



QBiotech Group

Harnessing the power of nature to improve lives

Company Overview



16 November 2023

Dr Victoria Gordon
CEO & Managing Director



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QBiotics Group Limited (public unlisted)

Discovery and development of cell signalling small molecules

2000

 **EcoBiotics**
Innovation in Biodiscovery

Biodiscovery company

EcoLogic™ discovery platform technology:

Discovery partnerships:



2010

 **QBIOTICS**

Pharmaceutical development company

- Oncology focus
- Human & veterinary

2017

 **QBiotics Group**

EcoBiotics and QBiotics merged to form the QBiotics Group

- Oncology
- Wound healing

2023

 **QBiotics Group**

Where are we today?

- Oncology
 - Human Clinical Phase II
 - Marketed vet drug STELFONTA®
- Wound healing
 - Human Clinical Phase I/IIa
 - Veterinary clinical Phase II
- Anti-inflammatories - preclinical
- Antibiotics - preclinical

QBiotech Overview

As of 30 June 2023 (AUD)



59

No. of employees



\$439M

Market capitalisation
- at last capital raise at
\$0.90 per share (June 2021)



\$194M

Capital raised to date



\$0.70-\$1.00

Unlisted entity –
Grey Market**



\$51.7M

R&D tax incentive
refunds received to date



\$59.1M

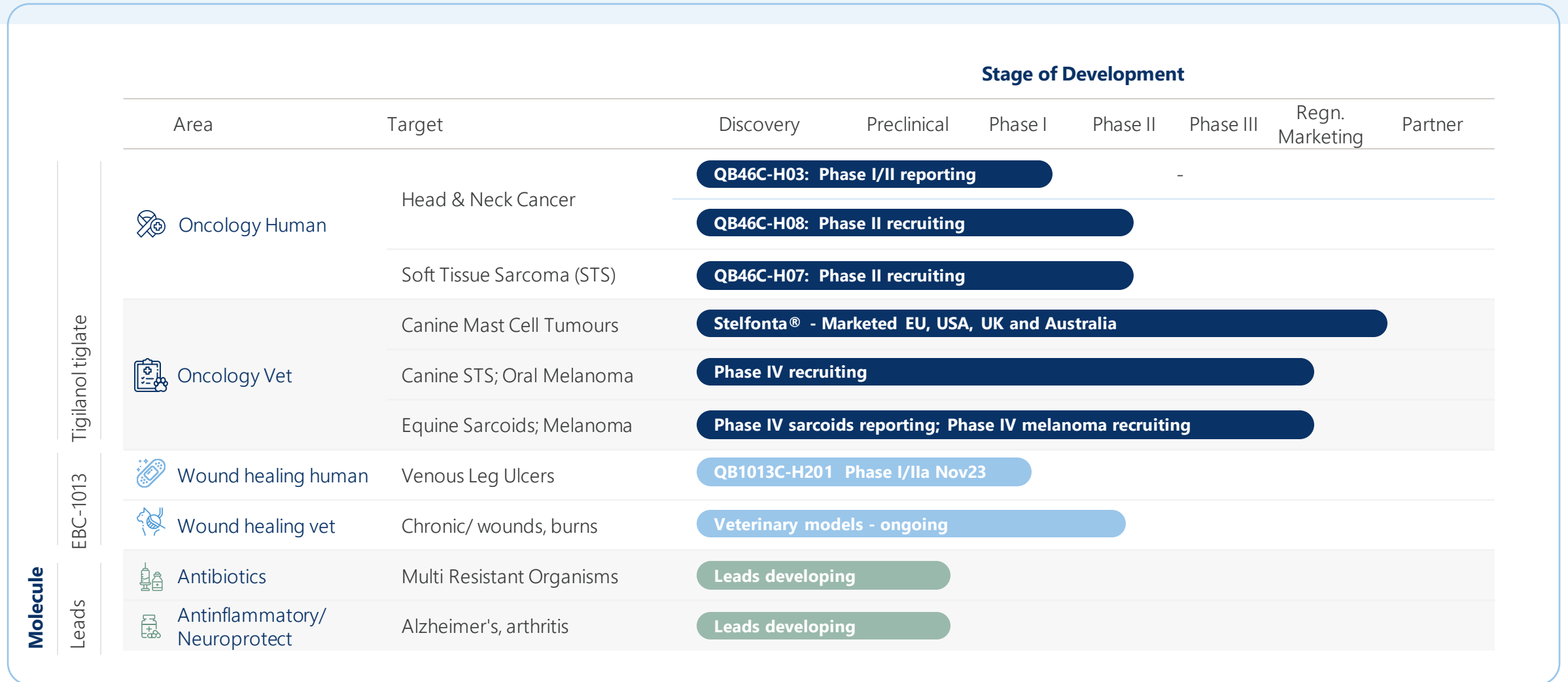
Current cash at bank*



\$5.4M

Quarterly burn rate**

Product pipeline



QBiotech strong patent portfolio

2025 2030 2035 2040 2045

Tigilanol tiglate family

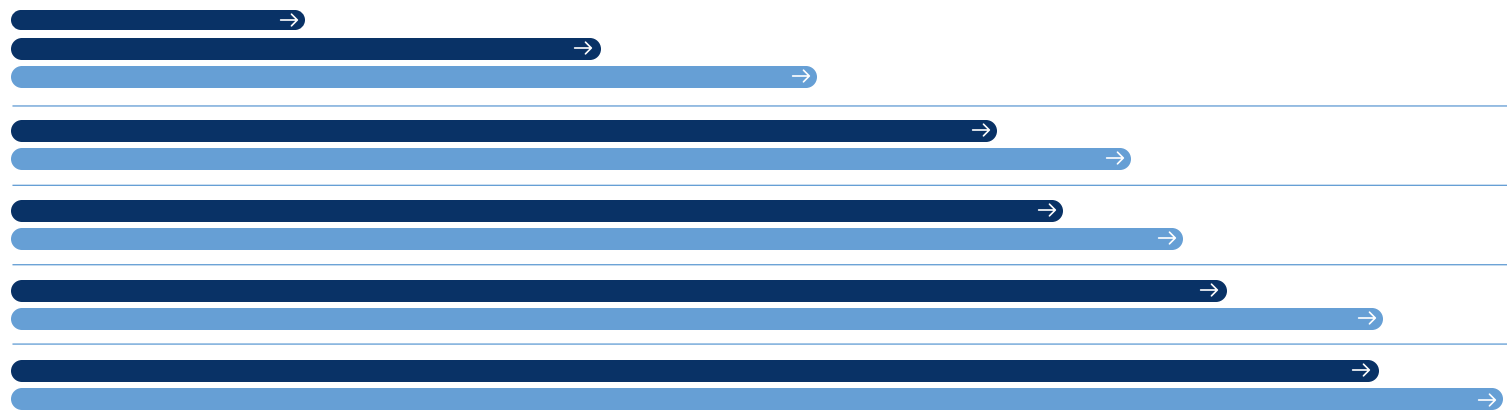
Tiglien-3-one derivatives / P99797
Expiry: 22 Dec 2026-May 2030/Dec 2031

