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# QBiotics

Healthcare

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## Implications of the Moderna-Merck trial result

**Moderna and Merck's positive Phase III INTerpath-001 result in resected melanoma represents an important validation of combining immune priming with checkpoint inhibition. For QBiotics, the key read-across is broadly mechanistic: while Moderna-Merck's intismeran seeks to teach the immune system to recognise the tumour, tigilanol tiglate is designed to destroy tumours in a way that directly shows the immune system. Early clinical data from tigilanol tiglate support this immune-activating approach, while recent Phase IIa studies showed encouraging tumour ablation rates in head and neck cancer and soft tissue sarcoma. Although we caution against direct read-across given differences in technologies, trial designs and controls, tigilanol tiglate may offer potential advantages in speed, manufacturing complexity and cost. Overall, we believe the encouraging readout from the Moderna-Merck programme is validating of, and may provide momentum to, QBiotics's broader strategy.**

### Phase III result validates immune-priming thesis

The INTerpath-001 Phase III study met its primary recurrence-free survival endpoint and key distant metastasis-free survival endpoint in 1,137 patients with completely resected stage IIB–IV melanoma. The study compared intismeran autogene plus pembrolizumab (Keytruda) with Keytruda alone, building on Phase IIb data that showed 49% and 59% reductions in the risks of recurrence or death, and distant metastasis or death, respectively. Overall, the result provides important clinical validation for combining immune priming with checkpoint inhibition in this setting.

### Mechanistic read-across favours simplicity

For QBiotics, the key read-across is broadly mechanistic. While intismeran seeks to teach the immune system to recognise tumours, tigilanol tiglate is designed to destroy the tumour in a way that activates the immune system directly. Early clinical data support this approach (as discussed in our prior report), while recent Phase IIa studies showed complete or partial tumour ablation in 78% of head and neck cancer tumours and 82% of soft tissue sarcoma tumours. Further, Moderna-Merck's process requires tumour and tissue sequencing, neoantigen selection and synthesis of a bespoke construct, taking c six weeks per patient, with every dose unique, which will likely entail a sizeable price tag. In contrast, tigilanol tiglate is a small molecule made to one fixed specification, is injected directly into the tumour and is active the same day, with no sequencing or bespoke manufacture required.

### Validation, but maturity gap remains key

We caution against direct read-across given differences in the technologies, trial designs and controls. Intismeran is a Phase III adjuvant therapy, while tigilanol tiglate remains earlier stage (having treated more than 100 participants but with only 24 evaluable patients across the two recent Phase IIa studies). Nevertheless, it is our opinion that the developments in the Moderna-Merck programme should be interpreted as supportive of QBiotics's broader immunological strategy, while also leaving open a differentiated role for tigilanol tiglate, should larger studies confirm its early efficacy signals.

#### Business description

QBiotics is a clinical-stage biotechnology company focused on the development of novel small molecule therapies derived from natural compounds. Its lead asset, tigilanol tiglate, is designed to directly target tumours following local injection, with immune-mediated effects. The company is advancing this programme across multiple solid tumour indications.

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