U.S. FOOD & DRUG ADMINISTRATION

Ophthalmic Devices Panel of the Medical Devices Advisory Committee Meeting

March 21, 2024

DENXXXXX2:
BALANCE OPHTHALMICS
FSYX™ OCULAR PRESSURE ADJUSTING PUMP
(FSYX OPAP)

FORMERLY: MERCURY MULTI-PRESSURE DIAL (MPD) SYSTEM
UNDER DENXXXXX1

Mira Sethi
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FDA/CDRH/OPEQ/OHT1

March 21, 2024

FDA Review Team

Type	Name	Home
Lead Reviewer	Mira Sethi	OPEQ/OHT1/DHT1A/THTA4
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Vision Science	Bruce Drum, PhD	OPEQ/OHT1/DHT1A/THTA4
Statistics	Tianyu Bai, PhD	CDRH/OCEA/DCEA2/TCEA2B
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De Novo

- FSYX OPAP is eligible for De Novo classification:
  - Device does not fit into any existing Class I/II regulation
  - Device does not fit into existing Class III regulation
  - No approved PMAs for the same device

- Granting De Novo request requires determination of reasonable assurance of safety and effectiveness
  - Determine if probable benefits of the device outweigh probable risks to health
  - Determine what regulatory controls are needed to mitigate risks
    - General and special controls
    - Includes clinical testing, non-clinical testing, information in labeling, and other requirements

Device Description

The FSYX OPAP consists of the following components:

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- Eye goggles
  - Separate tubes attached to each eye-piece for creating and monitoring the negative pressure for independent treatment of each eye

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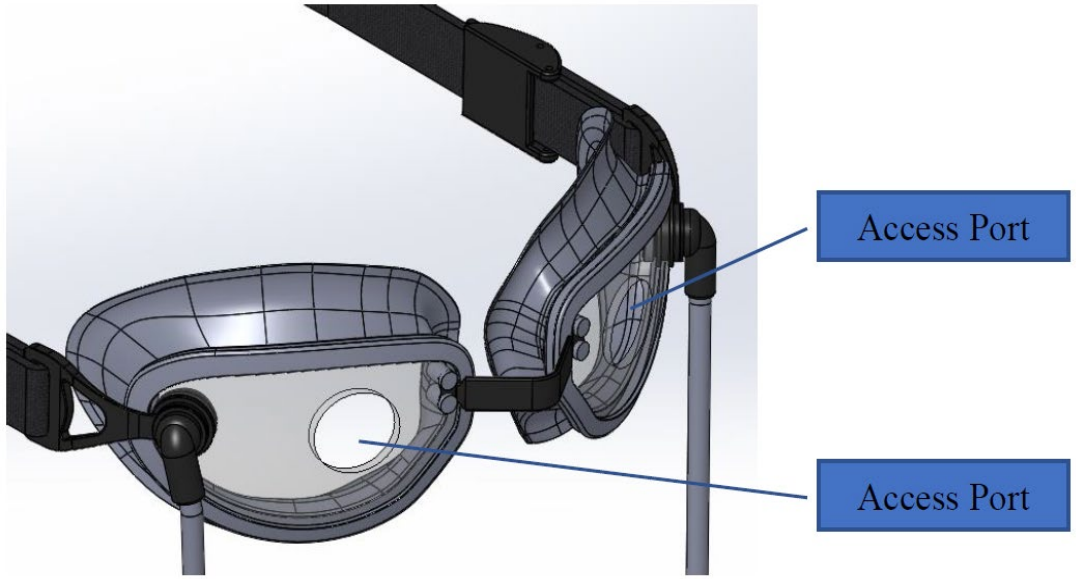
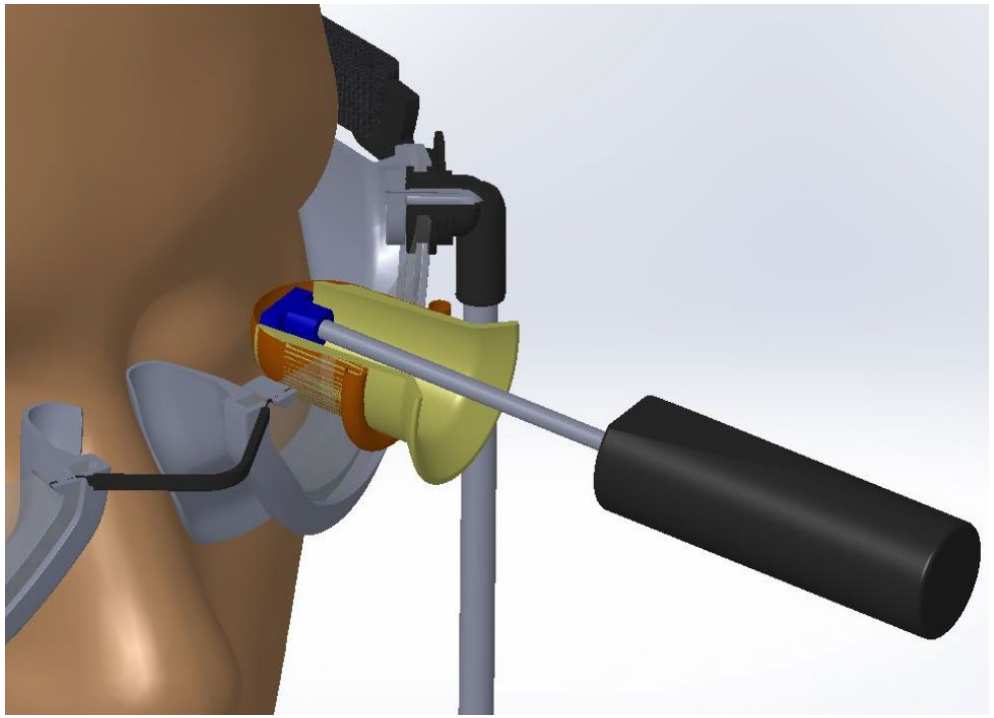
- Eye goggles
  - Separate tubes attached to each eye-piece for creating and monitoring the negative pressure for independent treatment of each eye

- Programmable pressure-modulating pump
  - 2 mini diaphragm pumps for creation of negative pressure levels independently for each eye
  - Pumps can exert up to –40 mmHg relative to atmospheric pressure but are limited to –20 mmHg for clinical purposes.