Method of Treatment (MCTs)/ P103717
Expiry: 28 July 2037 (+any PTE/SPC)

Combination Therapy with ICIs / P104575
Expiry: 23 Mar 2038 (+ any PTE/SPC)

Treating Tumours (abscopal effects) P110949
Expiry: 9 April 2040 (+any PTE/SPC)

Combination therapies RT & chemo P118076
Expiry: 17 Feb 2043 (+any PTE/SPC)



Wound healing and antimicrobial

Compositions for Wound Healing /P99795
Expiry: 17 Apr 2034 (+any PTE/SPC)

Biofilm disruption / P111271
Expiry: 19 June 2040 (+any PTE/SPC)



Epoxytigliane manufacturing methods

Crystalline intermediates / P115574.PCT
Expiry: 21 Dec 2042

Crystalline Forms / P119261
Expiry: Dec 2043



Tigilanol Tiglolate Oncology

Tigilanol Tiglate intratumoural anticancer drug

Potential in early and late settings



Effective & well tolerated
Treats wide range of solid tumours

- Tumour agnostic potential



Usually only a single treatment
Rapidly destroys local tumour with good cosmetic outcome
Also systemic (abscopal) effect



Currently in two human clinical Phase II open label trials

1. Soft tissue sarcoma
- FDA Orphan Drug Designation potential
2. Head & neck cancer



Easy to use, low COGs, long shelf life → sound marketing potential



Proven and registered therapeutic in dogs → marketed in major regions

Working with leading KOLs and institutes USA, UK, France and Australia



Memorial Sloan Kettering
Cancer Center

The ROYAL MARSDEN
NHS Foundation Trust



NHS
Guy's and St Thomas'
NHS Foundation Trust

NHS
The Clatterbridge
Cancer Centre
NHS Foundation Trust



HNSCC market & tigilanol tiglate potential

Specific potential for tigilanol tiglate organ preservation & good cosmetic outcome

Incidence and unmet need



- HNSCC 7th most common cancer globally
~ **932,000** new cases in 2020¹
OS a major unmet need
- SOC are surgery and chemoradiation, with EGFR inhibitors (Erbix, Eli Lilly) and CPIs (Keytruda, Merck) in later lines
- Surgery is complex due to need to preserve appearance and vital organs –

Opportunity



- No intratumoural product is approved
- Fewer products in development for HNSCC than other cancers
- Adjunct to systemic treatments
- Significantly larger patient pool in India and Asia, that need simple treatments
- Excellent cosmetic outcome with tigilanol tiglate

Market Size



- **HNSCC market ~\$US2.1B in 2020²**
- CAGR of 9.8% sales of \$5.2 B by 2030²

Market Drivers



- Launch and expansion of premium-priced therapeutics, including CPIs replacing inexpensive chemotherapies
- Increased incidence of HNSCC

STS is a rare, heterogenous cancer

Specific potential for tigilanol tiglate Orphan Drug Designation



STS SOC is surgery, radiation and chemotherapy



Branded Market \$233M in 2022
- US was ~35% (\$83M)

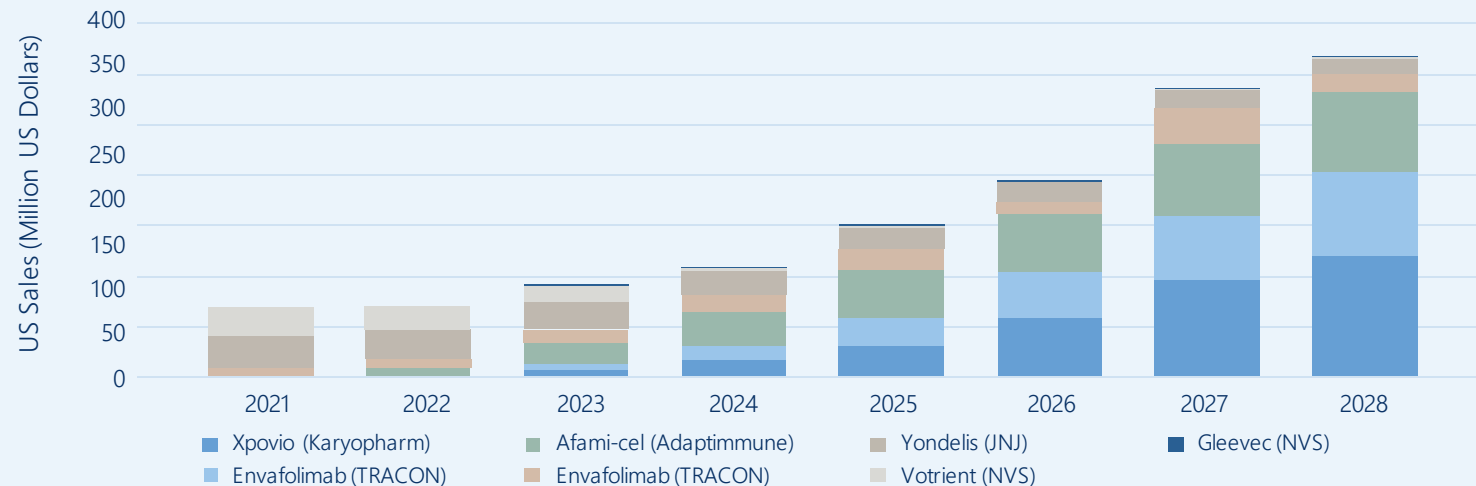


- Global market expected by 2028 to be ~\$596M
- US market expected by 2028 to be ~\$372M

