QBiotics Annual General Meeting

CEO Presentation

Dr Victoria Gordon



QBiotics Group

Harnessing the power of nature to improve lives.

4 November 2022

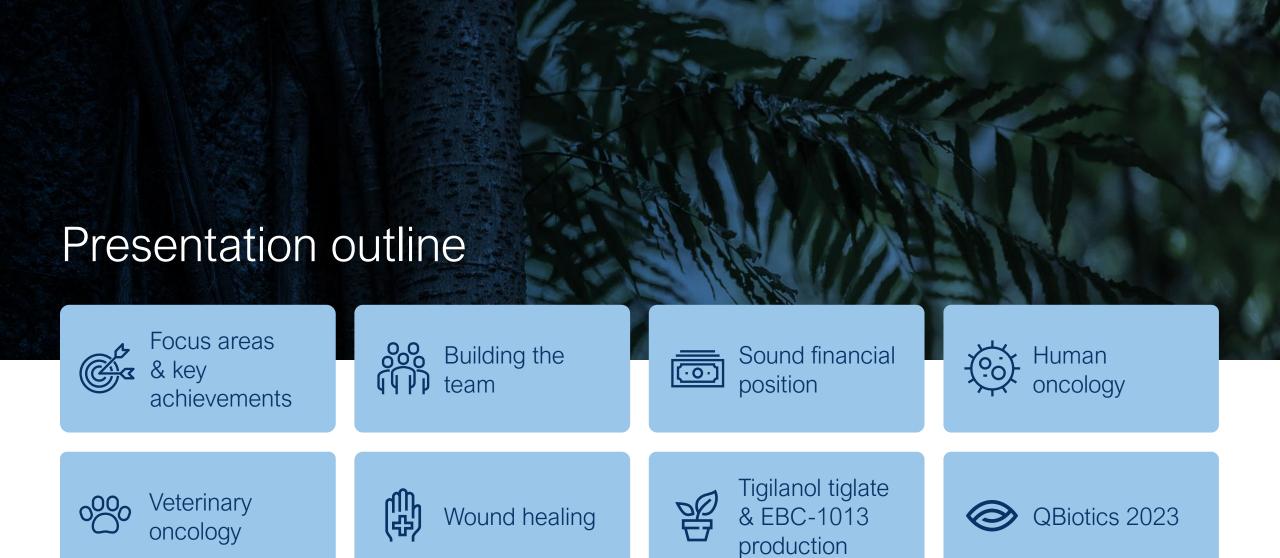
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Company focus areas & key achievements

Human oncology clinical trials

Melanoma (QB46C-H04 and QB46C-H06)

- Patient recruitment extremely slow strong competition for patients in AU
- Strategies for patient recruitment actively pursued including sites in UK and Norway
- First dose escalation achieved in Keytruda combination trial

COVID-19 Pharma Bulletin



31 October 2022

Disrupted clinical trials

- 1,214 disrupted clinical trials (+5)*
- 1,328 organizations (industry and academia) impacted (-2)
- 711 companies are impacted (+9)
- 1,460 drugs involved (+8)
- Majority of delays in oncology and CNS trials

*change since last update

Currently 845 ongoing melanoma clinical trials

QB46C-H03: Phase I/IIa Head & neck SCC

- In-life stage finalised
- Tumour biopsy data indicating immune cell infiltration
- Final report mid Nov 22

QB46C-H08: Phase II Head & neck cancers

- Patient recruitment open AU
- Investigators Meeting in UK held this week
- UK sites recruitment awaiting final MHRA regulatory approval –Dec 2022

QB46C-H07: Soft tissue sarcoma

- FDA IND approval for Phase II STS trial
- Preparation for site activation – Feb 2023

Translational research to refine MOA

- Patient blood & biopsy assessment for H&NC & STS trials with leading UK and USA
- Researchers
- In-depth MOA



Company focus areas & key achievements

Wound healing (EBC-1013)

- Positive Scientific Advice meeting with UK MHRA regulatory agency
- Protocol for first-inhuman trial well advanced
- Selection of international trial sites commenced
- Human clinical trial open
 Q3 2023

Veterinary development

 Dose definition trial for canine chronic wounds commenced

Understanding MOA

- Significant progress in biofilm antimicrobial activity and immune system stimulation
- Publication in prestigious international journal Science Translational Medicine

