

DW-1002 licensee DORC announces decision to develop MEMBRANEBLUE-DUAL® in the US, received orphan drug designation from the US FDA for expedited review, etc.

SUMMARY

✳️ DWTI announced that it has updated its development pipeline (see below) on DW-1002 licensee Dutch Ophthalmic Research Center (DORC) announcing its decision to develop MEMBRANEBLUE-DUAL® in the US for the indication of ILM and ERM membrane staining during vitreoretinal surgery. Since the DW-1002 single-agent formulation TissueBlue™ was launched in the US in 2020, it has been used in over 100,000 surgeries and is preferred by over 40% of U.S. retinal surgeons. Combination ophthalmic surgical aid MEMBRANE BLUE-DUAL® (DW-1002 Brilliant Blue G + Trypan Blue) has been used in over 500,000 surgeries in Europe since its launch in 2010. Unlike in Europe, where the drug is treated as a medical device, in the US it is treated as a drug for regulatory purposes. The orphan drug designation is expected to provide preferential treatment, such as expedited review of mfg. and marketing authorization applications in the US and an extension of the exclusive marketing period after the launch of the product.

MEMBRANEBLUE-DUAL®

Features:

- MEMBRANEBLUE-DUAL® is a dye to stain both the ILM as well as the ERM and PVR membrane, without compromising the staining effect within one injection.
- By injecting MEMBRANEBLUE-DUAL® in the vitreous cavity the membrane will be clearly stained and easily distinguished from the underlying, unstained retina and can be removed selectively.
- MEMBRANEBLUE-DUAL® is a stable mix and stains the ILM at the same level as ILM-Blue® and stains the ERM and PVR at a higher level than the classic MembraneBlue.
- Due to a new integrated carrier 4% PEG solution, MEMBRANEBLUE-DUAL® can be injected in a BSS filled eye and sinks immediately as a cohesive ball to the fundus of the eye and only stains the targeted tissue without diffusion throughout the whole globe.

Specifications:

- Composition of one 0.5ml syringe:
- 0.125 mg • Brilliant Blue G
 - 0.75 mg • Trypan Blue
 - PEG • 4% PEG 3350
 - Density kg/l • 1,01

MEMBRANEBLUE-DUAL® dye for staining ILM, ERM & PVR membranes consists of:

- Combination of TrypanBlue 0,15% + BBG 0,025% + 4% PEG
- Highly purified TB + BBG - min 97% purity

Source: Dutch Ophthalmic Research Center (International) B.V. (DORC) website.
<https://dorcglobal.com/product/membraneblue-dual>

News Flash



D. WESTERN THERAPEUTICS INSTITUTE

Focus Points:

Drug discovery bio-venture with strengths in the kinase inhibitor mechanism and treatments for ophthalmic diseases such as glaucoma and ocular hypertension.

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DWTI Development Pipeline Progress Plan to Achieve Goals

Pipeline Name, etc.		Region	2022	2023	2024	2025
DW-1002	ILM staining	China		File for approval → Approval →	Launch	
	ILM staining ALC staining	Japan		File for approval →	Approval →	Launch
	ILM staining and ERM staining	US	New update		Application preparation	File for approval

Source: excerpt from July 24, 2023 press release "Notice Concerning Update of Business Plan and Growth Potential."

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