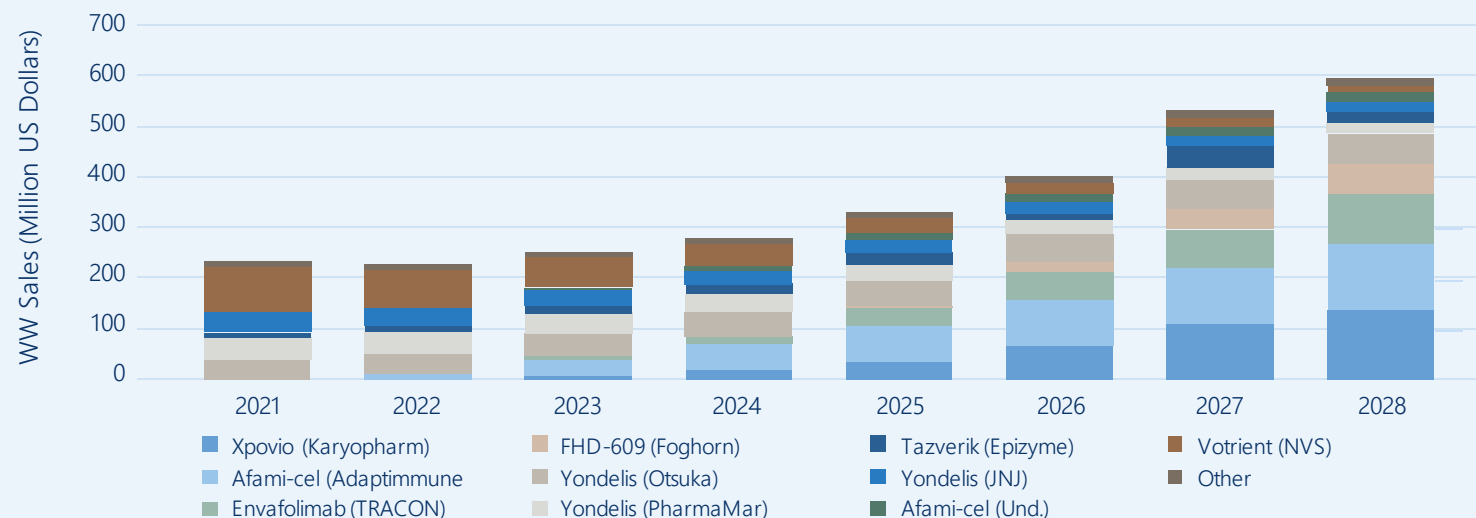


Market driven by subtype specific therapies such as Votrient, and new approvals for targeted agents such as Xpovio, Envafolelimab, and Afami-cel - significant market shares by 2028

US STS Market (2021-2028)



Global STS Market (2021-2028)



Tigilanol tiglate MoA in destruction of injected tumours

Disrupts tumour vasculature

Induces an acute localised inflammatory response

Directly kills tumour cells by oncosis/pyroptosis

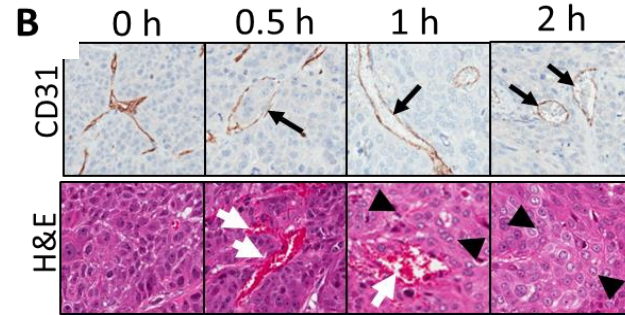
- Release of DAMPs and tumour antigens (ICD)

Induces a tumour specific adaptive immune response

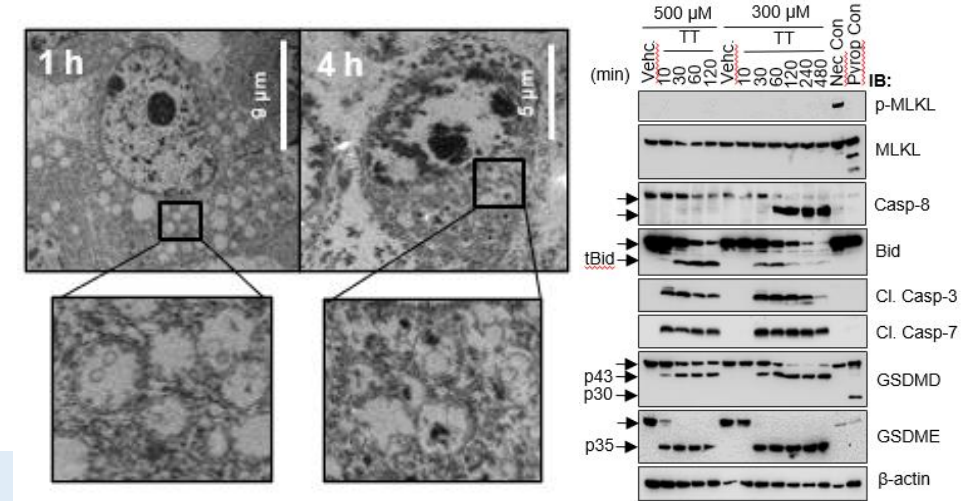
Stimulates healing at the treatment site

- Induces transcriptional changes conducive to wound healing in skin resident cell types

