

## Investigational New Drug (IND) amendment submitted to the US FDA to commence H-1337 late-stage PIIb trials

### SUMMARY

- ❖ DWTI announced that it has submitted an Investigational New Drug (IND) amendment to the US FDA to commence late-stage Phase 2b clinical trials for H-1337 glaucoma and ocular hypertension treatment (Dec. 15 local time). The study will be a multicenter, randomized, double-blind, active-controlled, dose-finding study investigating the efficacy and safety of H-1337 in patients with glaucoma and ocular hypertension. The study will enroll 200 patients, with top-line data expected in the 2H of 2023.
- ❖ H-1337 is multi-kinase inhibitor that inhibits various protein kinases, chiefly leucine-rich repeat kinase 2 (LRRK2), for the treatment of glaucoma and ocular hypertension. Animal studies and other tests have confirmed that it has the effect of lowering intraocular pressure, attributed to its new mechanism of action. In 2018, DWTI carried out in-house Phase I/IIa clinical trials in the US, and safety and efficacy were confirmed (clinical PoC was obtained). For DWTI, this is the first foray into late-stage clinical development.
- ❖ Prostaglandin analogues (PGs) demonstrate the strongest IOP pressure-lowering effect among first-line drugs, however, PGs also have little to no effect on many patients, and more than half of drug-treated patients use multiple medications. First-line drugs have little to no effect on a surprisingly large number of patients, and single-drug treatment has shown limited efficacy. Multiple-drug treatments are standard (3–4 drugs used in some cases); however, side effects are more common when using multiple drugs.
- ❖ **H-1337 has strong prospects as “first choice as a second-line Glaucoma drug.”** DWTI estimates the target market for 1) patients who do not respond to first-line drugs and 2) patients who receive multiple drugs and suffer side effects is up to a maximum 40% of the estimated US market of \$3 billion.

### News Flash



#### Focus Points:

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

#### Chris Schreiber CFA

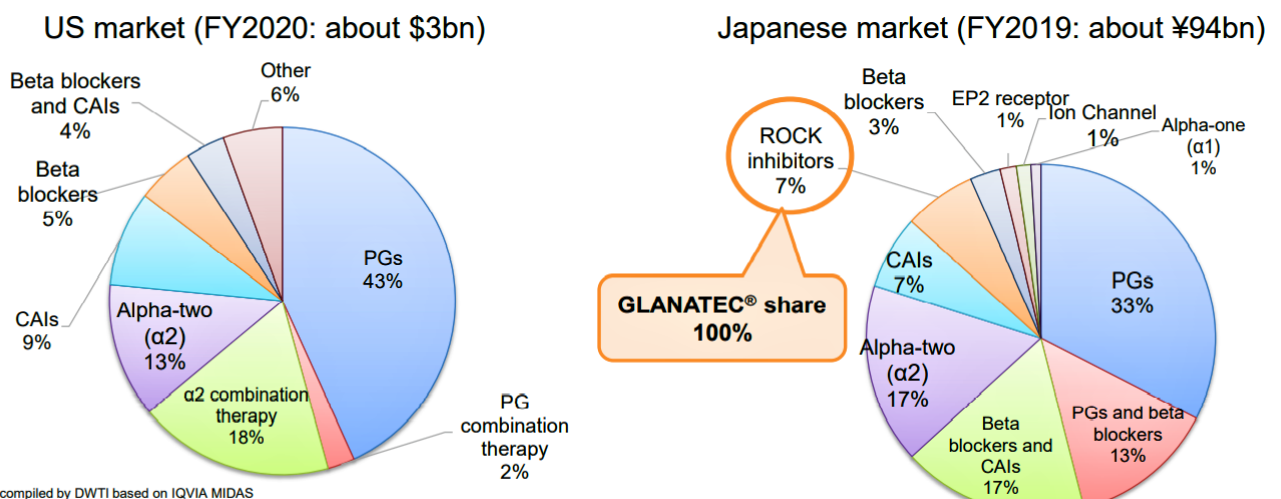
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### Estimated Glaucoma treatment markets in the US and Japan



Source: Classified and compiled by DWTI based on IQVIA MIDAS  
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Source: Calculated by DWTI based on the 6th NDB Open Data released by Japan's Ministry of Health, Labour and Welfare

Source: excerpt from DWTI Q2 FY22/12 IR results briefing materials.

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