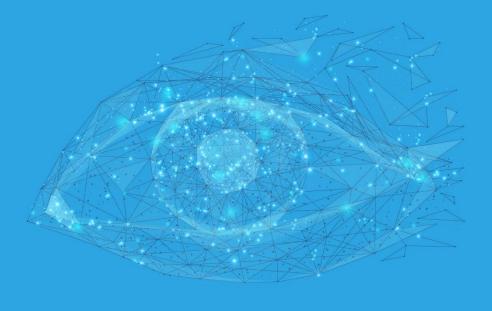
Tacrosolv

A new Tacrolimus solution against ophthalmic inflammation

December 2023





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Executive summary: Tacrosolv

Novel low dose, preservative-free eyedrops targeting ocular inflammation

Business model

- Classical license deal with downpayment, milestones and royalties
- Patent protected until 2036

Tacrosoly

- Low dose Tacrolimus formulation based on Marinosoly
- Preservative-free and clear solution
- Significant reduction of ocular symptoms after one week of treatment

Clinically proven

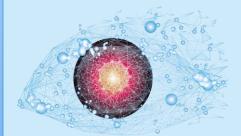
In a clinical phase IIa
 5µg/day Tacrolimus
 were effective

Line extension

- Severe allergic conjunctivitis
- Herpetic stromal keratitis
- Vernal keratoconjunctivitis

Safety

- Tacrolimus eyedrops are marketed in Japan and Korea at higher concentrations
- Preclinical safety of the formulation established



Attractive market

- Tacrosolv addresses the Dry Eye Disease market
- The market is strongly growing with a CAGR of 7% until 2030

Regulatory path

 Hybrid application in EU (Article 10(3), 2001/83/EC)



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Marinomed at a glance





Marinomed at a glance

Publicly listed biopharmaceutical company located in the Vienna region

2006 Foundation

2008Launch of Carragelose

2016

Invention of Marinosolv 2019

IPO and Marinosolv clinical validation

2021

Marinosolv deal and Solv4U launch

2022

Deal with
Procter & Gamble



Prime Market Segment of the Vienna Stock Exchange MARI:AV; ATMARINOMED6; MARI.VI

Therapeutic areas

VIROLOGY

Revenue-generating OTC portfolio

IMMUNOLOGY

High-value products in late-stage development



Solubilization technology partnerships for customers



Platforms & Therapeutic Areas



Universal blocking of viruses and allergens as well as moistening of mucosal tissues

Cough & cold portfolio Viral respiratory

infections

Allergy nasal spray Mild allergic rhinitis



Eye drops Dry, irritated eyes



Marinosolv®

Solubilization of poorly water-soluble compounds and improving local onset of action

Budesolv Allergic rhinitis



Tacrosoly Inflammatory eye diseases



Solv4U **Technology** partnerships



VIROLOGY

IMMUNOLOGY

SOLV4U



Tacrolimus: Highly potent macrolide immunosuppressant

A substance that could benefit so many more patients if solubilized

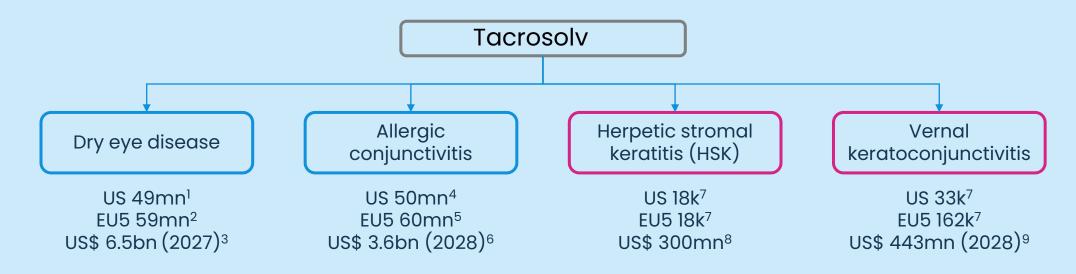
- Highly hydrophobic macrolide calcineurin inhibitor
- Immunosuppressive effect on T-cells and mast cells with indirect effects on many immune reactions
- ~100 times more active than Cyclosporine
- Steroids usually should not be used longer than three weeks and are not routinely used in chronic inflammatory situations
- Proof of concept by a Tacrolimus containing drug marketed against vernal conjunctivitis in Japan and South Korea
- No marketed product in ophthalmology available outside Asia*