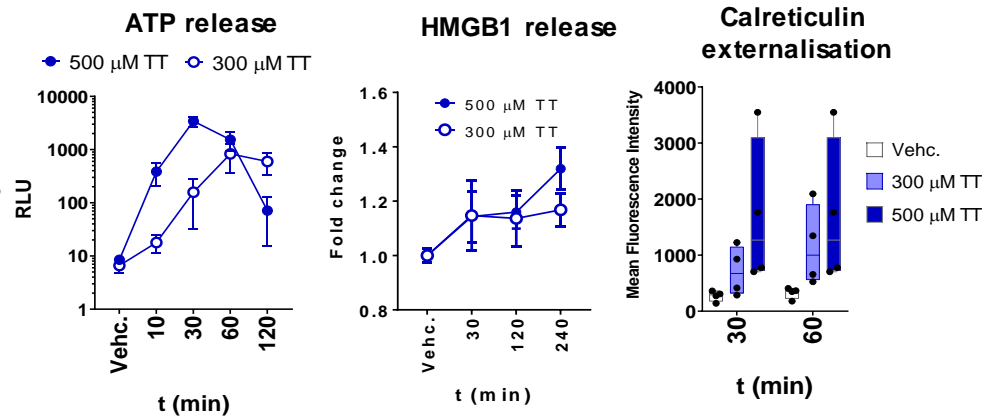
Disruption of tumour vasculature



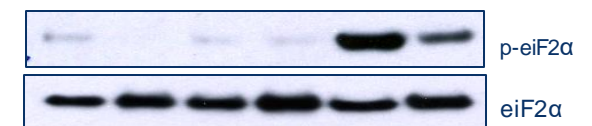
Induction of oncosis/pyroptosis



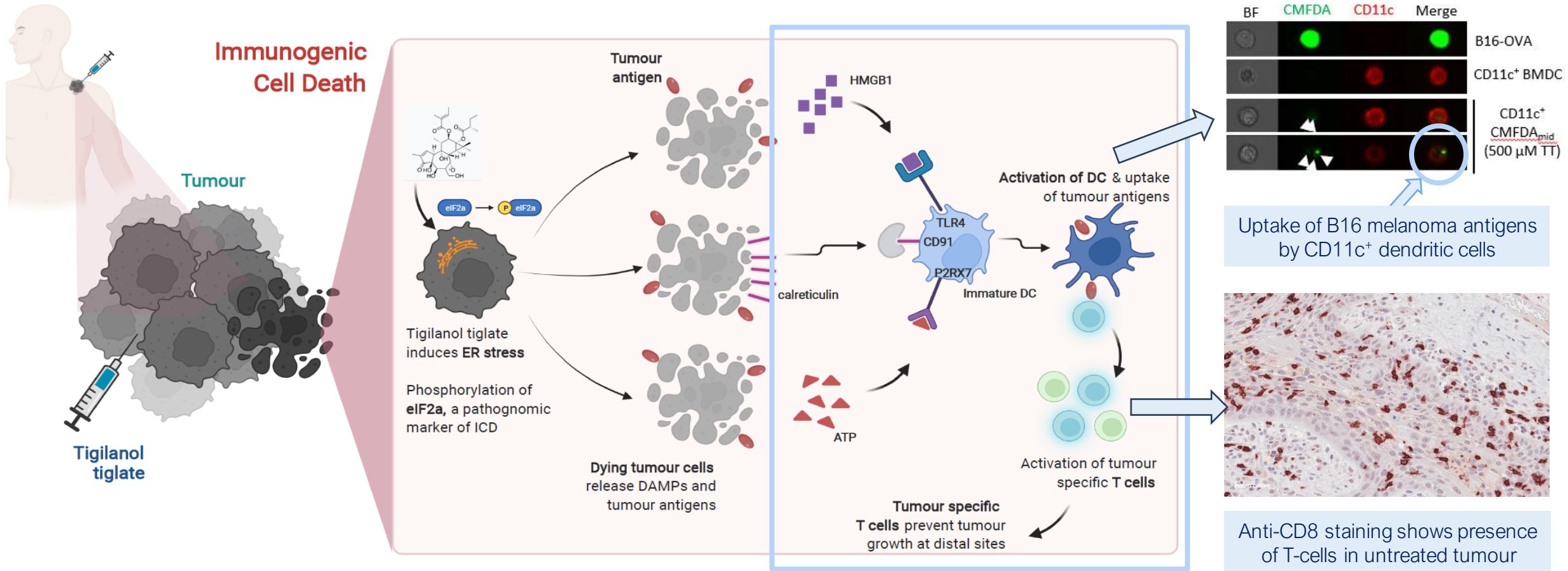
DAMPs release during TT-induced cell death



HMGB1 release



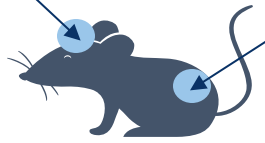
Tigilanol tiglate induced ICD promotes the development of tumour specific T-cells



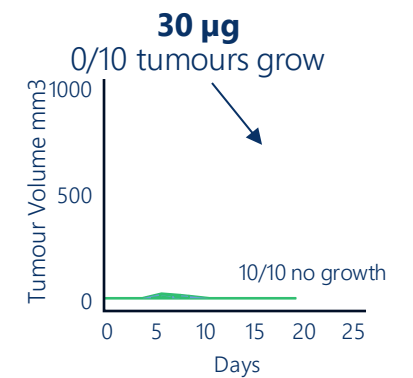
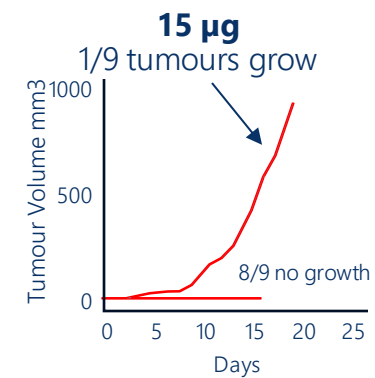
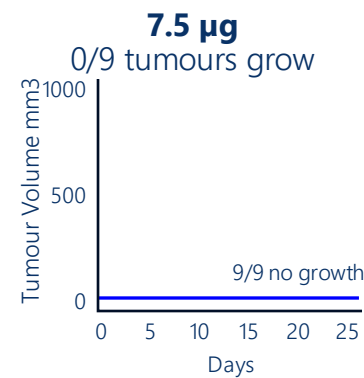
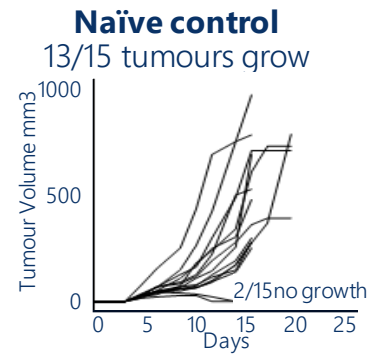
Murine data supports immune response and combination therapy

Induces immunological memory

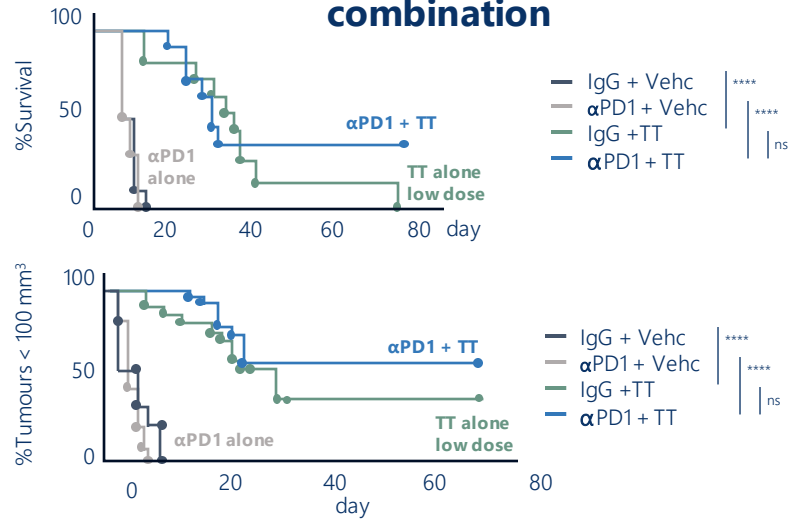
Re-challenge with CT26
1x10⁶ cells at distal site