STELFONTA® for canine mast cell tumours

- Sales less than original forecast but uptake slowly improving in all markets
- Recent independent market assessment supports original projected market size
- 3rd milestone payment €500,000 from Virbac
- Australian market launch well received
- Phase IV clinical trial with AU veterinary oncologists expanding knowledge on MCT treatment

Tigilanol tiglate for other veterinary indications

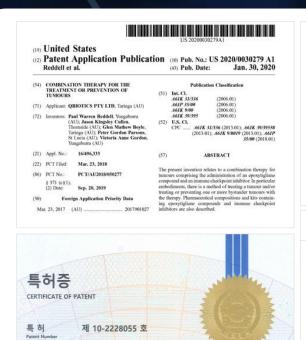
- International clinical trial with leading KOLs for treating equine sarcoids completed in-life phase
- International equine melanoma clinical trial open
- Canine STS trial with specialist oncologists open, first patients recruited



Company focus areas & key achievements

Strengthening intellectual property position & scientific publication/communication

- Patents granted tigilanol tiglate/ICI drug combinations numerous jurisdictions
- Two new patent applications under examination (PCT stage)
- Two provisional patents lodged (use & manufacture of epoxytiglianes)
- Scientific manuscripts published in well respected international journals
- STELFONTA data presented at 9 international veterinary conferences by independent veterinary oncologist and QBiotics team





- 1 -Method of Treating Tumours

The present invention relates to the localised administration, for example intratumourally or topically, of an epoxytiglienone compound (as a monotherapy) to cancerous tumours to generate a systemic anticancer abscopal and/or bystander effect.

Abscopal effects are a phenomenon observed in some metastatic cancers and involve the spontaneous regression of untreated non-adjacent and distant tumours following a localised treatment delivered to one or more target tumours.

The term abscopal, first introduced in the 1950s, is derived from the Latin (ab:"away from" and scopus:"target") and was used in reference to the regression of tumours



synchronous canine mast cell tumours using intratumoural tigilanol tiglate

Graham K. Brown^{1*}, Jessica R. Finlay², Rodney C. Straw³, Joy Y. Ziea3. Becky Leung3. Kathleen O'Connell4. Maurine J. Thomson⁴, Justine E. Campbell¹, Pamela D. Jones and Paul Reddell

generally occur as single tumours, multiple synchronous MCTs (msMCTs) of de novo/non-metastatic origin are reported in a proportion of the patier MCTs are effectively controlled by surgery and other local therapies. However, reatment of de novo msMCTs can be more challenging, especially when tiglate, a novel small molecule registered as a veterinary pharmaceutical for

scientific reports

Ziea JY, Leung B, O'Connell K, Thomson MJ, Campbell JE, Jones PD and Reddell P (2022) Treatment of multiple synchronous canine mast cei

OPEN Activation of PKC supports

the anticancer activity of tigilanol tiglate and related epoxytiglianes

Jason K. Cullen¹, Glen M. Boyle^{1,2,1,283}, Pei-YiYap¹, Stefan Elmlinger¹, Jacinta L. Simmons¹, Natasa Broit¹, Jenny Johns¹, Blake Ferguson¹, Lidia A. Maslovskaya^{1,4}, Andrei I. Savchenko⁴ Paul Malek Mirzayans¹, Achim Porzelle⁴, Paul V. Bernhardt², Victoria A. Gordon⁵,

been challenged by evidence that some PKC isoforms may act as tumor suppressors. To explore the hypothesis that activation, rather than inhibition, of these isoforms is critical for anticancer activity, we isolated and characterized a family of 16 novel phytholisis closely-related to tigiliano



SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICL

Topical, immunomodulatory epoxy-tiglianes induce biofilm disruption and healing in acute and chronic skin wounds

Lydia C. Powell^{1,2}+, Jason K. Cullen^{2,4}+, Glen M. Boyle^{3,4}, Tom De Ridder², Pei-Yi Yap², Wenya Xue³, Carly J. Pierce³, Manon F. Pritchard¹, Georgina E. Menzies³, Muthanna Abdulkarim Jennifer Y. M. Adam², Joana Stokniene³, Lewis W. Francis³, Mark Gumbeton³, Jenny Johns³. Katja E. Hill¹, Adam V. Jones⁸, Peter G. Parsons³, Paul Reddell⁵, David W. Thomas