These two components are mechanically and pneumatically connected via the tubing system

Excursion Goggles





Proposed Indications for Use

DENXXXXX2/SXX1: The FSYX™ Ocular Pressure Adjusting Pump (FSYX OPAP) is indicated as **adjunctive therapy** for the reduction of intraocular pressure **during nightly use** in adult patients with open-angle glaucoma and intraocular pressure **≤ 21 mmHg.**

Glaucoma

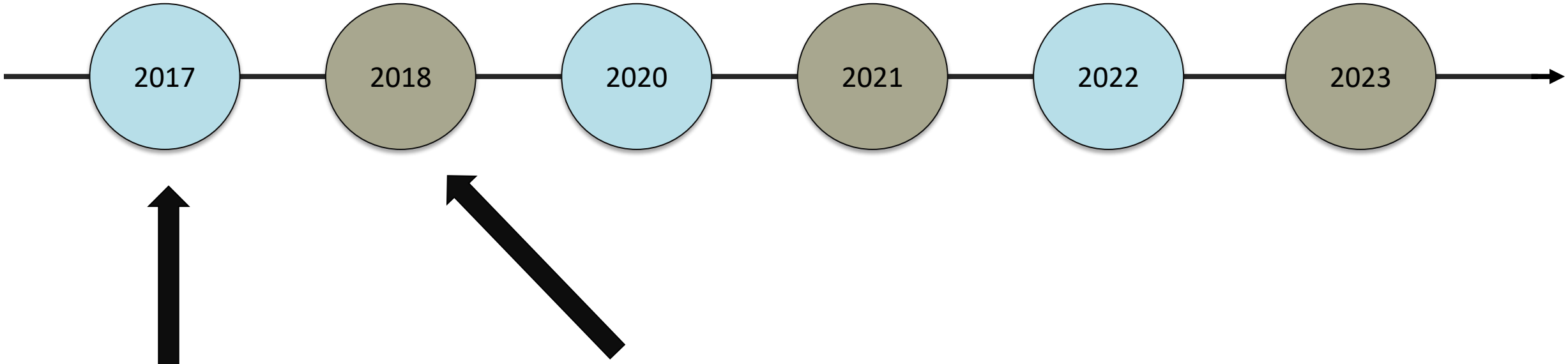
- Glaucoma is a group of eye diseases that damages the optic nerve of the eye[1]
- Currently available treatments for glaucoma are designed to reduce Intraocular Pressure (IOP)[2-4]:
  - Topical and oral medications
  - Drug-eluting implants
  - Laser and surgical treatments
  - Permanent implants

1. NEI, 2015.
2. FDA PMA Database
3. FDA 510(k) Database
4. FDA Drug Database

Rationale for Meeting

- **To solicit Panel's opinion on whether the probable benefits of the device outweigh the risks to health:**
  - Proposed Indications for Use (IFU):
    - The FSYX™ Ocular Pressure Adjusting Pump (FSYX OPAP) is indicated as adjunctive therapy for the reduction of intraocular pressure during use nightly use in adult patients with open-angle glaucoma and IOP intraocular pressure ≤ 21 mmHg.

Regulatory History



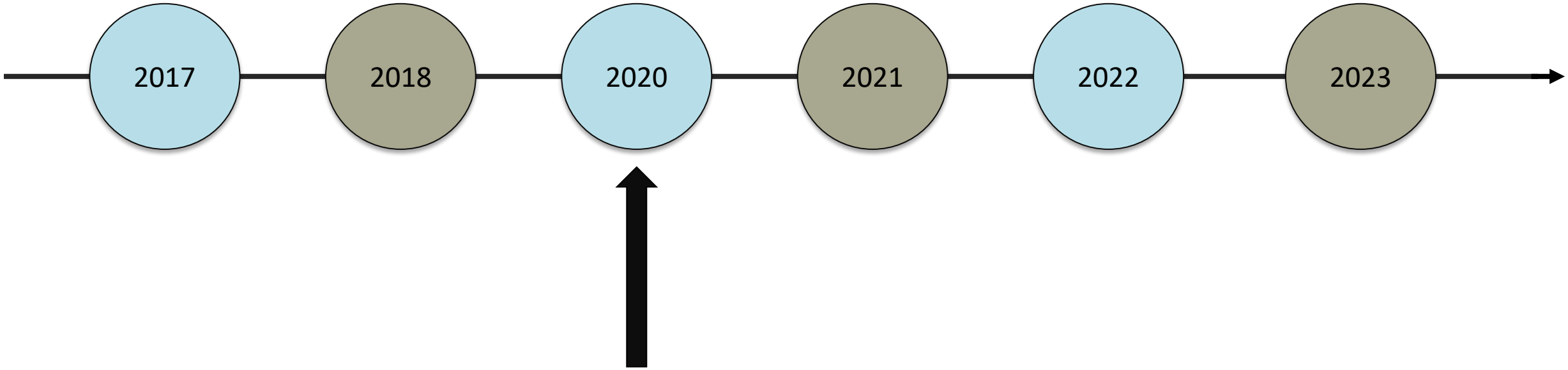
September 8, 2017- QXXXXX1

- Introduction of the Equinox Balance Goggles System (BGS)
- FDA recommendation to submit a De Novo request

April 3, 2018- QXXXXX1/SXX1

- Provided:
  - Bench testing
  - Human factors test plan
  - Clinical trial study design

Regulatory History



June 1, 2020- DENXXXXX1

- IFU: “The Mercury Multi-Pressure Dial System is indicated for the reduction of intraocular pressure in adult patients with **suspected glaucoma, ocular hypertension, or open angle glaucoma**.”
- Introduction of the CP-X10 clinical study

CP-X10 (Apollo Study)

- Prospective, multicenter, 90-day trial of patients with ocular hypertension (OHTN), diagnosis of “glaucoma suspect,” or open-angle glaucoma (OAG)
- Randomization and control: One eye to OPAP; fellow eye to OPAP with zero negative pressure (control)
- Primary effectiveness endpoint: % Eyes at the Day 90 with IOP reduction ≥20% **during device use**
- No formal safety endpoints