Treat with
TT to CR

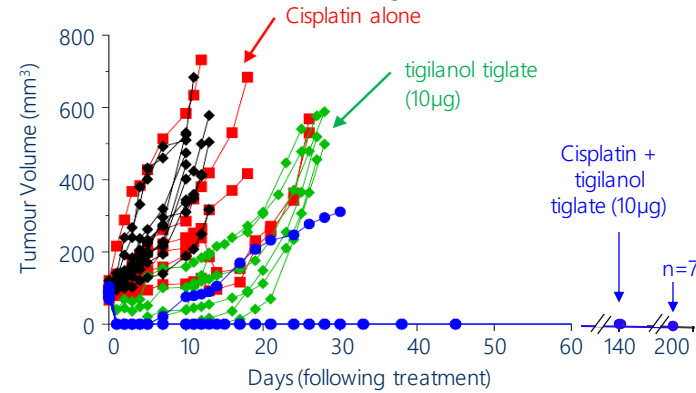


Anti-PD-1 combination



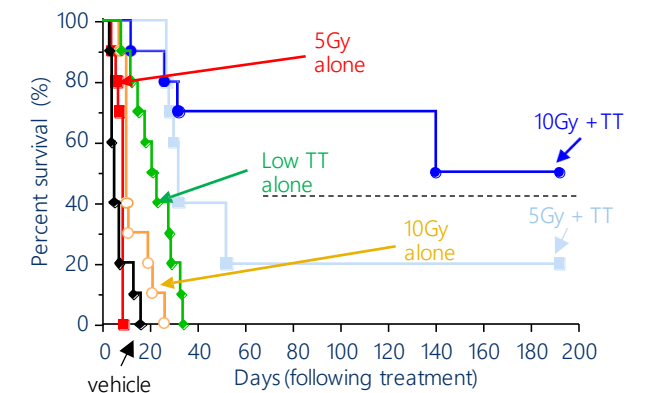
Synergistic response low dose TT combine with anti-PD-1

Chemotherapy combination



Vehicle – 7 days median survival
 Cisplatin – 12 days median survival
 Cisplatin + TT (low dose) – **193 days median survival**

Radiation combination



Vehicle – 5 days median survival
 10Gy – 12 days median survival
 10Gy + TT (low dose) – **166 days median survival**

QB46C-H01/2 Human Clinical Phase I/IIa safety trial

Open label dose escalation of single intratumoural treatment with tigilanol tiglate



Patient population:

- Advanced refractory skin & subcut. tumours
- 22 patients



Dosing:

- IT based on mg drug/kg BW, not tumour volume as per cases of intent to treat (%v/v)



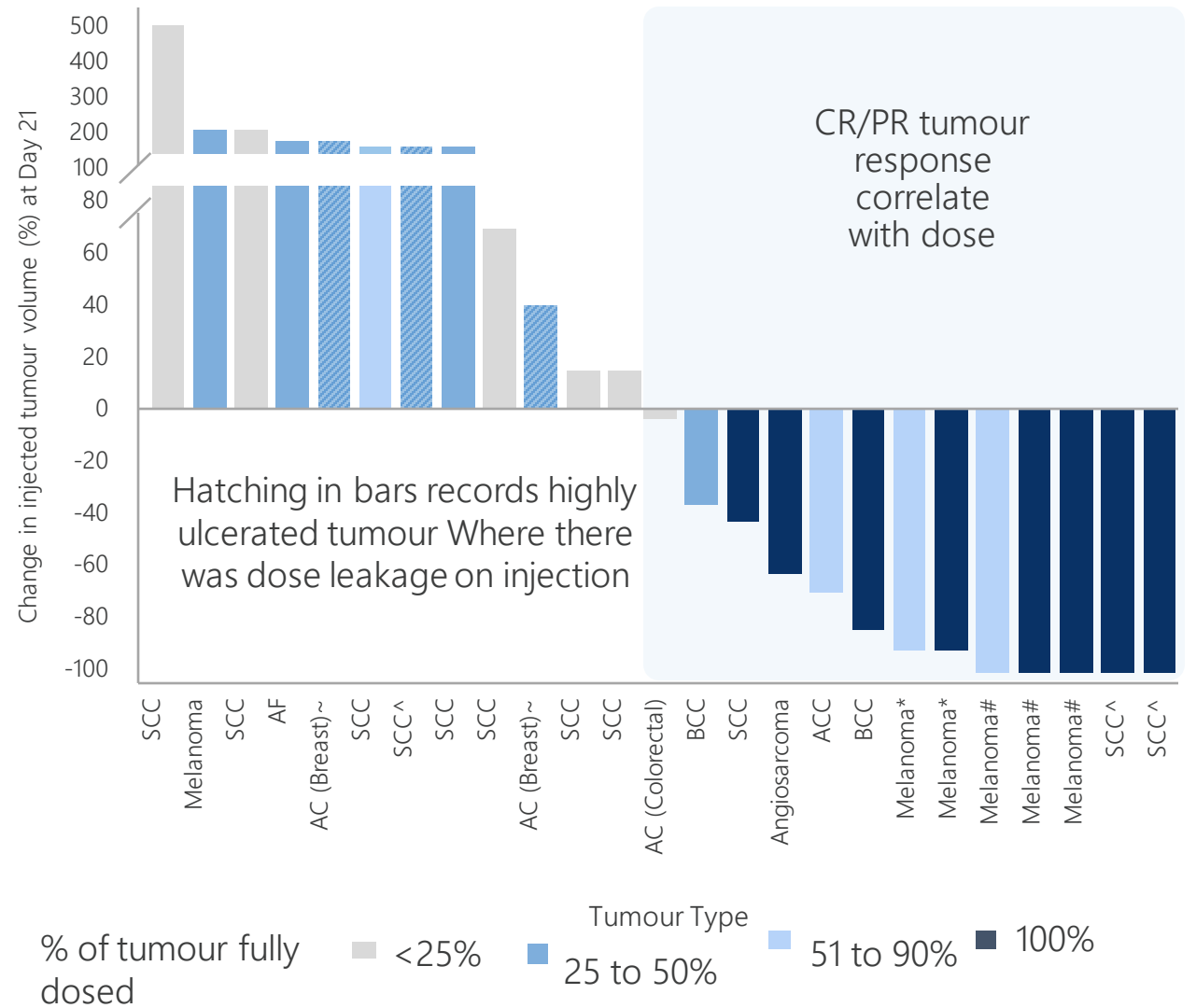
Good safety profile:

- No serious AEs - most expected/desired re MOA
- MTD not reached - final dose 3.6 mg/m²



Signs of efficacy in all 9 tumour types treated:

- Complete Response at optimal dose
- Abscopal effect noted



Phase I - Case Study Soft Tissue Sarcoma

Complete response with a single injection of tigilanol tiglate

- Patient had failed multiple surgeries
- Difficult to treat lesion, patient initially advised a total rhinectomy

Pt 407 - Soft Tissue Sarcoma (Angiosarcoma)

