Receipt of Complete Response Letter from FDA for STN1011700

Santen Pharmaceutical Co., Ltd.

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Imagine Your Happiness

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CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

“Exploring the secrets and mechanisms of nature in order to contribute to people’s health” *

WORLD VISION

Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

* Santen’s original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius.

Identified the Unresolved Issue Preventing Approval in Nov. 2021

Japan time

2021/10/20: As follow up to final query on NDA, Santen requested meeting with FDA, which was granted

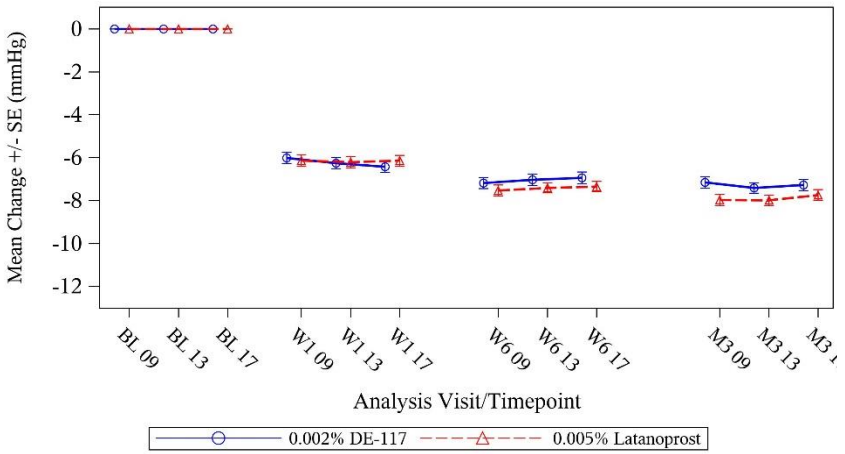
2021/11/2 : Meeting with FDA

FDA shared that non-compliance with GMP regulations at the contract commercial manufacturing sites (unresolved FDA inspection observations) prevented approval of NDA (details were not disclosed)

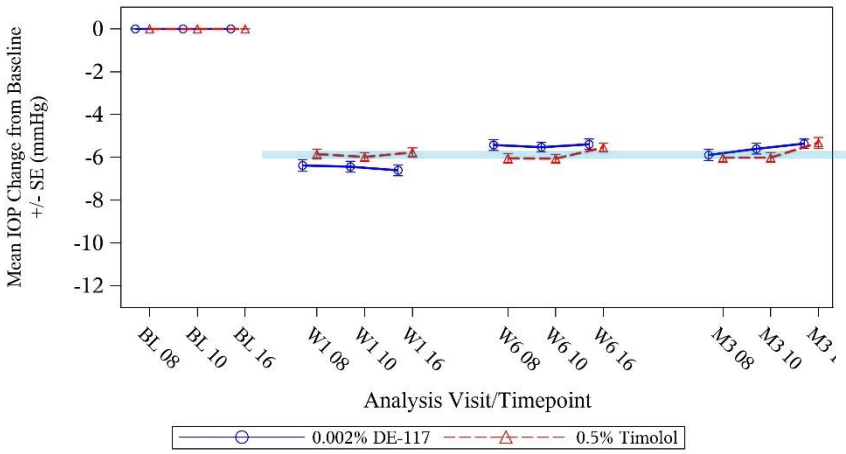
2021/11/10: CRL received

U.S. NDA Included Three Phase 3 Studies, Two of Which Demonstrated Statistically Significant Non-inferiority, Thus Meeting Requirements for FDA Approval

PEONY ✓



Spectrum-4 ✓



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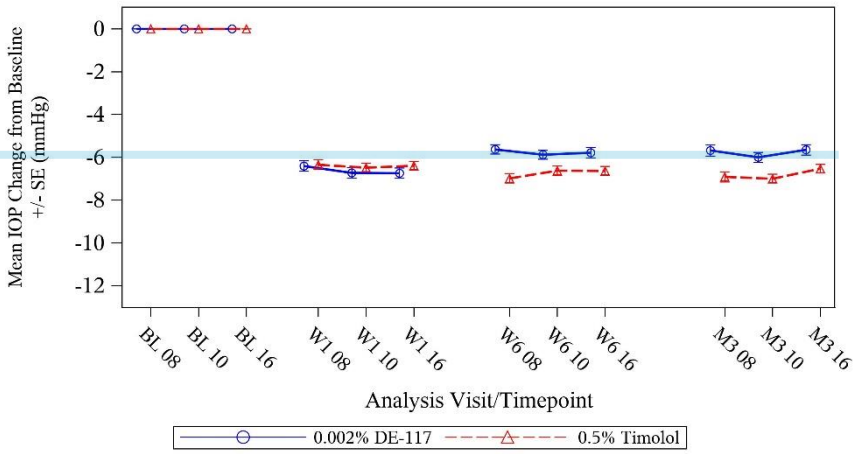

No additional pivotal studies are needed for approval

Re-printed from Q1 FY2021 presentation.

GMP Issues at Contract Manufacturing Sites Must be Resolved for NDA Resubmission

- **The unresolved inspection observations (GMP non-compliance) at the contract commercial manufacturing sites <u>MUST BE RESOLVED</u>**

  (The observations are ordinary issues during inspections for other company's products and that impacts the reviewing of STN1011700)

- To continue the communication with FDA for resubmission, including some other matters

Aiming for resubmission as rapidly as possible in cooperation with FDA and contractors

Status Planned to be Updated at Financial Results Meeting in Feb, 2022

To Continue communication with contractors in the followings after FDA shared the information;

- ✓ **Response to the observations from the FDA**
- ✓ **Possibility of inspections**
- ✓ **Inspection timing**

Takeaway

Santen's action

- Continue communication with FDA, aming for quick resubmission
  (Continue effective communication with FDA regarding the GMP status of the contract commercial manufacturing sites, in order to ensure resolution of the non-compliance, GMP issues and subsequent NDA approval)

Impact on MTP2025

- **No change on strategies and initiatives of MTP2025**
- Minimize the influence on U.S. business by maximizing the value of existing products (Eyevance products, *Verkazia* and others)

Appendix

Today's Announcement

Santen and Ube Industries receives Complete Response Letter from FDA for STN1011700/DE-117

https://www.santen.com/en/news/2021_2.jsp

STN1011700 (DE-117)

Generic name: Omidenepag isopropyl
Indication: Glaucoma, ocular hypertension
MOA: EP2 receptor agonist

Current status outside U.S. (as of October, 2021)

Region	*Development Status*
Japan	Launched (November, 2018)
Asia	Launched (since February, 2021) Launched: S. Korea, Taiwan, Thailand Approved: Singapore, Malaysia