Apollo (CP-X10) Results

- Participants:
  - 91 enrolled;
  - 64 (70.3%) underwent randomization and completed Day 90 visit
    - 66% OAG; 25% OHTN; 9% GS
- Number of days/month with device use- 24.8 – 27.3
- Duration of use at Day 60-90 = 4.4 hours (range 1.22 – 9.78)
- Effectiveness:
  - Primary effectiveness endpoint met– 52/64 (81.3%) study eyes and 2/64 (3.1%) control eyes (p-value < 0.001).
  - Exploratory endpoint – Mean % change in GAT IOP before vs. after device use
    - -5.7% study eyes vs. -4.8% control eyes

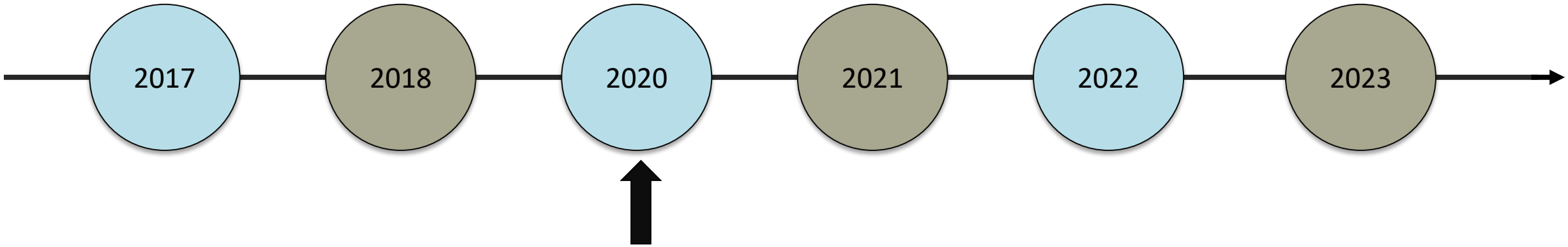
Apollo (CP-X10) – Safety Results

Ocular and periorbital AE or finding	Study eyes (N=64)			Control eyes (N=64)		
	# Reports	# Eyes	%Eyes	# Reports	# Eyes	%Eyes
BCDVA loss ≥10 letters	2	2	3.1%	2	2	3.1%
VF change: MD loss ≥2.5 dB (Day 60, 90)	11	11	17.2%	11	11	17.2%
Lid edema	11	11	17.2%	5	5	7.8%
Dry eye	5	4	6.3%	3	3	4.7%
Eye pain	3	3	4.7%	0	0	0%
Conjunctival hyperemia	3	3	4.7%	3	3	4.7%
Periorbital edema	9	9	14.1%	7	7	10.9%
Periorbital pain, sensitivity, or contact dermatitis	1	1	1.6%	1	1	1.6%

- Non-ocular AEs – 21.9%
  - Headache – 10.9%*

    *All OAG
  - Difficulty sleeping – 1.6%

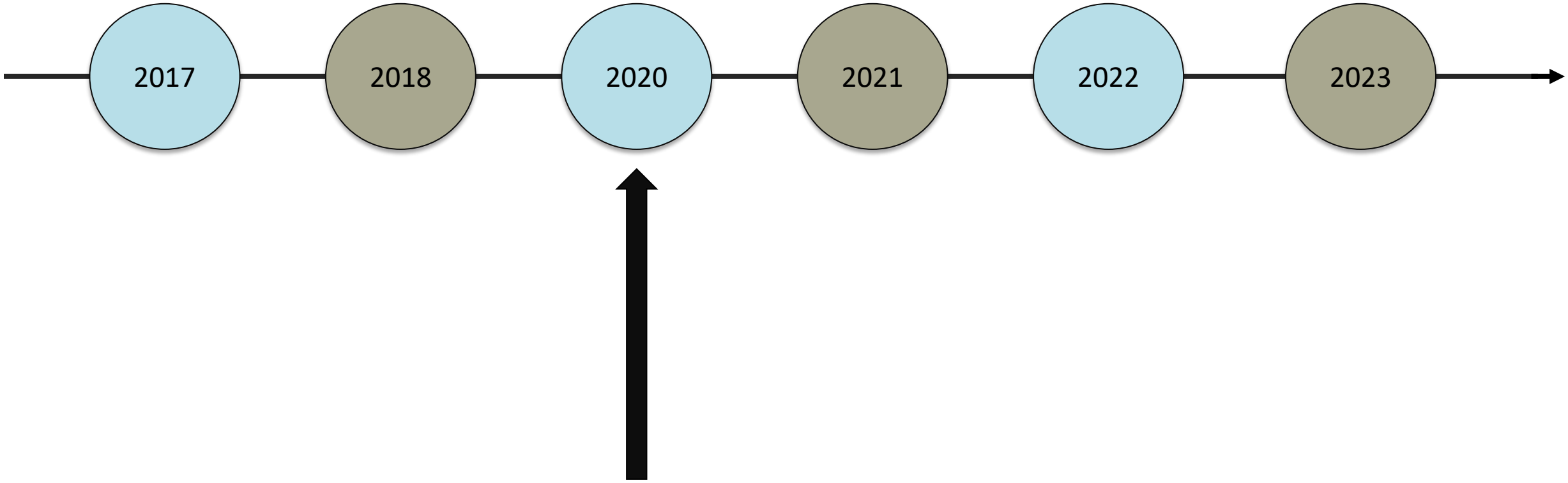
Regulatory History



DENXXXXX1: Deficiency Letter (August 14, 2020)

- Clinical concerns:
  - Insufficient data to support proposed IFU:
    - *The Mercury Multi-Pressure Dial System is indicated for the reduction of intraocular pressure in adult patients with suspected glaucoma, ocular hypertension, or open angle glaucoma.*
  - Safety concerns
  - Unclear benefit of temporary IOP lowering
  - Programming of the device & unclear dose-response relationship
- Non-clinical concerns
  - Additional validation for the excursion goggles
  - Other non-clinical testing