Identification of Gene Biomarkers for Tigilanol Tiglate Content in Fontainea picrosperma

Shahida A Mitu 1,2, Praphaporn Stewart 2, Trong D Tran 1,20, Paul W Reddell 30, Scott F Cummins 1

Key team additions

Primary focus is strengthening our clinical trial capabilities

Chief Translational Research

Officer

Dr Steven Ogbourne

Human Clinical Project Managers

Katrina Pirlo

Sarah Knight

Human Clinical Quality Manager

Leonora Pearson

Senior Research Chemist

Dr Simone Gaeta

Senior Veterinary Research

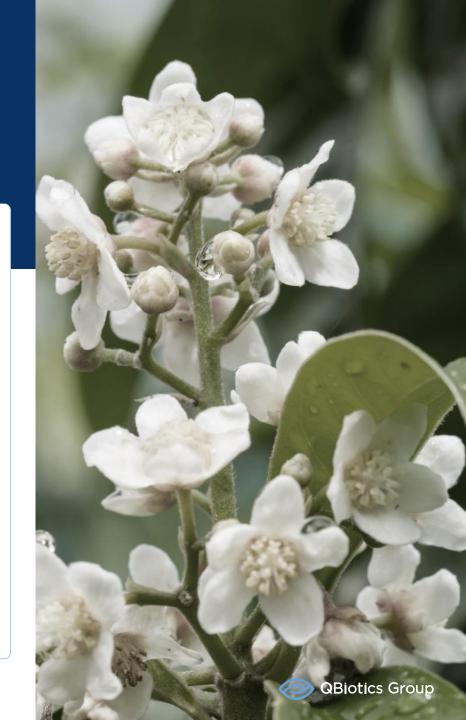
Scientist

Dr Raphael Labens

Research Scientist – Antimicrobial

Therapeutics

Dr Joana Stokniene



Sound financial position

Cash at bank AU\$74.3 (Sept 22)

R&D tax Incentive AU\$6.4M (Dec 22)

Quarterly burn rate ~AU\$9M

Secondary market share price AU\$1.11

Share price drop but fairing well against industry average







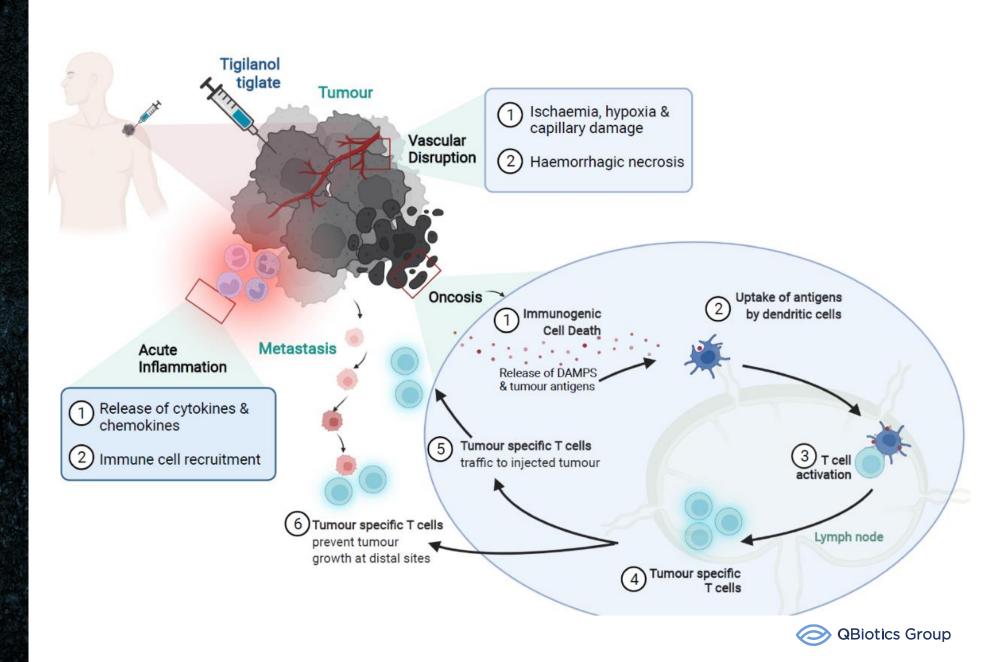
Human oncology clinical programme summary