Tumour size:
5,141 mm³

Single IT
treatment at
optimal dose rate



Pre-treatment



Day 2: vascular disruption and haemorrhagic necrosis of tumour



Day 15: Tumour necrosis continues



Day 43: Complete Response²

Complete Response & Organ Preservation
No residual tumour at 12 weeks (punch biopsy)¹

Patient disease free (CT scan) at 25 months and clinically disease free at 30.5 months¹
Tigilanol tiglate well tolerated; AEs mild and transitory

Phase I - Case Study Metastatic Melanoma

Complete response with a single injection of tigilanol tiglate

Pt 102 - Multiple melanoma, on upper arm

Single IT treatment into top 3 tumours - 4th tumour (circled) not treated



Pretreatment



Day 1: 30 minutes
Top 3 tumours - single IT treatment
Vascular disruption and tumour haemorrhagic



Day 3: Necrotic tumours slough



Day 8: Non-injected, 4th tumour regresses



Day 29: Complete Response in injected and non-injected tumour
Injected sites healed

Lung & sternum tumours regression reported off study

QB46C-H03

Phase I/IIa head and cancer dose escalation window of opportunity before surgery trial meets Primary Endpoints



Safety and tolerability met in 19 patients with HNSCC
Late stage very large tumours - partial tumour treated then surgically removed Day 14 - 21 for assessment

- Treatment was well tolerated at all dose levels
- No SAEs other than extension of overnight stay for one patient
- AEs local, expected, mostly desired and associated with the MoA of the drug
- Rapid induction of haemorrhagic necrosis was evident within hours in all injected tumours at all dose levels with no necrosis reported in the surrounding normal tissue



ICD & T-cell infiltration in human tumours treated with tigilanol tiglate

HNSCC Clinical Phase I/IIa QB46C-H03

Window of opportunity before surgery

- Patients with large HNSCCs
- Part of tumour treated
- Remnant surgically excised at day 15 to 21

Immunohistochemistry on biopsies taken:

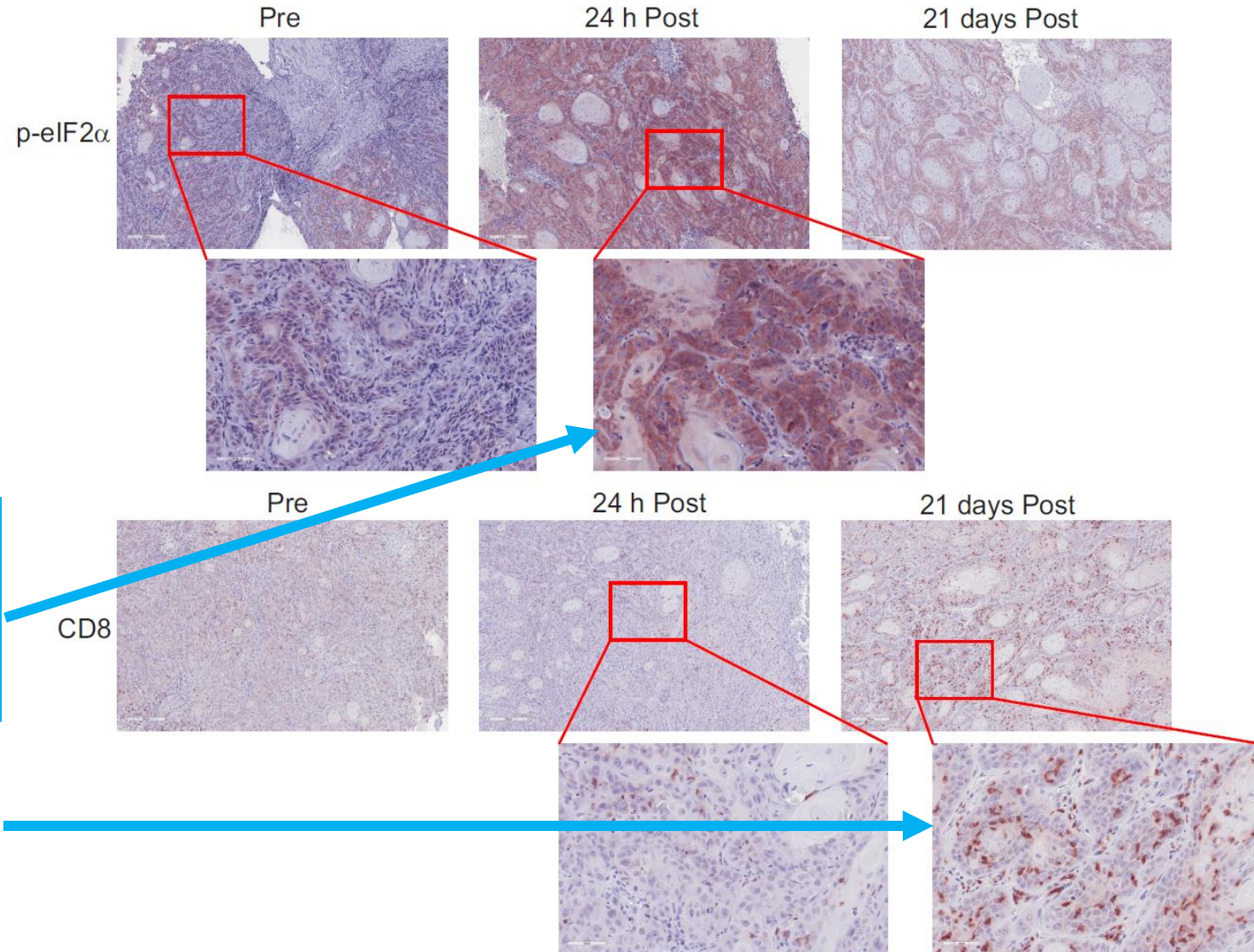
- Before treatment
- At 1 hr or 24 hr post treatment
- After surgical excision from untreated area of remnant tumour

Pathognomonic marker of immunogenic cell death (p-eIF2 α):

- Present in treated tumours by 24 hr
- Not present in untreated tumour

CD8+ T cells:

- Minimal background pre-treatment and at early timepoints
- At time of excision: CD8+ T-cells ~ 10% of tumour cell numbers



Canine FDA registration trial

Single treatment with tigilanol tiglate induces Complete Responses in 75% canine mast cell tumours