Regulatory History

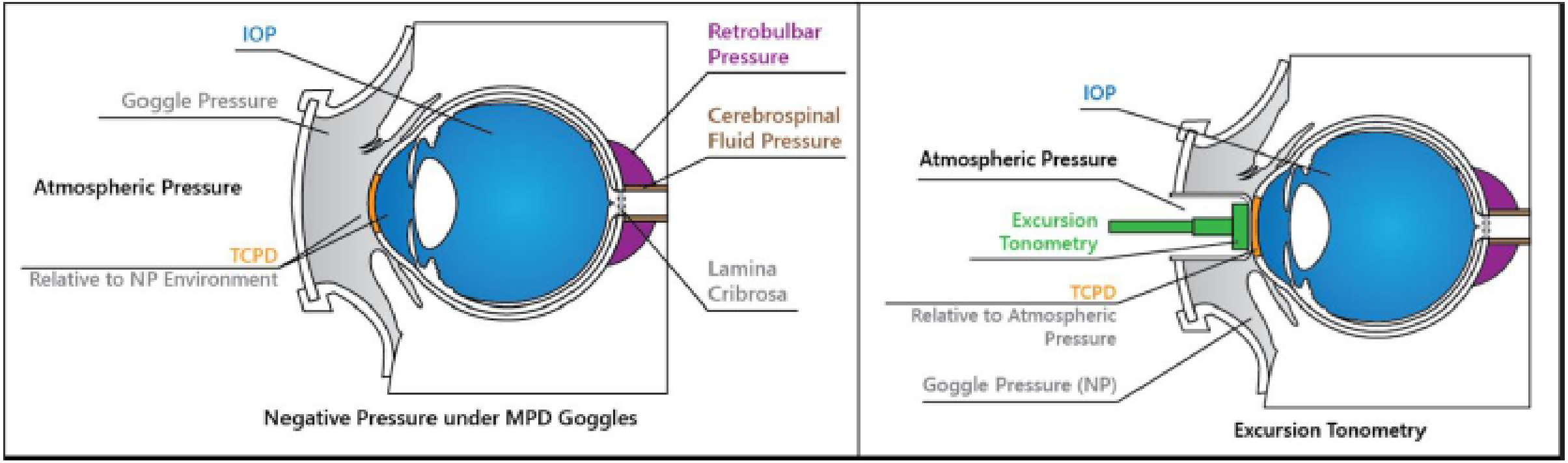


November 17, 2020- DENXXXXX1/S001

- IFU: “The Mercury™ Multi-Pressure Dial System is indicated for the reduction of intraocular pressure, **during use**, in adult patients with suspected glaucoma, ocular hypertension, or open-angle glaucoma.”

Measurement of Intraocular Pressure (IOP)

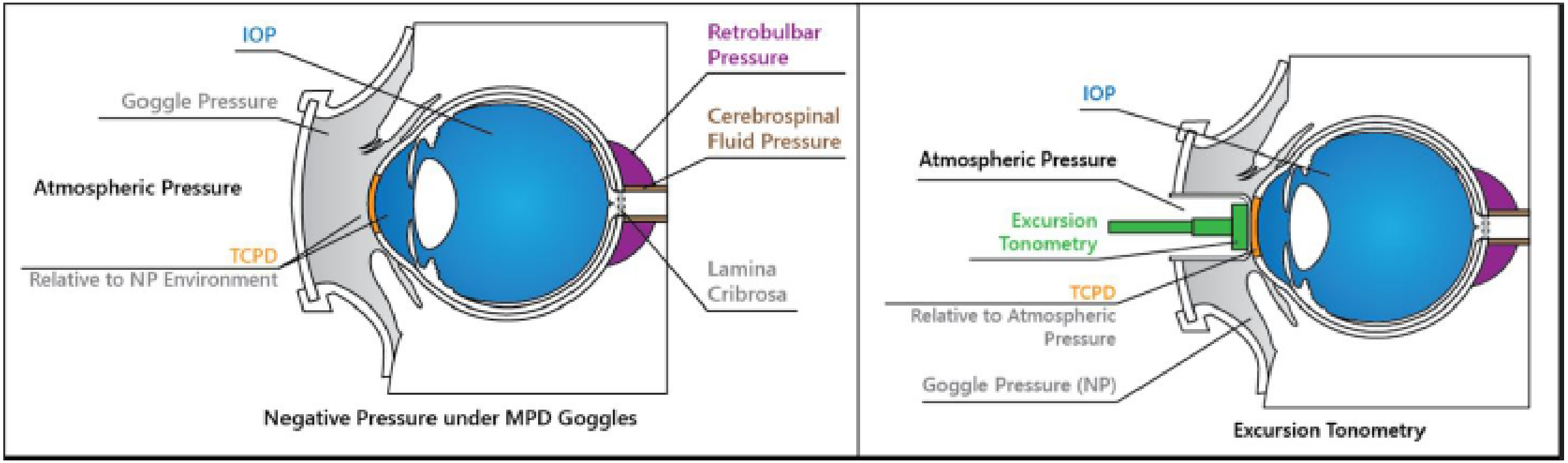
Figure 1 – Specification of Different Pressures



Transcorneal pressure difference (TCPD)

Definition of IOP

Figure 1 – Specification of Different Pressures

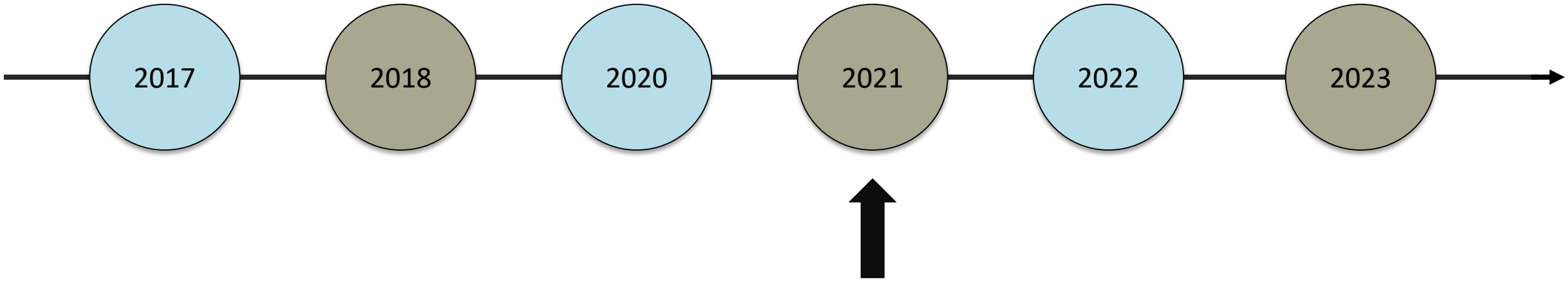


Transcorneal pressure difference (TCPD)

Ethier CR; Yoo P; Berdahl JP, Experimental Eye Research, 2020.

Sit, Arthur, Editors Selection, International Glaucoma Review, Issue 21-1.