Potential to treat a multitude of ophthalmic inflammatory diseases



Attractive ophthalmic market

Total target populations & market sizes



Common disease

Rare disease

All numbers reflecting patients, except US\$

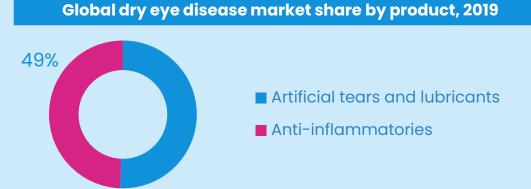
- 1 Paulsen AJ et al. Am J Ophthalmol 2014; 157:799e806
- 2 Ferrero A et al., Ocul Surf. 2018 16:112-119., Viso E et al., Ophthalmic Epidemiol 2009;16 Malet F, et al. Acta Ophthalmol 2014; 92:e429e36 Vehof J et al., Br J Ophthalmol 2014;98:1712e7. Vehof J, et al., Ophthalmology. 2017;124:505-511 Vehof J et al., Ocul Surf. 2021; 19:83-93.
- 3 Fortunebusinessinsights.com: Dry eye report, public information as of 12/2022
- 4 Fortunebusinessinsights.com: Allergic conjunctivitis report, public information as of 12/2022
- 5 Sources: Cibella FF et al., Allergy Asthma Immunol Res, 2015; 7:44-50 Klossek JM et al., Presse Med. 2009; 38:1220-9
- 6 Fortunebusinessinsights.com: Allergic conjunctivitis report, public information as of 12/2022
- 7 McCormick I et al.; Ophthalmic Epidemiology 2021; 8:1-1010
- 8 Internal calculation based on addressable patient numbers and estimated treatment costs
- 9 Coherent market insight: vernal keratoconjunctivitis market report, public information as of 12/2022



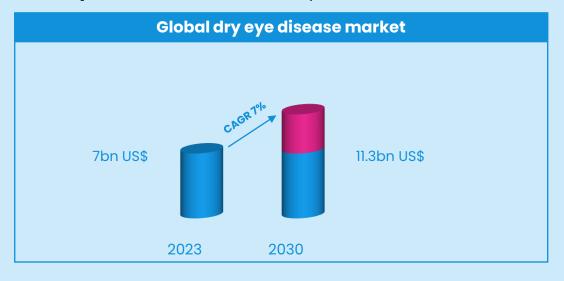
Dry eye disease market

Tacrosolv eye drops target an underserved multi-billion Dollar market

- Caused by either reduced production of tears or an increased evaporation of tears
- Symptoms: dryness, irritation, redness, fatigued eyes, and blurred vision
- Affects 360mn people with increasing prevalence due to growing use of screens and contact lenses increase in LASIK surgeries
- Up to 30% of the population is affected to some degree



- Markets expected to increase to \$11.3bn in 2027
- Largest market is the **US with \$3.1bn** in 2022
- Growth returning to pre-pandemic levels **CAGR 7%**
- Growth driven by huge unmet medical need and new products
- Competitors: Lubricants and pharmaceuticals





Tacrosolv: Exploratory phase 2a

Allergic conjunctivitis as model indication

Study	Demonstration of safety and efficacy of two doses of Tacrosolv
Location	Vienna Challenge Chamber, Austria
Enrollment	64 participants
Design	Double blind, placebo-controlled, randomized, crossover Continuous allergen challenge over 4 hours
Treatment	Tacrosolv eye drops, 50µg/ml solubilized Tacrolimus (0.005%), Placebo eye drops, (buffer + propylene glycol)
Treatment regimen	1 or 2 eye drops (50µl) for 8 days (0.005%)
Primary Endpoint	Total Ocular Symptom Score (TOSS ¹) on day 8 (12 max score), (baseline adjusted mean of TOSS during allergen challenge)
Secondary Endpoints	Change in ocular redness image score, Total Nasal Symptom Score (TNSS²), Total Respiratory Symptom Score (TRSS³), Nasal airflow
Ocular Safety Endpoints	Intra-ocular pressure, Cornea staining, Conjunctiva staining, Conjunctival chemosis, Eyelid edema, Conjunctival papillae

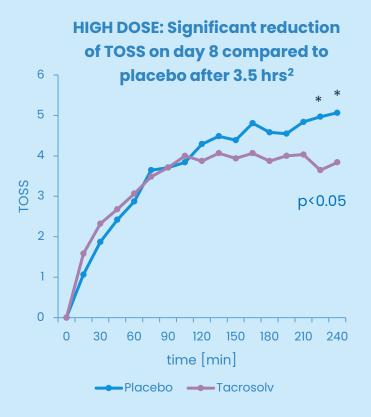


¹⁾ TOSS: ocular itching, watery eyes, ocular redness, gritty feeling 2) TNSS: nasal congestion, rhinorrhea, itchy nose, sneezing

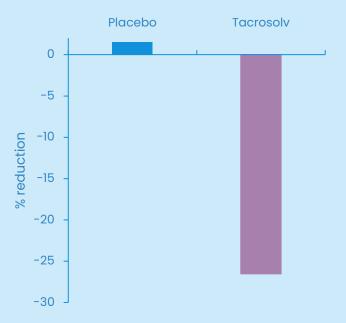
³⁾ TRSS: cough, wheeze, dyspnea

Tacrosolv solution (0.005%): Exploratory phase 2a

Anti-inflammatory activity in model indication allergic conjunctivitis¹



HIGH DOSE: 26% reduction of TOSS* on day 8 in Tacrosolv study group compared to day 12



