Carragelose eye drops for lubrication and beyond

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Executive summary: Carragelose eye drops

Lubricant eye drops to treat DED with a potential in viral keratoconjunctivitis





Licensing opportunities - overview

2 product licenses available

	1. Carragelose Dry Eye Relief	2. Carragelose Antiviral Eye Drops
Description Claims	 Sterile, preservative free ophthalmic solution in a multi dose container Unique & patent protected Shelf life: 3 years Approved claims: Relief of irritated and dry eye 	 Sterile, preservative free ophthalmic solution in a multi dose container Unique & patent protected Shelf life: 3 years Planned claims: Prophylaxis and Relief of
Launch timelines	 Regulatory status: Medical Device Class IIa (IIb under MDR) First Launch in EU: Austria Q3/2024 Possible first launch in other countries: Q1/2025 License available: global and territorial Private label possible 	 Planned Claims: Pophylaxis and Keller of irritations due to viral ophthalmic infection (keratoconjunctivitis, "pink eye disease") Planned Regulatory status: Medical Device Class IIb under MDR Estimated first Launch in EU: 2026/2027 Additional clinical study in planning License available: global, territorial Private label possible

Marinomed at a glance

Publicly listed biopharmaceutical company located in the Vienna region



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

Pipeline

Including late-stage projects with low risk and high upside potential

Pharmaceutical Products

Therapeutic area	Product Indication	Status	Pre-clinical	Phase I	Phasell	Phase III	Filing		
	MAM-1004-1/Budesolv Treatment of severe allergic rhinitis	Filing in preparation							
IMMUNOLOGY	MAM-1003-1/Tacrosolv Severe inflammatory eye diseases	Phase II clinical study							
	MAM-1004-2 Autoimmune gastritis	Pre-clinical							
VIROLOGY	MAM-2001-1/Carravin Nasal congestion	Filing in progress							
OTC Medical Devices									
Therapeutic area	Product Indication	Status	Pre-clinical		Clinical studies		Certification		
IMMUNOLOGY	MAM-1001-4 nasal spray Prophylaxis of mild allergic rhinitis	Pre-launch							
	MAM-1001-3 eye drops Dry, irritated eyes	Pre-launch							
VIROLOGY	MAM-1001-1/Inhaleen Viral pneumonia	Clinical studies				•			

⁵ Target market volume: 28% of total CCA market (topical decongestants, sore throat) as depicted in CHC Yearbook 2023, Nicolas Hall

⁶ Target market volume: 19% of total CCA market (allergy) as depicted in CHC Yearbook 2023, Nicolas Hall

Carragelose®

Protective layer against viruses and allergens – multi-use potential

Viral respiratory diseases

- Broadly-active against numerous respiratory viruses
- Clinically validated¹
- Marketed product portfolio in 40+ countries

HERMES



 Carragelose/Sorbitol combi shows significant decongestant effect in clinical trial¹

mucoadhesive properties • Eye drops: relief for dry eyes Active against several Adenoviruses⁴: prospective treatment for adenoviral

keratoconjunctivitis

Allergy

market

volume:

US\$ 5.7bn³

Carragelose has excellent

moisturizing and

Eye care

Eve care market volume:



CCA² market volume:

US\$ 36 bn³

US\$ 6bn⁶



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¹Publications available at: <u>https://www.marinomed.com/en/news/scientific-publications</u> ²CCA = Cough, cold & allergy

Cold

market

volume:

US\$ 10bn⁵

- ³ CHC Yearbook 2023, Nicolas Hall
- ⁴ Marinomed internal data



Carragelose



Carragelose® mode of action and benefits



Without iota- carrageenan: Virus / allergens interact with mucosal cell

Mode of action¹

- Carragelose non-specifically covers the mucosal surface and prevents binding of virus/allergen to the mucosa, thereby reducing the immune response without being pharmacologically active
- Carragelose is mucoadhesive and lubricating