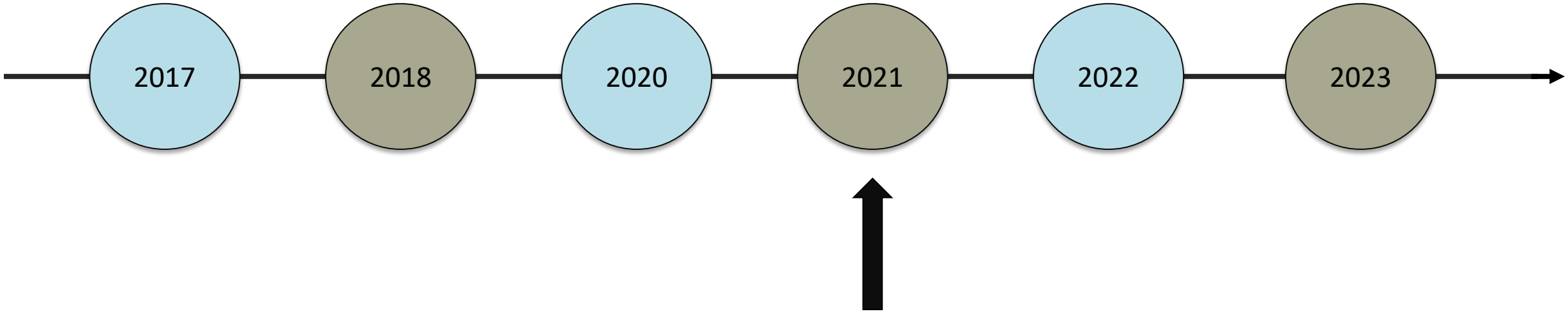
Regulatory History



DENXXXXX1/S001: Second AINN Letter (January 6, 2021)

- Potential glaucoma worsening in some of the participants
- Absence of data demonstrating safety and effectiveness of long-term use of the device
- Inadequate discussion of the benefit of temporary reduction of IOP during nightly device
- Observation of TCPD increasing during device use
- Distention of ocular tissues
- Requested non-clinical testing to establish whether NP application may increase stresses on other ocular tissues

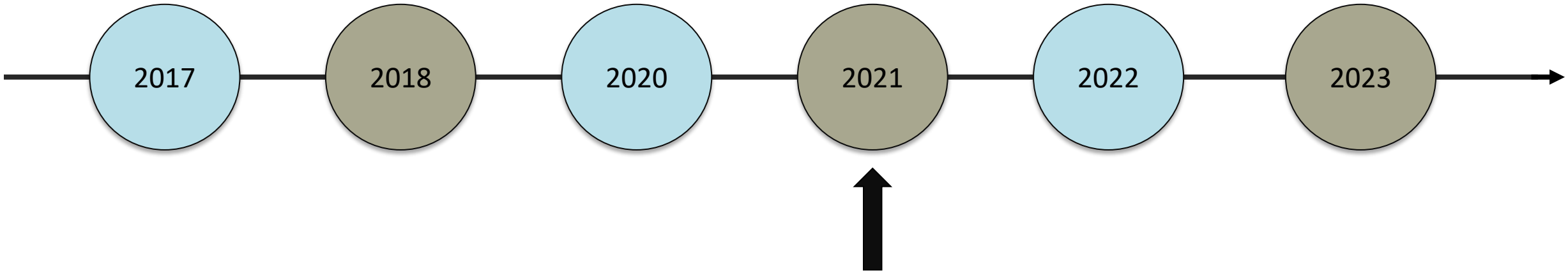
Regulatory History



February 19, 2021- QXXXXX3

- Discussion Items:
  - Proposed different terminology to clarify the definition of IOP
  - Preliminary data from several studies to demonstrate pressure decrease inside the eye
  - Increase in TCPD
- FDA Feedback
  - Recalculate the IOP data collected based on the TCPD definition

Regulatory History



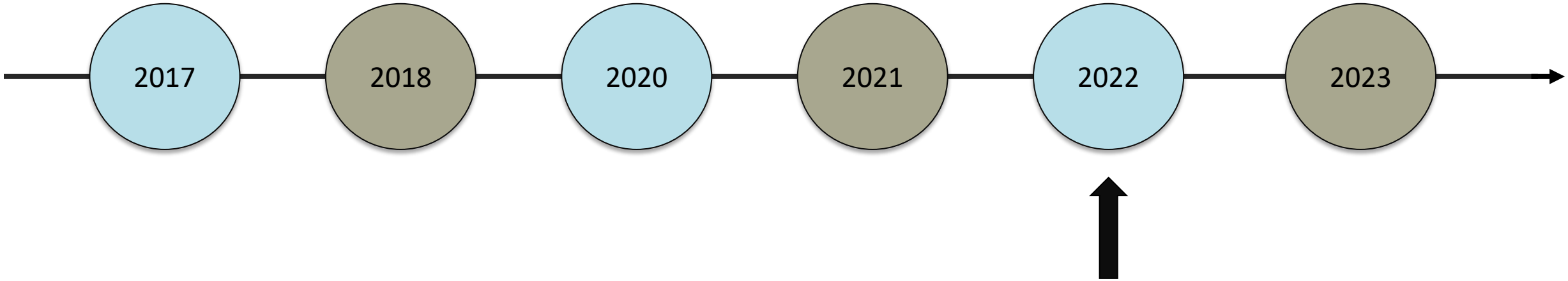
August 17, 2021- DENXXXXX1/S002

- IFU Modified – restricted to patients with OAG
- TCPD **increases** between **21.7 to 26.9%** across all study visits
- Ancillary Studies Provided:
  1. Living donor model
     - 2 subjects; application of NP for 2 minutes
  2. Full body cadaver model
     - 2 eyes of 2 cadavers
  3. Evaluation of intraocular blood flow via laser speckle flowgraphy
     - 7 glaucoma eyes; 22 healthy eyes; application of NP for 5 minutes
     - Need to validate accuracy of measurement and validity as surrogate
  4. OCT/OCTA imaging

DENXXXXX1/S002- Decline

- Effectiveness:
  - Outstanding concern that excursion measurement of pressure decrease in the eye is not correlated to clinical benefit in light of increase in TCPD
  - Significant limitations to the ancillary studies
- Safety:
  - Inadequate assessment of glaucoma progression
  - Outstanding concerns of deformation to lamina cribrosa and increased stress at ONH during NP application
  - Inadequate long-term data for labeled wear time
- Unclear Benefit/Risk:
  - Short, 90-day trial design would not address long-term safety concerns (i.e., progression of glaucoma, long-term lowering of IOP)
  - Small sample size of 50 OAG participants
  - Inadequate characterization and investigation of probable anterior segment risks resulting from TCPD elevation

Regulatory History



January 4, 2022- QXXXXX4
Purpose: “to obtain input from the Agency, and its Network of Experts (NoE), to align on evidence (i.e., empirical data and test methods for data collection) needed to address the questions in the denial letter and further demonstrate that the benefits of the MPD outweigh the risks for the proposed indication for use (IFU).”

