

QB46C – C24 Quick Reference Guide

Inclusion Criteria

- Signed owner consent form.
- Dog is ≥ 1 year of age.
- Dog has a cytological diagnosis of 1 or more cutaneous or subcutaneous mast cell tumours without evidence of metastasis.
- If the MCT is subcutaneous, the tumour location is at or distal to the elbow and/or hock.
- In the opinion of the investigator, the dog has a life expectancy of at least three (3) months without treatment.
- Adequate liver and kidney function and blood cell count within normal limits.
- The total calculated volume of the treated MCT/s must be $\leq 10\text{cm}^3$ before tigilanol tiglate injection on treatment day.
- Target tumours must have an intact surface to minimise leakage of the IVP during administration.
- If a biopsy has been collected from the treatment site, treatment should be scheduled a minimum of 14 days later.
- No more than 5 MCTs selected for treatment with TT per patient, even if >5 MCTs are present.
- The dog is expected to be manageable and cooperative with study procedures.

Exclusion Criteria

- The dog has metastatic disease.
- The treatment site has received radiotherapy or surgical resection within 30 days prior to treatment.
- The patient has received systemic chemotherapy within 14 days prior to enrolment.
- The dog has received non-steroidal anti-inflammatory drugs (NSAIDs) ≤ 7 days prior to screening.
- The dog has received immunosuppressive therapy such as corticosteroids, cyclosporins, oclactinib (Apoquel) or caninised anti-cIL-31 monoclonal antibody (CANINE IL-31) ≤ 14 days or long-acting corticosteroids (e.g., injectable methylprednisolone acetate) ≤ 21 days prior to screening.
- The calculated dose of IVP is greater than 0.25mg/kg or greater than 5mg (5mL) maximum dose per dog per treatment cycle.
- The dog is considered unsuitable for study enrolment by the investigator.
- The dog is pregnant or lactating.
- The dog has received tigilanol tiglate within 28 days prior to treatment day.
- The treatment site has received 3 or more treatment cycles with tigilanol tiglate.

Funding

- Send all invoices for funding to accounts@qbiotics.com

STUDY CONTACTS

Study Monitor	Name	Dr. Graham Brown
	Phone	0448 686 744
Study Co-Monitor	Name	Dr. Justine Campbell
	Phone	0408 146 221
Study Co-Monitor	Name	Dr. Wade Smorfitt
	Phone	0476 223 694
	Email	vets@qbiotics.com

QB46C-C24 – Timeline Checklist

1. Case workup and screening	<ul style="list-style-type: none"> - Perform diagnostics based on investigators discretion and owners' budget - Ensure primary enrolment criteria are fulfilled before screening: <ol style="list-style-type: none"> 1. Confirmed cytological diagnosis of mast cell tumour 2. If subcutaneous, the MCT is at or distal to the elbow or hock 3. Adequate liver and kidney function and a blood cell count within normal limits Screening: <ul style="list-style-type: none"> - Patient examination - Confirm final enrolment criteria are fulfilled - Map and photograph all MCTs - Send FNAs of target MCTs to IVP for grading - Dispense concomitant medications: Corticosteroid, H₁ Antagonist, H₂ Antagonist and pain relief if required - Data submission: Upload <i>Screening form</i>, history (incl lab results) and photographs to SharePoint, or email to vets@qbiotics.com regardless of eligibility
Funding	- Send \$400 invoice to QBiotics (whether excluded or enrolled) for screening fund allocation
2. Treatment (Day 0)	<ul style="list-style-type: none"> - Ensure pre-treatment checklists are complete - Sedate if required - Map and photograph all MCTs with labelled ruler in view - Administer tigilanol tiglate intratumourally - Do NOT dispose of used tigilanol tiglate vials, as they are to be sent back to QBiotics at the end of the study
Funding	- Send \$1600 invoice to QBiotics for first half of treatment fund allocation
3. Day 1 clinic follow up	<ul style="list-style-type: none"> - Record examination findings on <i>Case Report Form</i> - Request photographs of treatment site with labelled ruler in view
4. Day 4 phone call	<ul style="list-style-type: none"> - Record data on <i>Case Report Form</i> - Request photograph from owner with ruler in view
5. Day 7 clinic follow up	<ul style="list-style-type: none"> - Record examination findings on <i>Case Report Form</i> - Photograph treatment site with labelled ruler in view
6. Day 14 phone call	<ul style="list-style-type: none"> - Record data on <i>Case Report Form</i> - Request photographs from owner with ruler in view
7. Day 28 clinic follow up	<ul style="list-style-type: none"> - Record examination findings on <i>Case Report Form</i> - Photograph treatment site with labelled ruler in view - Determine tumour response - If measurable tumour is still present, re-screen and organise re-treatment - If response cannot be determined, book the next recheck consultation or phone call - If a complete response has been achieved, complete case closeout
Re-treatment funding (If applicable)	- If re-treatment is required, send QBiotics invoice for \$1200
Case closeout	<p>When a case is closed out:</p> <ul style="list-style-type: none"> - Inform owner of QBiotics long term follow-ups (3, 6, 12, 18 and 24 months) - Upload completed <i>Case Report Form</i> pages, patient history and photographs to SharePoint, or email to vets@qbiotics.com
Funding	<p>After case closeout:</p> <ul style="list-style-type: none"> - Send invoice to QBiotics for remaining cost allocation of \$1000 - Payment will be sent upon receipt of final documentation
Hard copy and TT vial submission	<p>At the end of the QB46C-C24 Study:</p> <ul style="list-style-type: none"> - Post hard copies of all relevant documentation from all cases, and all tigilanol tiglate vials whether open or closed, empty or not, to PO Box 1, Yungaburra, 4884. Use separate express post bags supplied