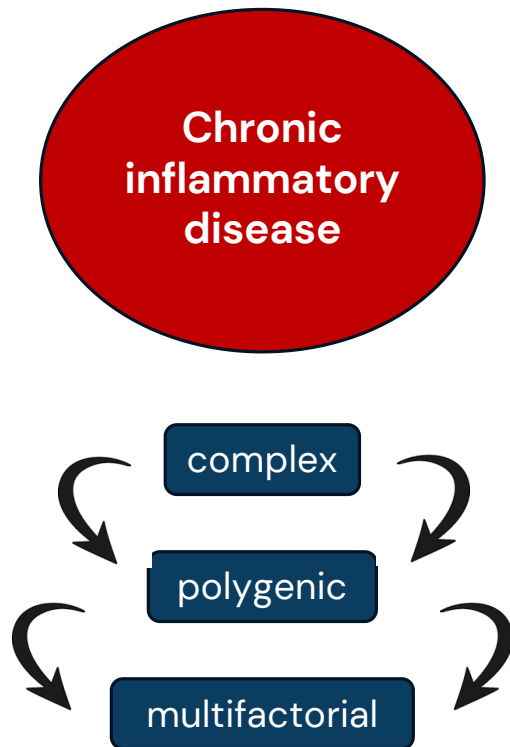


Next generation drugs for Chronic neuro-inflammatory diseases



Eye
Central nervous system
Peripheral nervous system

BIONNOVA. April 2026



Minimum essentials

1. A molecule that is the antithesis of targeted medicine by having multimodal anti-inflammatory action

2. A **disease-modifying drug** that treats the underlying inflammatory disease rather than just focusing on providing symptomatic relief

3. A drug that readily crosses the blood-brain barrier

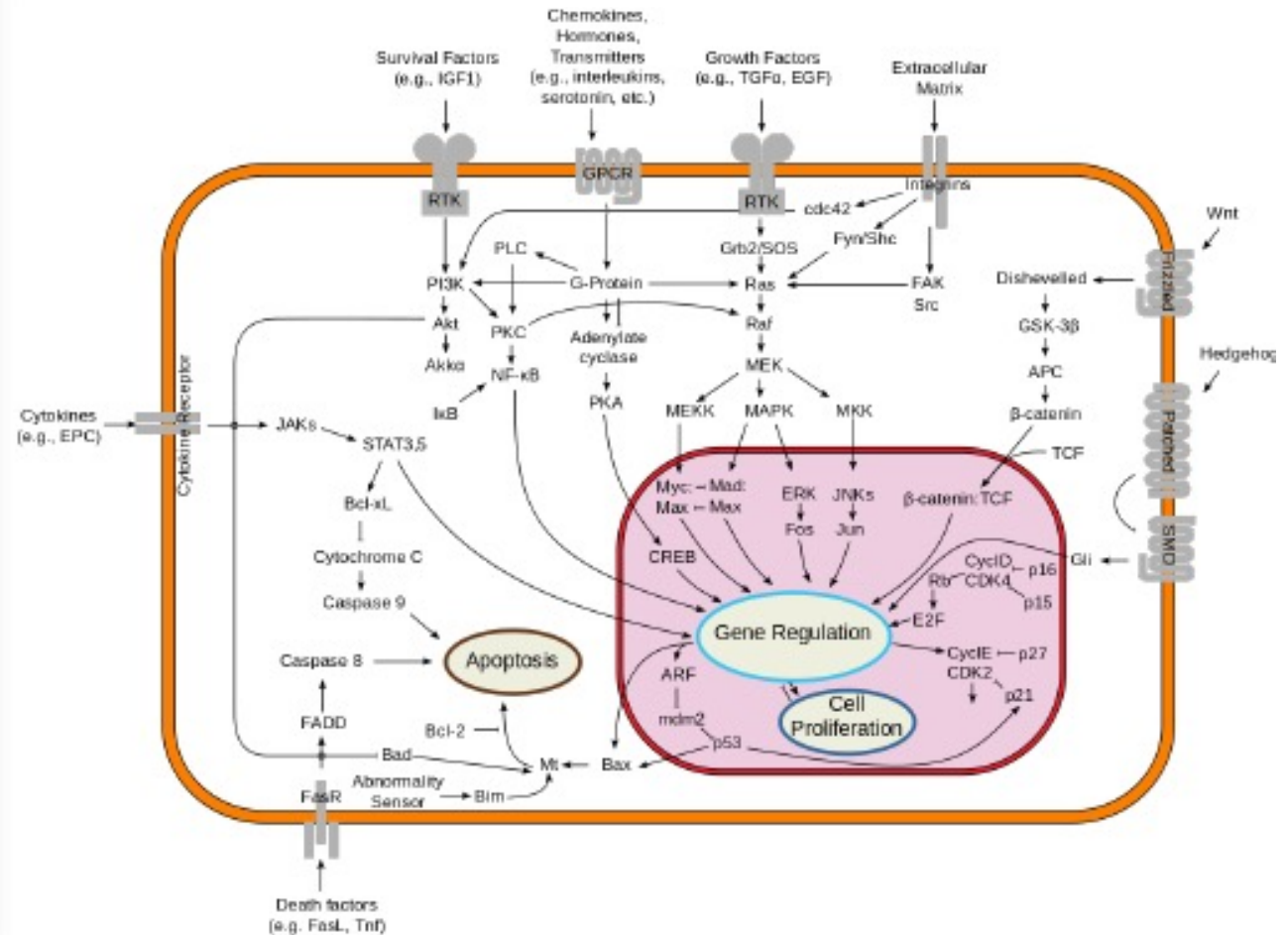


Ras-Raf-MEK-ERK pathway

Obvious target for treatment of chronic inflammation, but the complexity of cross-talk between MEK (7 isoforms) and ERK (7 isoforms) and their key roles in homeostasis means

- severe long-term side-effects
- narrow therapeutic window
- ready development of resistance
- complex administration protocols.