Special Government Employee (SGE) Agency Directed Assignment

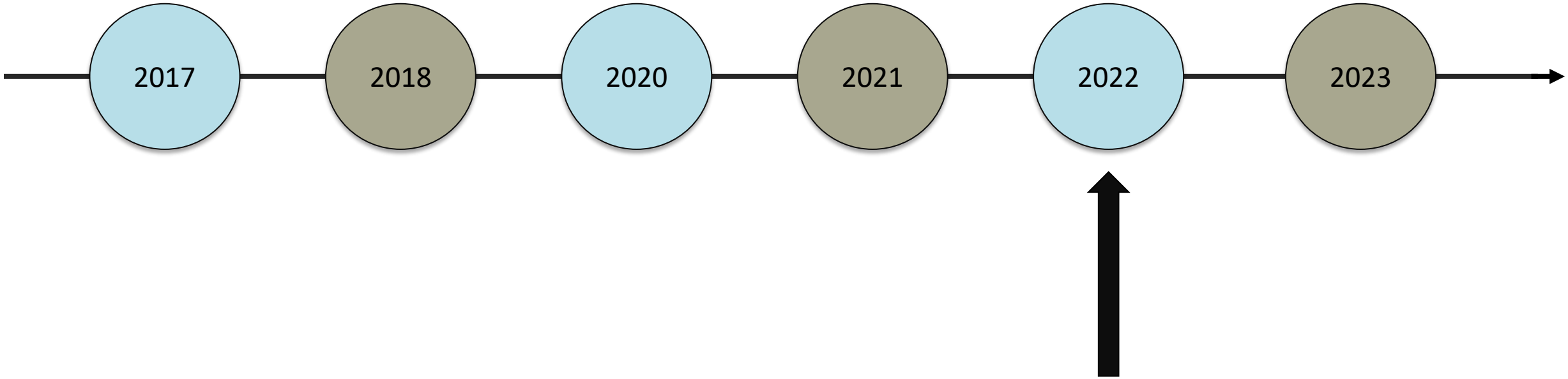
Questions

- Appropriate assessments for both safety & effectiveness
- Appropriate terminology for IFU
- Given documented increase in TCPD from device's MOA, are there safety concerns that were not identified in 90-day pivotal trial (e.g., worsening of glaucoma, narrowing of angle or damage to ocular tissue & structures in the eye)
- Proposed 12-month study to address safety concerns
- Proposed directions for use (dose-response relationship concerns)

Recommendations

- Effectiveness
- Safety

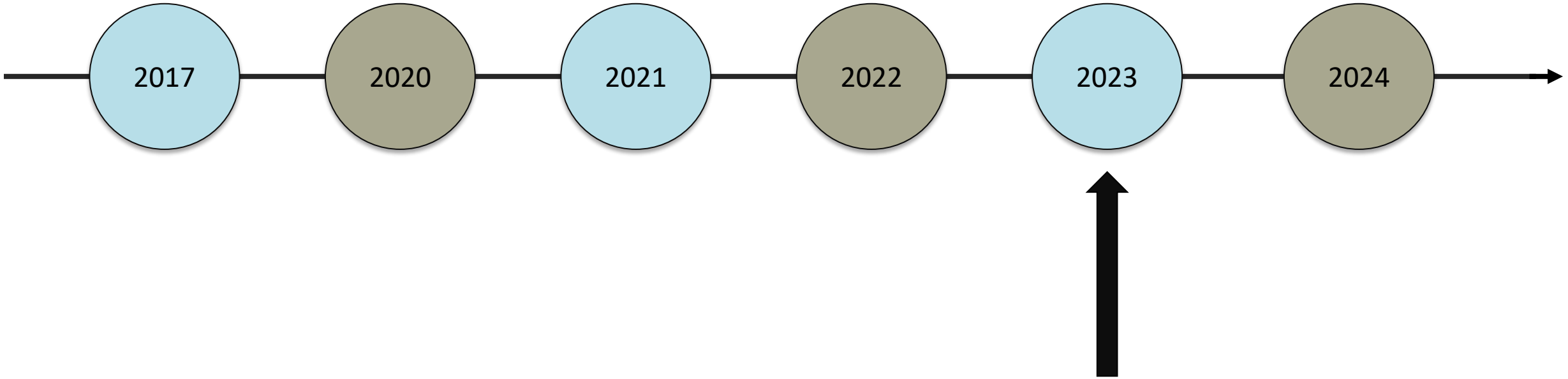
Regulatory History



June 16, 2022- QXXXXX4/SXX1

- **Revised IFU:** "The Mercury™ Multi-Pressure Dial System is indicated as **adjunctive therapy** for the reduction of intraocular pressure**, relative to atmospheric pressure**, during use in adult patients with open-angle glaucoma."

Regulatory History



August 25, 2023- DENXXXXX2

- **Revised IFU:** "The FSYX™ Ocular Pressure Adjusting Pump (FSYX OPAP) is indicated as **adjunctive therapy** for the reduction of intraocular pressure **during use** in adult patients with **open-angle glaucoma** and **IOP ≤ 21 mmHg.**"

Non-Clinical

- Biocompatibility
- Sterilization, Packaging, and Shelf-Life
- Software/Firmware & Cybersecurity/Interoperability
    - Ongoing
- EMC, Wireless, Electrical, Mechanical, and Thermal Safety & Risk Analysis
- Human Factors
- Bench Testing

DENXXXXX2:
BALANCE OPHTHALMICS
FSYX™ OCULAR PRESSURE ADJUSTING PUMP
(FSYX OPAP)

FORMERLY: MERCURY MULTI-PRESSURE DIAL (MPD) SYSTEM
UNDER DENXXXXX1

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FDA/CDRH/OPEQ/OHT1

March 21, 2024

Clinical Data Submitted

- Artemis study (Protocol CP-X19) – Pivotal study
- Apollo study (Protocol CP-X10) – DENXXXXX1
- 10 pilot and feasibility studies
- CONFIRM study (Protocol CP-X24)

Artemis Study (Protocol CP-X19)

- Title: “Negative Pressure Applied by the FSYX™ Ocular Pressure Adjusting Pump (OPAP) as an Adjunct Therapy for Lowering Intraocular Pressure in Subjects with Normal Tension Glaucoma (The Artemis Study)”

- Objective: “To evaluate the safety and IOP-lowering effectiveness of the Multi-Pressure Dial (OPAP) with negative pressure (NP) application as an adjunct treatment for patients with normal tension glaucoma (NTG).”