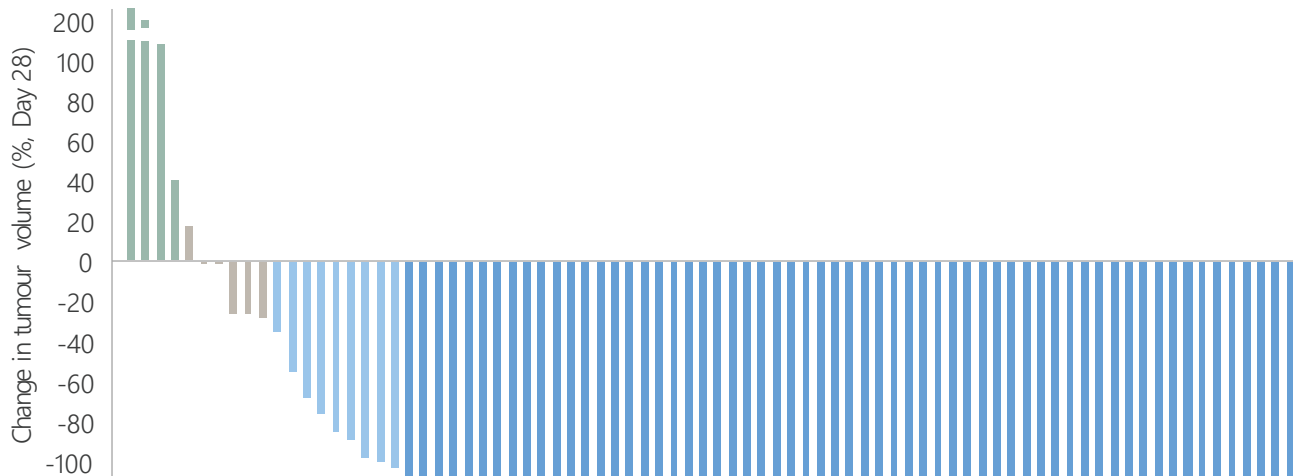


Fully blinded and controlled trial

Full treatment Rate

- 75% CR with a single IT treatment ($p < 0.0001$ vs sham control)
- Objective Tumour Response Rate (CR/PR) of 80%
- 88% CR with a second treatment for partial responders.
- No tumour recurrence in 89% at 12 months

- Complete Response Stable
- Partial Response
- Disease
- Progressive Disease



Tumour response in tigilanol tiglate treated dogs (n=81)

Clinical case from US FDA-CVM registration trial



Day 0: Pretreatment



Day 1: Tumour haemorrhagic necrosis



Day 7: Tumour destroyed (CR)



Day 28: Site healed, excellent cosmesis

Tigilanol tiglate brand name STELFONTA[®] commercialised across key markets



Veterinary pharmaceutical registration for canine MCT

Off label use in development for other species & tumour types



Provides treatment and CMC validation in major markets

~20,000 dogs treated to date



Disruptive technology – replacement for surgery GPs and specialists
≥20% annual growth across markets



EUROPEAN MEDICINES AGENCY



SWISSmedic



FDA



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



Veterinary
Medicines
Directorate

EBC-1013 Wound Healing



EBC-1013 for chronic and acute wounds and burns

6.5 million cases
US chronic wounds p.a.¹

14-29 million cases
globally p.a.²



Driven by ageing and increasing incidence of diabetes and obesity



Significant Unmet Need: 10% of chronic wounds do not heal



Current treatments - advanced wound dressings and medical devices, not pharmaceuticals



One product Regranex (Becaplermin) approved in USA



None approved in EU



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



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



Cellular signalling with multifactorial MOA affecting different stages of the wound healing process



Pharmaceutical not a device so competition is low



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



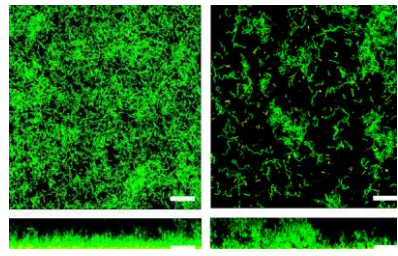
Preparation for First-In-Human safety trial current in patients with venous leg ulcers – to commence CYQ1 2024

EBC-1013: A novel small molecule for wound healing

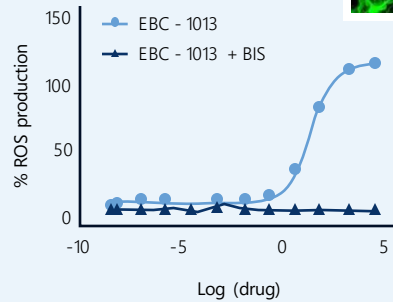
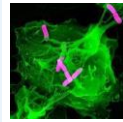
Antimicrobial

Disrupts the structure of established biofilms of multidrug resistant bacteria

Control EBC-1013

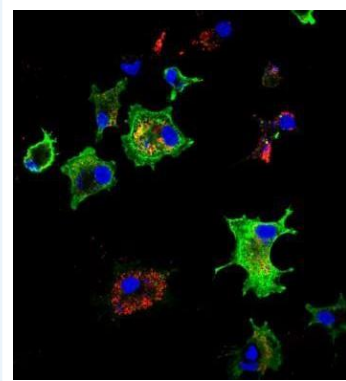


Induces respiratory burst by neutrophils



Drug induced debridement

Patrolling monocytes differentiate into M1 & M2 macrophages

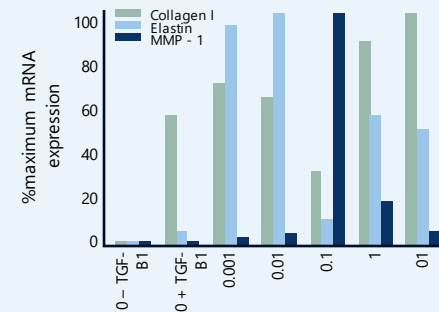
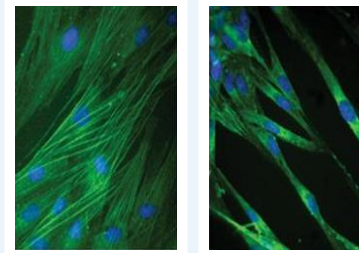


Proteolytic remodelling and deposition of extracellular matrix

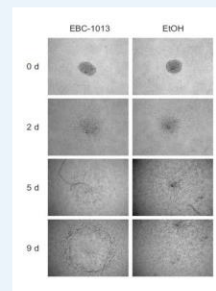
Downregulates differentiation & formation of stress fibres by fibroblasts

Changes relative expression of key genes involved in ECM synthesis & remodelling

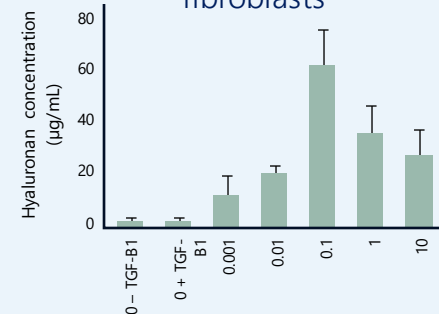
Control EBC-1013



Degrades scar forming type I collagen (100 ng/ml)