Significant reduction³

- Ocular symptoms on day 8 of treatment compared to day 1
- Ocular symptoms after one week of treatment at 3.5 hours after challenge begin
- Nasal symptoms on day 8 of treatment



^{*}TOSS: total ocular symptom score: ocular itching, watery eyes, ocular redness, gritty feeling

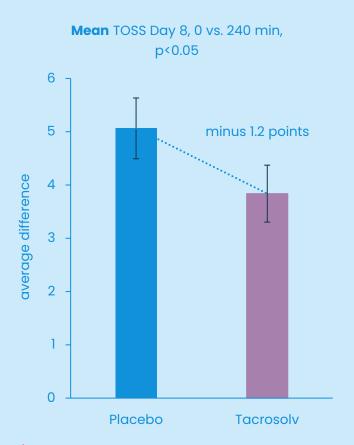
¹⁾ Data on file from phase II clinical trial sponsored by Marinomed

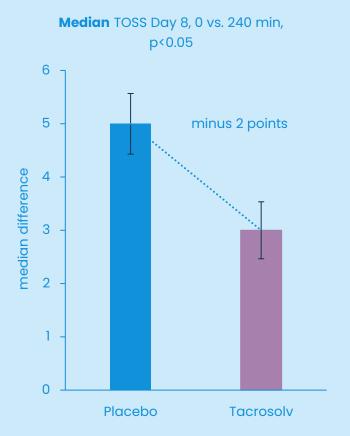
²⁾ Baseline corrected

³⁾ In higher dose group

Tacrosolv solution (0.005%): Exploratory phase 2a

Day 8 mean change from baseline TOSS under allergen challenge (high dose)





Difference of TOSS was calculated by subtracting TOSS at 0 minutes from TOSS at 240 minutes during continuous grass pollen challenge. Significance was tested with paired t-Test (nominal). n=31 (all groups in cross-over design). Baseline adjusted.



Background technology

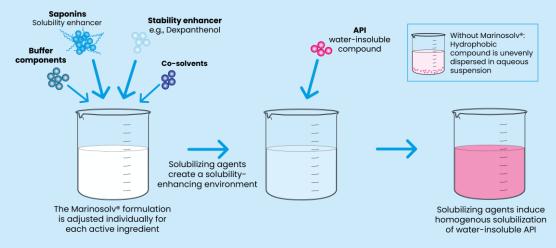
Marinosolv is a patent-protected technology to dissolve hardly soluble compounds

Tacrosolv formulation development

- Tacrosolv is a fully dissolved clear solution of Tacrolimus based on the Marinosolv technology platform
- Marinosolv is a combination of water-soluble solvent, saponins, stability enhancer, and buffer
- Marinosolv is particularly suited to increase the solubility and consequently the bioavailability of hydrophobic pharmaceutical ingredients
- Tacrosolv contains a significantly lower concentration of the active pharmaceutical ingredient compared to marketed products in Japan and Korea
- Tacrosolv is clinically tested and patent protected

Formulation technology

Marinosolv® formulation & solubilization of water-insoluble API



Marinosolv allows a complete dissolution of Tacrolimus

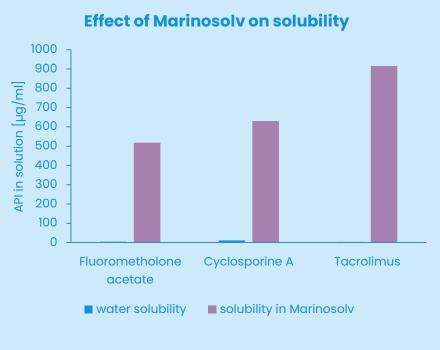


Tacrolimus: Suspension versus solution

Marinosolv allows 600-fold increased solubility of Tacrolimus¹









^{*} Picture does not show the original primary packaging; formulation was transferred into a glass vial for comparison purposes

Quotes from Medical Experts

Key opinion leaders confirm the medical need for fully solubilized Tacrolimus

"Tacrosolv could be a breakthrough."

Expert at Tufts University, Boston USA

Expert at Institut de la Vision, Paris **France**

Marinomed is in a "very good field of activity that is underappreciated," and "formulations are important."

"There is definitely a need for it. There is nothing compared with steroids in terms of safety and efficacy and that could be used as steroidsparing."

"You don't have to convince me that tacrolimus works."

Expert at Tufts

USA

University, Boston

Institute

Expert at University of Cologne, Cologne Germany

Expert at Wilmer Eye USA

"It is quite unheard of to have a signal of efficacy in just 8 days."



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