Artemis: Study Design

- Prospective, multi-center, evaluator-masked study at 11 sites
- Duration of follow-up – 52 weeks
- Adults with “normal tension glaucoma” and no documented unmedicated IOP >21 mm Hg in either eye recruited
- Randomization – One eye (study eye) randomized (on Day 0) to treatment with negative pressure (NP) on, fellow eye (control eye) randomized to no NP
- Key IOP assessments performed through “excursion goggles” using pneumatonometry

Artemis: Endpoints

- **Effectiveness:**
  - **Primary effectiveness endpoint –** %Eyes with Week 52 in-clinic IOP reduction ≥20% during NP application as compared to before NP
  - **Secondary effectiveness endpoint –** %Eyes with Week 52 sleep-lab IOP reduction ≥20% during NP application as compared to before NP
- **Safety:**
  - No formal safety endpoints
  - Outcomes: BCDVA loss ≥10 letters, AE rates, SLE findings, IOP by GAT, VFs

Artemis Visit Schedule

- 2-week “run-in” phase
- Randomization at Day 0 visit
- Two sleep lab visits
- 5 office visits after randomization

Artemis: Enrollment

- First participant screened on January 22, 2020.
- 165 participants were enrolled
- 94 participants were randomized
  - 1 was found ineligible after randomization
- 31 of 93 (33%) exited early; 62 completed both Week-52 in-office and sleep-lab visits
  - Majority withdrew consent or non-adherent

Artemis: Inclusion and Exclusion Criteria

- ≥40 years of age
- Orbital anatomy permitting proper goggles seal
- Normal tension glaucoma
- No documented unmedicated IOP >21 mm Hg in either eye, or demonstration of unmedicated IOP ≤21 mm Hg after washout
- Baseline unmedicated IOP≥12 mm Hg and ≤ 21 mm Hg in both eyes
- Can successfully average ≥3 hours of device use across ≥ 3 nights of a consecutive 7-day run-in period
- Prior trabeculectomy or tube shunt implant
- Narrow anterior chamber (AC) angle in either eye (Shaffer grade ≤2 in any quadrant)
- Best-corrected visual acuity (BCVA) 20/200 or worse
- Uveitis or conjunctival chemosis in either eye
- Eyelid edema, festoons or excessive skin laxity in either eye
- Active or history of prior retinal pathology

Artemis: Negative Pressure (NP) Programming

- Study eye programmed NP = Measured IOP minus 6 mm Hg
  - Revision 5 (May 17, 2021) changed post-randomization NP programming to be at investigator's discretion

Artemis: Analysis Cohorts

Analysis Cohort	~~N~~ n (%)
Intent-to-Treat (ITT) cohort – All randomized participants	94 (100%)
Modified Intent-to-Treat (mITT) cohort – All randomized participants who had at least one full application of NP (minimum 20 minutes at home) in the study eye after randomization (between Visit 3 and 8)	93 (98.9%)
Safety cohort – All participants who had at least one full application of NP of any duration after randomization	93 (98.9%)
Per-Protocol cohort – All participants in mITT cohort who met all eligibility criteria, had no major protocol deviations, and completed final (Week 52) sleep-lab and in-office visits	60 (63.8%)

Artemis: Effectiveness Results

- **Primary endpoint was met**
  - For the mITT cohort:
    - **58.1%** (54/93) of study eyes achieved ≥20% IOP* reduction during NP application at Week-52 in-clinic vs. 1.1% (1/93) of control eyes. (p<0.001)
    - Between-group difference = 57.0% (95% CI 45.4% to 66.2%)
- **Secondary endpoint was met**
  - For the mITT cohort
    - **63.4%** (59/93) of study eyes achieved ≥20% IOP* reduction during NP application at Week-52 sleep lab vs. 3.2% (3/93) of control eyes. (p<0.001)
    - Between-group difference = 60.2% (95% CI 48.6% to 69.3%)

Artemis: Adherence to home use and NP levels used

- Mean wear time = 5.4 – 5.6 hours/day
  - 4 (4.3%) used >7.5 hrs/night during majority of intervals
  - 8 (8.6%) used NP -17 to -20 mm Hg for at least 26 weeks

Artemis: “Run-in” phase AEs

- Periorbital AEs – 4.9% (6/122)
- Headache – 2.5% (3/122)

Artemis: Ocular AEs

Ocular AE	Study eyes (N=93)			Control eyes (N=93)		
	# Reports	# Eyes	% Eyes	# Reports	# Eyes	%Eyes
Eyelid edema*	12	11	11.8%	1	1	1.1%
Signs/symptoms of dry eye*	6	5	5.4%	5	5	5.4%
Conjunctival hyperemia*	4	4	4.3%	2	2	2.2%
Eye pain*	4	3	3.2%	0	0	0%
Lid erythema*	2	2	2.2%	1	1	1.1%
Loss BCDVA ≥10 letters	2	2	2.2%	2	2	2.2%
Posterior vitreous detachment	2	2	2.2%	0	0	0%

- 20.4% (study) vs. 4.3% (control) device-related.
- One study-eye AE “severe” – eyelid edema

Artemis: Periorbital and Non-ocular AEs

Periorbital AE	Study eyes (N=93)			Control eyes (N=93)		
	# Reports	# Eyes	% Eyes	# Reports	# Eyes	%Eyes
Periorbital edema*	12	12	12.9%	1	1	1.1%
Periorbital contact dermatitis*	4	4	4.3%	3	3	3.2%
Periorbital pain*	2	2	2.2%	1	1	1.1%

