D. Western Therapeutics Institute | 4576

Sponsored Research
Jun 1, 2023

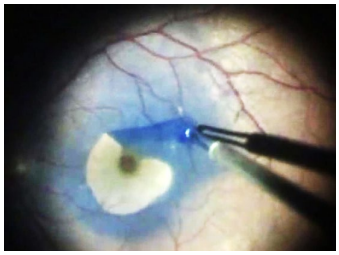
Sessa Investment Research

New drug application submitted to China's NMPA for approval of DW-1002 for ILM staining in vitreoretinal surgery

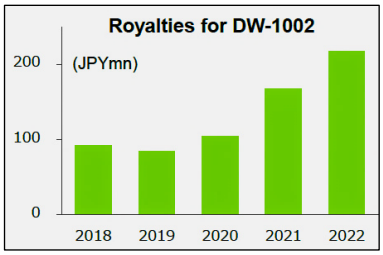
SUMMARY

- DWTI announced that out-license partner Dutch Ophthalmic Research Center (International) B.V. (DORC) has submitted a new drug application for approval of DW-1002 to the National Medical Products Administration (NMPA) of China for the indication of ILM staining in vitreoretinal surgery (May 30 local time). No milestone will be received as a result of this transaction, and there will be no change to the forecast of financial results for the fiscal year ending December 31, 2023.

- DWTI granted an exclusive sublicense for DW-1002 for all regions worldwide outside Japan to DORC, which has been manufacturing and selling the product in Europe and other countries since September 2010. Approved in the US in 2019, and launched in April 2020. Approved in Canada in 2021, and launched in October 2021. DW-1002 (ILM-Blue®, TissueBlue™, MembraneBlue-Dual®) is on sale in 76 countries and regions, including the US and Europe.



Source: Journal of Ophthalmology



News Flash

DWTI
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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Development Pipeline Plan

Products and Clinical indication		Region	2022	2023	2024	2025
H-1337	Glaucoma and ocular hypertension	US	Preparing for P2b	P2b		P3 *2025 or later
K-321	Fuchs endothelial corneal dystrophy	US	P2 P3	*Phase III study started in August 2022. Future plan undecided.		
DW-5LBT	Neuropathic pain after shingles	US		Re-application Approval	Launch	
DW-1001	Ophthalmic treatment agent	Japan	P1		P2	P3
DW-1002	ILM staining	China	★	Application Approval	Launch	
	ILM staining ALC staining	Japan		Application	Approval	Launch

Note: Development plans for out-licensed products are based on development plans of the licensees and the company's expectations. Hence, actual development progress may differ from the plan.
Development plan for regenerative cell therapy DWR-2206 will be released once finalized.

Source: excerpt from FY2022/12 4Q IR results briefing materials.

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