 months in greyhound resolved in 1 month with single EBC-1013 application

Post wound formation



Day 5

Day 154

Post single application of EBC-1013 gel (0.3 mg/ml)



Day 0

Day 3

Day 7

Day 14

Day 28

Day 35

Equine traumatic penetrating wound (1 gel application)



Day of wounding



Treatment Day
(Infected wound 5 days after trauma)



5 days after treatment

Canine thermal burn (3 treatments, 7 days apart)



Treatment Day 1
(8 days after burn)



Day 14



Day 38

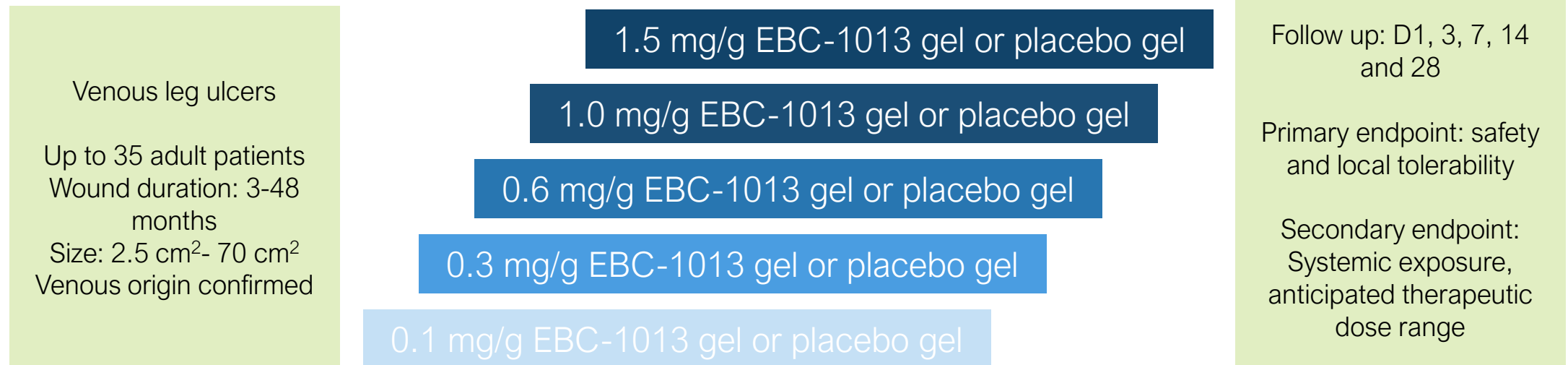


Day 73

Phase I study recruiting patients across escalating doses of EBC-1013

A phase I first-in-human multi-centre dose escalation study to assess the safety and tolerability of EBC-1013 gel in participants with venous leg ulcers.

Single application of EBC-1013 gel or placebo at ascending doses



QBiotics: financial overview and upcoming milestones



\$194M Capital raised to date



\$43.5M Current cash at bank¹



\$60.3M R&D tax incentive refunds and government grants received to date



\$3.9M Average quarterly operating expense²

H2 CY2024

H1 CY2025

H2 CY2025

QB46C-H07: Tigilanol tiglate Phase II in STS: preliminary presentation at ESMO 2024 and CTOS 2024

QB46C-H07: Tigilanol tiglate Phase II in STS: full study results early 2025

QB46C-H08: Tigilanol tiglate Phase II in HNSCC recruiting

QB1013C-H201: EBC-1013 Phase I in VLU recruiting

1. As of 30 June 2024, 2. Average cash burn rate per quarter from 1 July 2023 to 30 June 2024

CTOS: connective tissue oncology society, CY: calendar year, ESMO: European Society of Medical Oncology, HNSCC: head and neck squamous cell carcinoma, VLU: venous leg ulcers