* AE for which some or all of the study eye reports were considered device related

Non-ocular AEs

- 12.9% of participants (24 reports in 12/93)
  - 2.2% (2/93): Device-related headaches
    - resolved after decreasing NP level

Artemis: Visual Field (VF) Testing

- VF testing – Day -14* (Visit 1), Week 26 (Visit 6), and Week 52 (Visit 8)
  - *Unreliable tests or VFs with MD loss ≥2.5 dB repeated
- ≥-2.5 dB MD loss
  - 10.9% (7/68) at Week 26
  - 6.5% (4/62) at Week 52
  - Not reported as an AE until Revision 6 (Nov. 10, 2021)

Artemis: Optical coherence tomography (OCT) testing

- OCT imaging at baseline, Week 26, Week 52

- Mean retinal nerve fiber layer (RNFL) thickness
  - Study: 77.9 ± 13.6 µm (baseline, Week 52)
  - Control: 77.3 ± 14.5 µm (baseline), 77.5 ± 14.8 µm (Week 52)
  - One control eye RNFL thinning ≥10 µm (Week 52) – signal strength 4/10 (vs. 8/10 baseline scan)

Artemis: Glaucoma Progression Assessment

- Optic nerve head evaluation performed
- VF and OCT data
  - Week 26 and Week 52 assessed **post-hoc** by a reading center (Iowa VFRC)
  - Two readers + adjudication by third
  - First analysis VFs only, then VFs + OCT data
  - Same post-hoc assessment performed for Apollo

Artemis: Visual Field Reading Center (VFRC) report

- 68 of 93 (73.1%) had VFs
- VFs “sufficient for analysis of glaucomatous progression” – 79% (49/62) study eyes, 72.6% (45/62) control eyes
- Progression by VFs alone – One participant (both eyes)
- 2 participants (2 controls) **“indeterminable”** by VF+OCT
- ≥-2.5 dB MD loss
  - Week-26: 7 (4 study, 5 control); 57% (4/7) **Insufficient for analysis**; 43% no progression either eye
  - Week 52: 4 (3 study, 3 control); 75% (3/4) **Insufficient for analysis** (2 study, 3 control); 25% **“indeterminable”** in one control eye

Apollo: VFRC report

- 64 participant randomized; 58 completed Day 90 (final) visit
- 90.5% eyes had sufficient-quality VFs
- Progression by VFs
  - 2 participants (1 study eye, 1 control eye); 2 **“indeterminable”** (1 study eye, 2 control eyes)
- Progression by VF+OCT
  - 2 participants **“indeterminable”** by VF+OCT (2 study eyes, 1 control eye)

- ≥-2.5 dB MD loss at Day 90 – 6 participants (6 study eyes, 4 control eyes)
  - 50% (3/6): **“Insufficient”**
  - 17% (1/6): 1 eye with progression, fellow eye no progression
  - 33% (2/6) no progression

Pilot and feasibility studies

- CP-XXX (pilot) – N=3
- CP-XX1 – N=30; on healthy volunteers
- CP-XX4* – N=5
- CP-XX5* – N=51 (consistent cohort); on healthy volunteers
- CP-XX6* – N=10
- CP-XX7* – N=10; home use × 7 days
- CP-X13* – N=13; home use × 4 weeks
- CP-X18* – N=11
- CP-X22* – N=61
- CP-X23* – N=9

"CONFIRM" Study: Direct Manometric Measurement of Intraocular Pressure (IOP) During Application of Negative Pressure in Adult Subjects Undergoing Cataract Surgery

- Objective: “The objective of this study was to evaluate the physiological change in IOP with application of negative pressure from the FSYX Ocular Pressure Adjusting Pump (OPAP) using manometry.”

Confirm: Study Design

- Eligibility Criteria: Adults undergoing cataract surgery
  - Glaucoma diagnosis was not an inclusion criteria
- Procedure:
  - NP applied “immediately prior to cataract surgery”
  - IOP was measured manometrically while NP was on.
  - The NP treatment was administered at Visit 2 of the study (within 2 months of the initial or Day 0 visit, Visit 1). One follow-up visit (Visit 3) was scheduled to occur within 7 days of Visit 2.

Confirm: Results

- **Mean IOP Reduction from Baseline**
  - -10mm Hg: - 33.1% (-19.6% to -52.4%)
  - -20mmHg: - 51.2% (-35.4% to -80.5%)

- **Mean IOP Reduction by Applied Negative Pressure Dose**
  - -10mmHg: -56% (-35% to -78%)
  - -20mmHg: -40% (-22.5% to -54%)

Benefit-Risk Assessment[1]

- Proposed Indications for Use:
  - The FSYX™ Ocular Pressure Adjusting Pump (FSYX OPAP) is indicated as adjunctive therapy for the reduction of intraocular pressure during use in adult patients with open-angle glaucoma and IOP ≤ 21 mmHg.

[1]https://www.fda.gov/media/99769/download

Benefits

- The following pre-specified primary and secondary effectiveness endpoints were met:
  - Week-52 clinic visit – 58.1% (54/93) of study eyes and 1.1% (1/93) of control eyes demonstrated a ≥20% reduction of IOP (by excursion tonometry), while the device was in use.
  - Week-52 sleep lab visit – 63.4% (59/93) of study eyes and 3.2% (3/93) of control eyes demonstrated a ≥20% reduction of IOP (by excursion tonometry), while the device was in use.

Benefit Uncertainty:

- Impact of lowering IOP (as measured by Excursion tonometry) on glaucoma progression
- Unclear benefit if device is not used
- NP programming and dose-response effect

Risks

- No formal safety endpoints were pre-specified
- Safety outcomes included:
  - Eyelid and periorbital edema and erythema, conjunctival hyperemia, dry eye, eye pain, headache, posterior vitreous detachment (PVD)
  - Most were not severe; resolved after cessation of device use

Risks: Uncertainty

- Impact on glaucoma progression
- Impact on relevant aspects of patient's health-related quality of life
- Ability to tolerate device for the recommended duration (8 hours per night)
- Ability to tolerate maximum allowable NP level (-20 mm Hg)
- Long term effects of chronic biomechanical strain on eye under negative pressure

Thank you!


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FDA Q&A

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LUNCH BREAK

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OPEN PUBLIC HEARING

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FOLLOW-UP QUESTIONS

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PANEL DELIBERATIONS

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BREAK

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