Patient recruitment melanoma trials a major concern in AU – investigating UK & Norway sites Site initiation still slow average 9 months – working closely with CRO to meet timelines Positive Investigators Meeting Phase II H&N Cancer – potentially better recruitment rate

	Tumour Type	Phase	Treatment	Patient No.	Patients treated	No. sites	Location	Lead sites/stage
	Skin & subcut.	Phase I/IIa H01/2	Mono TT	22	22	4	AU	Finalised
ı	Head & neck cancer	Phase I/IIA H03	Mono IT	Up to 20	19	2, 2	AU, IN	Reporting Kinghara Canaar Cantra
(Phase II H08	Mono IT	37	Recruiting AU UK Nov/Dec	2, 6-8	AU, UK	Kinghorn Cancer Centre The Royal Marsden Hospital
	Melanoma	Phase I/IIA H06	TT - IT Pembro – IV	16-22	3	3	AU ? UK/NW	Melanoma Institute of Australia
		Phase II H04	Mono IT	20	1	4	AU ? UK/NW	Royal Prince Alfred Hospital
	STS	Phase IIA pilot H07	Mono IT	10	Open Feb 23	1	USA	Memorial Sloan Kettering Cancer Centre
	Special Access Scheme	Intent to treat	Mono TT	N/A	3	2	AU	Kinghorn Cancer Centre Melanoma Institute of Australia

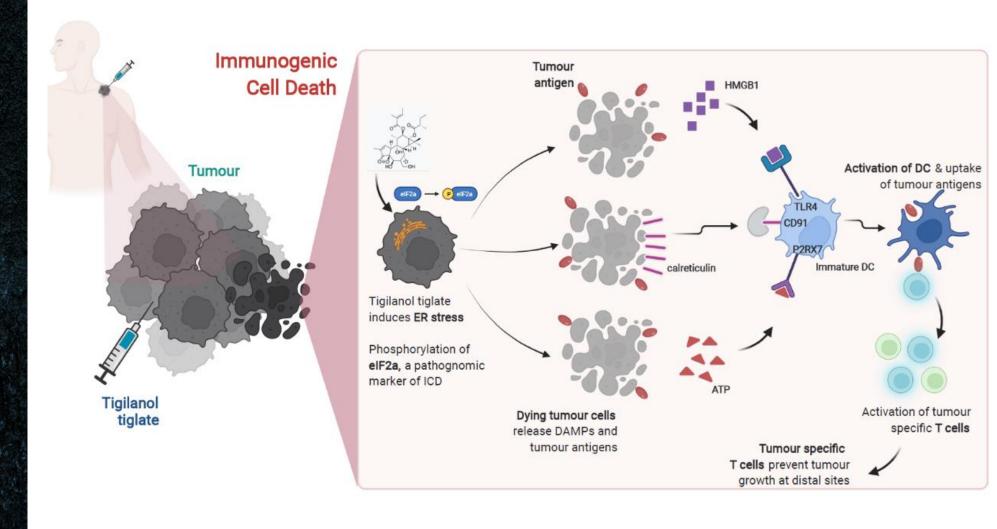
Mode of action revisited

Tigilanol tiglate acts directly through cell killing and indirectly through immune activation



Mode of action revisited Tigilanol tiglate induces immunogenic cell

death





Translational research with leading institutes adding value to the human oncology programme

Examination of patient's blood and tumour biopsies providing information on how the drug works locally and systemically



Blood assessment

- PBMCs TSNE/U-MAP for population changes:
 - T-cell population
 - NK cells and markers of proliferation
 - Myeloid lineages present post-injection

- ctDNA
- HPV –ve and +ve
- T cell receptor sequencing



Tumour biopsy assessment

- Vasculature disruption related – CD31 (IHC)
- Immunogenic cell death related – eiF2α for ER stress, HMBG1 and calreticulin as DAMPs
- TILS B, T and NK cells (IHC)
- Modulation of checkpoint pathways -- PD-1, PD-L1. CTLA-4