With iota-carrageenan: Barrier prevents interactions of viruses and allergens

Carragelose (lota-carrageenan): effective, safe & patent protected

- Carragelose acts as active ingredient in Marinomed's Carragelose product line
- Favourable safety profile established in several clinical studies in >1000 participants and also proven in post market surveillance data (<1 adverse events/100.000 sold units)
- Global patent protection until 2036

Broadly effective against viruses and allergens with a high safety profile

¹Morokutti-Kurz M. et al. , Int J General Medicine (2021), 14: 5241, Grassauer et al., Virology Journal (2008), 5:107, Leibbrandt et al., PLOSOne (2010), 5:12

Carragelose® beyond Virus and Allergens

Excellent hydrating and mucoadhesive properties

- Carragelose is iota-carrageenan derived from red seaweed in pharmaceutical quality
- Carragelose is a new opportunity to treat dry eye disease
- Carragelose has the potential to be the first product targeting adenoviral keratoconjunctivitis
- Carragelose is the active ingredient of multiple marketed products in the indication common cold
- The use of Carragelose is patent protected by several patent families
- Additional IP exists with respect to preclinical and clinical data, production knowhow, stability data
- Favourable safety profile may be used in children from six years up, and by pregnant and breastfeeding women (GRAS Status with the FDA)



Carragelose® as eye lubricant

A high molecular weight polymer with moisturizing and mucoadhesive properties

- High molecular weight polymers, such as Carragelose, do not penetrate mucosa or skin
- Carragelose is known for an exceptionally high water uptake¹ and excellent water retention properties². Carragelose has all properties to ensure a pronounced aqueous layer.
- Carragelose forms soft gels in contact with water and can support the natural gel-forming oligosaccharide of the secreted mucins to build a stable mucous layer
- Stabilizes tear film



Alternative to hyaluronic acid with additional virus- and allergen-blocking properties

Carragelose eye drops

Eyeleen



Product characteristics:

- Regulatory status: medical device class IIa (EU, MDD), application for MDR (IIb) by end of 2023; valid CE mark under transition period until 2028 (MDD)
- Legal manufacturer: Hälsa Pharma GmbH, Lübeck (MDR certified)
- Notified body: Medcert Lübeck, Germany
- 3.2 mg/ml Carragelose[®]
- Volume: 10 ml
- **Prophylaxis and Therapy:** 3 x daily
- for adults and children 6y+



Claims in EU and product characteristics:

- Eyeleen is used for the relief of symptoms due to dryness of the eye
- Eyeleen is an ophthalmic solution, which forms a protective barrier on the ocular surface, this moisture film supports the body's natural defense mechanisms
- Eyeleen can be used as lubricant to prevent further irritation or to relieve dryness of the eye
- Eyeleen protects against excessive tear evaporation
- Eyeleen can be used during the day as it does not cause blurred vision
- Eyeleen can be used from age 6 years onwards

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Taraet

market

volume: US\$ 6 bn¹

Carragelose® – Broadly active virus blocker

These viruses infect the respiratory tract or the eye and may worsen diseases such as COPD or keratoconjunctivitis

Virus type	In-vitro data	In-vivo data	Clinical data
Corona virus (OC43, 229E)	\checkmark		\checkmark
SARS-CoV-2	\checkmark		\checkmark
Rhinovirus A and B	\checkmark		\checkmark
Influenza A virus: human pathogenic	\checkmark	\checkmark	\checkmark
Influenza A virus: bird flu	\checkmark	\checkmark	
Influenza B virus	\checkmark		√*
Respiratory syncytial virus	\checkmark	\checkmark	√*
Parainfluenza virus	\checkmark		√*
Metapneumovirus			√*
Adenovirus 2, 8, 19, 32, 37, 50	\checkmark		
Coxsackievirus A10	\checkmark		





Literature: Grassauer et al, 2008, Leibbrandt et al., 2010, Eccles et al, 2010, Fazekas et al, 2012, Ludwig et al, 2013, Könighofer et al, 2014, Morokutti-Kurz et al, 2015, Morokutti-Kurz et al. 2017, Graf et al 2018, Morokutti-Kurz et al, 2020 *patients were recruited, but low number

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