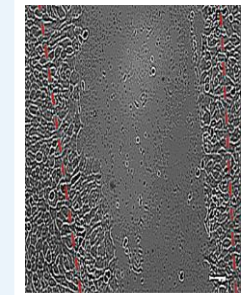
Stimulates production of hyaluronan by cultured fibroblasts



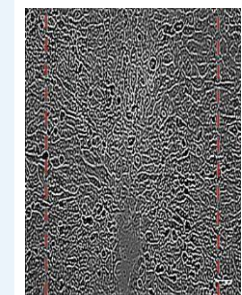
Wound closure

Stimulates migration of keratinocytes

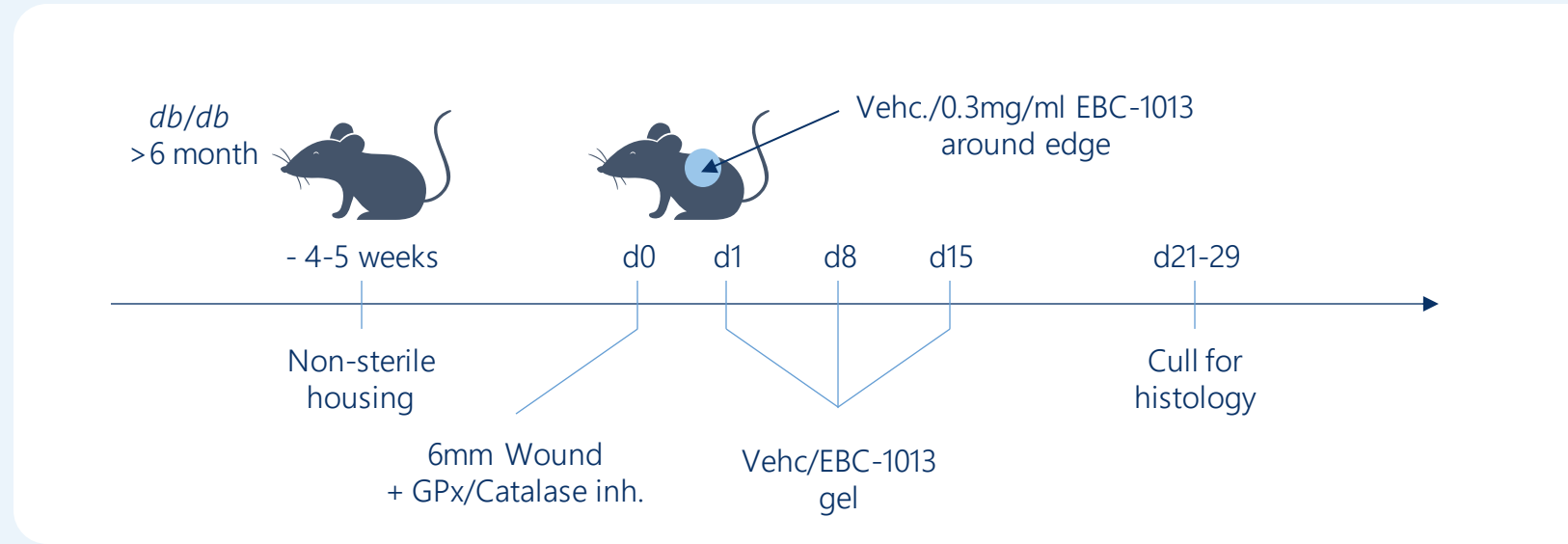
Control



EBC-1013 (0.1 µg/ml)



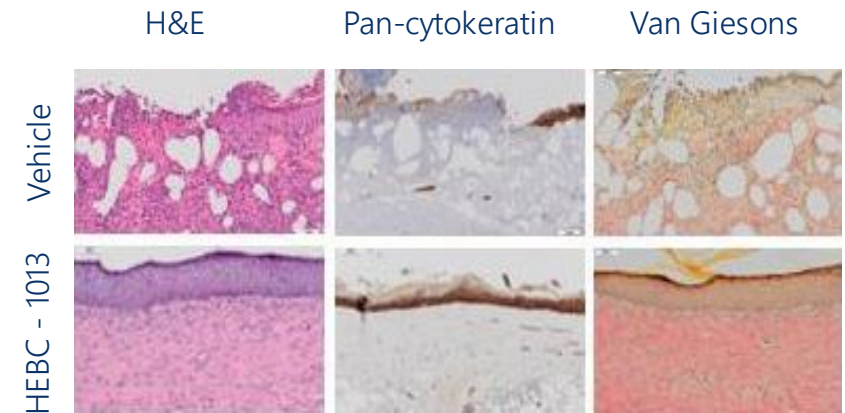
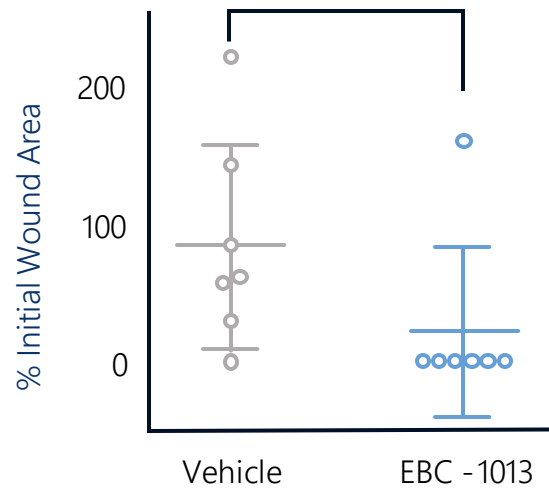
EBC-1013 stimulates closure of infected wounds in diabetic mouse model



Complete wound closure was observed in db/db mice treated with EBC-1013 within 21 to 26 days



Significant histopathological differences in the resolved treated wound in maturation of the underlying dermis and adhesion of the re-epithelialised epidermis to the basement membrane



EBC-1013: Reason to believe - veterinary case studies

Treatment with EBC-103 in gel – there were no other treatments such as antibiotics or dressings for all three cases

Canine surgical wound, closure not possible (3 treatments, 7 days apart)



Pre-treatment



Day 19: Wound in-fill



Day 42



Day 63



Day 78

Equine traumatic wound (1 gel application Day 0)



Day of wounding



Day 0 infected wound
(5 days after trauma)



5 day after treatment

Canine thermal burn (3 treatments, 7 days apart)



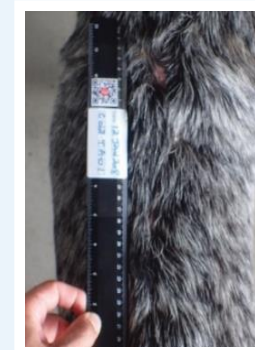
Treatment Day 1
(8 days after burn)



Day 14



Day 38



Day 73



QBiotics Group

Thank you

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