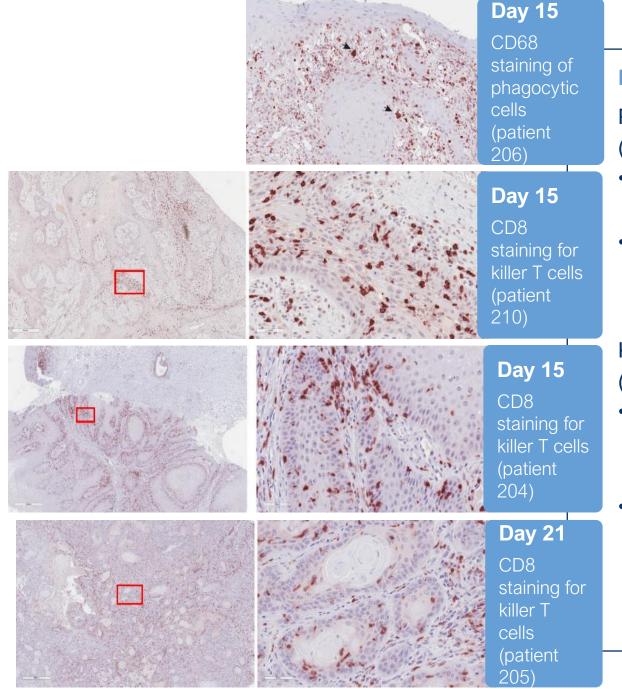
The Royal Marsden
Centre for Translational Immunotherapy

Memorial Sloan Kettering Cancer Center Research Unit QIMR Berghofer Medical Research Institute

QB46C-H03 Head & neck cancer trial trial

Window of opportunity before surgery

Preliminary analysis indicates immune cell infiltration of patient's treated tumours



Results

Phagocytic cells (CD68 staining)

- Minimal background pretreatment, 1 Hr and 24 Hrs
- At time of surgery: 20% strongly staining phagocytic

Killer T-cells (CD8 staining)

- Minimal background of killer T-cells pre-treatment,
 1 Hr and 24 Hrs
- At time of excision: killer Tcells ~ 10% of tumor cell numbers



Developing human tigilanol tiglate programme towards a sound commercial outcome



Clinical Strategy



- Potential for pan tumour registration
- As a monotherapy
- In combination with other drug
- Local & systemic efficacy



Commercialisation strategy

Preparation for commercialisation

- Market assessment and positioning
- Identify target companies
- Present/participate at bio business conferences
- Build relationships



STELFONTA® sales slow but positive growth

3rd milestone payment €500,000 from Virbac



United Kingdom

Sales Growth +31% vs PY

- 27% of vets prescribed **STELFONTA**
- 90% intend to prescribe STELFONTA again
- 39% already prescribed multiple times

European Union

Sales Growth +30% vs PY

Growth markets:

- Germany +48%,
- Scandinavia +26%
- Italy +40%

America

Sales Growth 11% and **Strong Plans**

- 17% of vets prescribed to date
- 83% intend to prescribe again
- 41% already prescribed multiple times

Australia

Already 3rd largest market

- Launched October 2021
- Strong sales with continued momentum
- 8% clinic penetration

Task: More vets prescribing STELFONTA® - Education and Confidence Once vets have prescribed STELFONTA®, repeat prescription is strong = STELFONTA® performs

Converting interest in STELFONTA® into prescription



Pet parentsRequest STELFONTA

- Aware of STELFONTA
- 2. Educated on how STELFONTA works
- 3. Request from Veterinarian
- 4. Support through treatment









GP veterinariansPrescribe STELFONTA

- Educated and confident in STELFONTA treatment
- 2. Sampling
- 3. Consultation with STELFONTA expert









KOLsPrescribe STELFONTA

- 1. Further build the community
- 2. Global Scientific Advisory Boards
- 3. Publications
- 4. Scientific Conferences







SEEING IS Virbac An innovative and effective A non-surgical treatment for mast cell tumours One injection for complete

Vet Expo: STELFONTA Booth and Lecture

Australian Veterinary Association National Conference



STELFONTA Australia

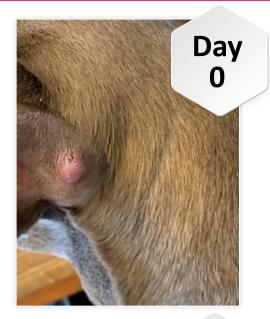
Virbac activity:

- Primary sales team focus
- Pre-and post prescription technical support
- National conferences
- Clinic penetration targets
- Repeat purchase metrics



- 6-year-old American Bulldog
- Mast Cell Tumour left ear base
- Alternative treatment extensive surgery/ear removal
- Single STELFONTA treatment











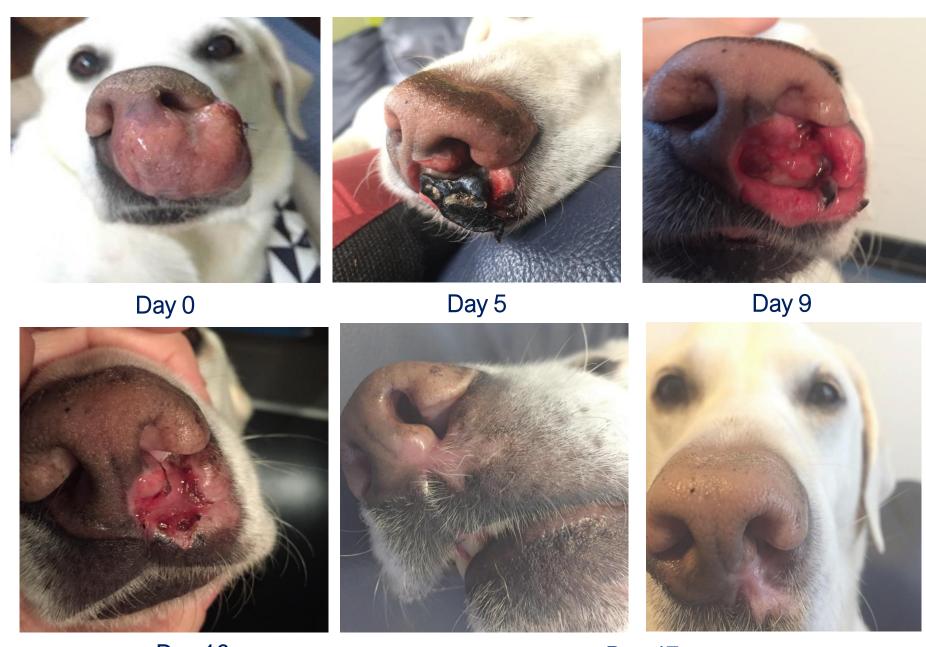




Mast cell tumour nasal planum

Alternative treatment Is a rhinectomy

CR & wound healing Day 47



Day 16 Day 47

QBiotics Group



EBC-1013 wound healing advancing towards human clinical trial

Human clinical

- Scientific Advice meeting held with UK Medicines and Health Products Regulatory Agency (MHRA) with positive feedback
- Protocol drafted
- CRO engaged
- Investigator and site selection commenced

Veterinary Clinical Models

- Dose determination studies ongoing in dogs and horses
- Supporting both veterinary and human clinical development programmes

Preclinical

- Final GLP toxicology study commenced
- CMC API & DP at GMP multiple batch production
- MOA refining antimicrobial activity associated with biofilm disruption and immune system stimulation



Patient ID. C01TA11

Traumatic wound following dog attack

Case:

Infected wound 8.6cm² dog leg Bone exposed

Treatment:

0.4mg EBC-1013 applied 6 days after initial injury

Wound intervention:

None - wound healed without bandage

Adverse events:

None





Day 0



Day 11



Day 4



Day 25 QBiotics Group

Tigilanol tiglate and EBC-1013 production

- 5th shade shelter constructed
- Expanding arboretum for discovery activities
- Refining active pharmaceutical ingredient (API) manufacture for both programmes – expanding patenting coverage





Value driving milestones for 2023



Human Oncology Tigilanol tiglate

- Primary focus on patient recruitment – melanoma; H&NC
- Open QB46C-H07 STS trial in USA
- Interim translational research data
- Build towards a deal with a partner



Vet Oncology STELFONTA®

- Continue to work with Virbac to increase market reach
- Finalise current equine and canine clinical trials and publish data



Wound Healing EBC-1013

- Finalise toxicology programme
- Gain MHRA CTA approval
- Commence first-in-human safety trial



Thank you

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QBiotics Group

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