Result = no MAPK inhibitor approved as a treatment of a chronic inflammatory disease.



BETA-TT8

Selective inhibitor of certain MEK and ERK isoforms.

Type 4 (allosteric) kinase inhibitor

- BETA drugs based on a screen of <300 human genes activated by IL-6
- >80 genes down-regulated
- Binds allosteric pocket of MEK1, MEK5 and MEK7 (no predicted binding to MEK2, MEK3, MEK4 or MEK6)
- In response to cytokine stimulation BETA-TT8 inhibits pERK1 and pERK2 and modifies gene expression via AP-1 family of transcription factors (FosB/ Δ FosB/cJun)



BETA-TT8

- Metabolically resilient
- Highly orally bioavailable
- 9.5 hour half-life in blood, brain and eye following oral dosing (mouse)
- AUC brain/blood ratio (mouse) = 2.3; eye = 1.2

Overall, the pharmacokinetic profile of oral BETA-TT8 is characterised by:

- rapid absorption
 - extensive tissue distribution
 - absorption-limited (flip-flop) kinetics
 - sustained tissue exposure.
-
- Readily crosses mouse and rabbit cornea from topical administration achieving high drug levels in retina and choroid



Filamon Ophthalmology

BETA-TT8

Eyedropper or oral treatment of intra-ocular inflammation

- de novo, or
- associated with systemic inflammatory disease

BETA-TT8

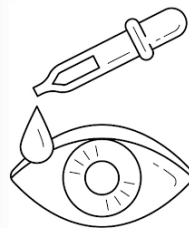
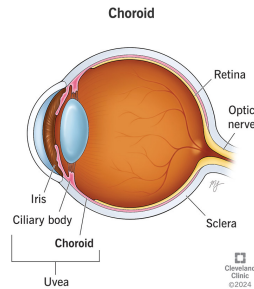
As a treatment of chronic inflammatory eye conditions.

- Inhibits pERK-1 signaling and AP-1 transcription resulting in down-regulation of expression of, VEGF, VCAM-1, ICAM-1, IL-1 β , IL-6, CXCL2, CCL20) expression) relevant to disease progression
- Potent inhibition of pathological angiogenesis
- Resulting in reduced immune cell recruitment, endothelial activation, and inflammatory amplification in the retina
- Strong access by the drug to back of eye by both oral and eyedropper dosage forms



BETA-TT8 Ophthalmic Gel

A first-in-class, eyedropper therapy designed to deliver potent **anti-inflammatory** and **anti-angiogenic** activity to both the anterior and posterior segments of the eye via non-invasive eyedrops.



Eyedropper administration achieves sustained high drug levels throughout rabbit eye:

Aqueous humour = 930 ng/g	Retina = 2,175 ng/g
Choroid = 1,300 ng/g	Vitreous = 100 ng/g
Plasma 7 ng/mL.	<i>Drug binds to melanin</i>

Significant inhibition of laser-induced CNV lesion in mice treated daily or 2nd daily. Fluorescein fundus angiography (FFA) at Day 7 post-laser injury show significantly reduced fluorescein leakage intensity and lesion size. Also, significant reduction in neovascular area (IB4 staining). Effects equivalent to that of IVT aflibercept.

Pre-clinical.

- Dose-frequency response, with tid giving best outcome.
- No ocular abnormalities detected on slit-lamp examination
- No local irritation or inflammation when administered 3 times daily for 28 days consecutively.

BETA-TT8 **Ophthalmic Gel**

A first-in-class, eyedropper treatment for intra-ocular inflammation.

An alternative treatment for VEGF-inhibitors and steroids and their attendant side-effects.

FIH trial in treatment-naïve nvAMD patients commencing Q3 2026 in Australian sites

Subsequent studies being planned in:

- Diabetic retinopathies
- Uveitis (recurrent, anterior)



BETA-TT8 Oral

A first-in-class drug to treat inflammatory conditions associated with MEK/ERK dysfunction in brain and eye.

Readily crosses blood-brain barrier (1.0 v 2.3 AUC) and blood-eye barrier (1.0 v 1.2 AUC)

Mouse laser-induced CNV model (12 days treatment):
60 mg/kg Q2D = equivalent CNV anti-leakage to aflibercept
120 mg/kg QW = near-equivalent anti-leakage and anti-neovascular effects to aflibercept

- Extensive tissue distribution (V_{ss} . ~3.5L/Kg)
- Absorption-limited (flip-flop) kinetics
- Sustained tissue exposure (including eye and brain)
- Chronic dosing at 60 mg/kg Q2D and 30 mg/kg daily (in mice) safe and well-tolerated.



BETA-TT8 Oral

Potential oral systemic conditions of inflammatory conditions of the eye associated with systemic inflammatory diseases

Systemic inflammatory and autoimmune diseases frequently cause serious eye diseases by triggering immune-mediated damage to ocular tissues.

Common conditions include rheumatoid arthritis, lupus, IBD etc (scleritis), ankylosing spondylitis (uveitis), and multiple sclerosis (optic neuritis).

This association with eye diseases highlights the systemic nature of chronic inflammatory disease and the call for drugs able to deliver multimodal and comprehensive anti-inflammatory effects in a well-tolerated way.



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