English translation for reference purposes only

FY2021
Business Plans and
Matters Related to High Growth Potential



In case of any discrepancy, the Japanese version shall prevail

(TSE4883)

Modalis therapeutics Corporation

November 15 , 2021

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1. Corporate Overview

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Corporate Overview(As of end Sep 2021)

Modalis Therapeutics is a biotech company to develop CRISPR-based gene therapies

Name	Modalis Therapeutics Corporation (Ticker symbol: 4883)
Foundation	Jan 2016
President CEO	Haru Morita
HQs	3-11-5 Nihonbashi-Honcho, Nihonbashi-Lifescience-Bldg.2 7F Chuo-ku, Tokyo 103-0023 Japan
US subsidiary	Modalis Therapeutics Inc. (51 Moulton st. Cambridge MA)
Business	Drug Development
Common stock	2,738,185 thousand yen
Outstanding share	28,861,700 common stock
Number of employee	24 (including 8 PhD) (4 in Japan, 20 in US)

Date	History
Jan 2016	Founded in Tokyo as EdiGENE Corporation
Apr 2016	Established 100% owned US subsidiary EdiGENE Inc. (Now Modalis Therapeutics Inc.)
Apr 2017	Entered into research collaboration with **Astellas** Pharma Inc.
Dec 2017	Series A round from **FUJIFILM** Corporation and 8 other companies through third-party allotment
Dec 2017	Expanded research collaboration with **Astellas**
Jan 2019	HQs moved to new facility
Mar 2019	Established license agreement on a genetic disorder with **Astellas** Pharma Inc.
Mar 2019	Cambridge Lab moved to the new facility
Aug 2019	Company name changed to Modalis Therapeutics
Sep 2019	Established 2nd license agreement on a genetic disorder with **Astellas** Pharma Inc.
Nov 2019	Entered into research collaboration with **Eisai** Inc.
Apr 2020	Entered into a license agreement with **Editas Medicine**, Inc to obtain access to foundational CRISPR IP.
Aug 2020	Listing on Mothers, Tokyo Stock Exchange (Ticker symbol: 4883)

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Modalis' 6 strengths

In the right time, the right place, with the powerful technology and the best brightest

GTx and Gene Editing, the "next big thing"

- **Expected Strong market growth** after the dawn period
- Huge opportunities of **100s monogenic disorders**

Leading non-cleaving CRISPR company

- The **precision** of gene editing but even **safer** as it doesn't cut DNA
- **unique IP position** with access to CRISPR foundational IP

Diversified and scalable pipelines

- Solid discovery process and predictable clinical outcome
- **4** on-going collaboration pipelines with large pharma companies and **4** internal pipelines

Pharma Partnerships

- Collaboration with **3** multinational pharma companies
- Aggregated milestone of the 2 out license programs worth **>$350M** (MDL201,MDL202)

Hybrid pipeline model

- Hybrid of earlier cash flow from **collaboration pipeline** and upside potential from **Internal pipeline**

Strong team

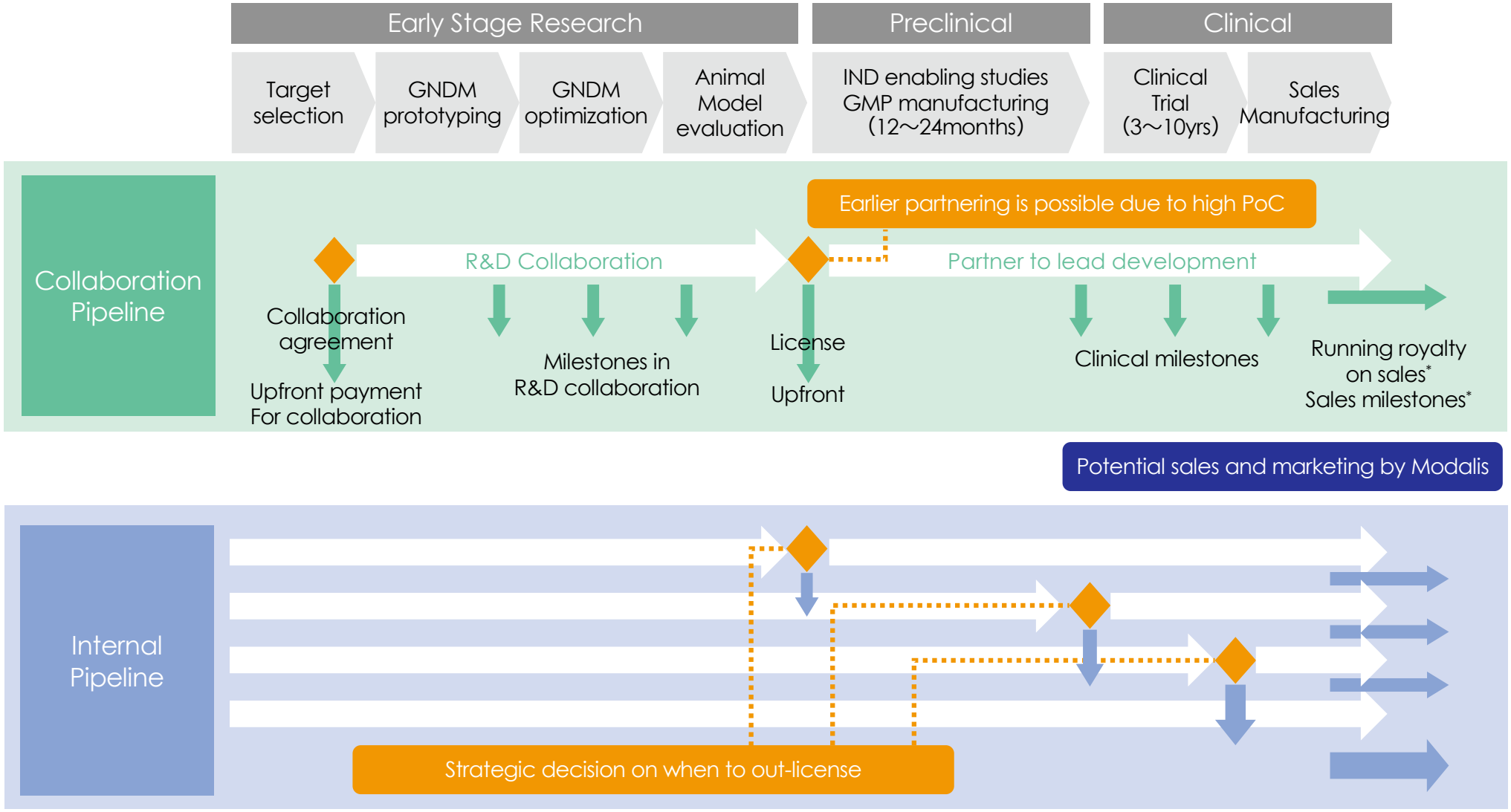
- Combination of seasoned management and talented scientists from all over the world

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Business Model

Hybrid of own pipeline and collaboration pipeline

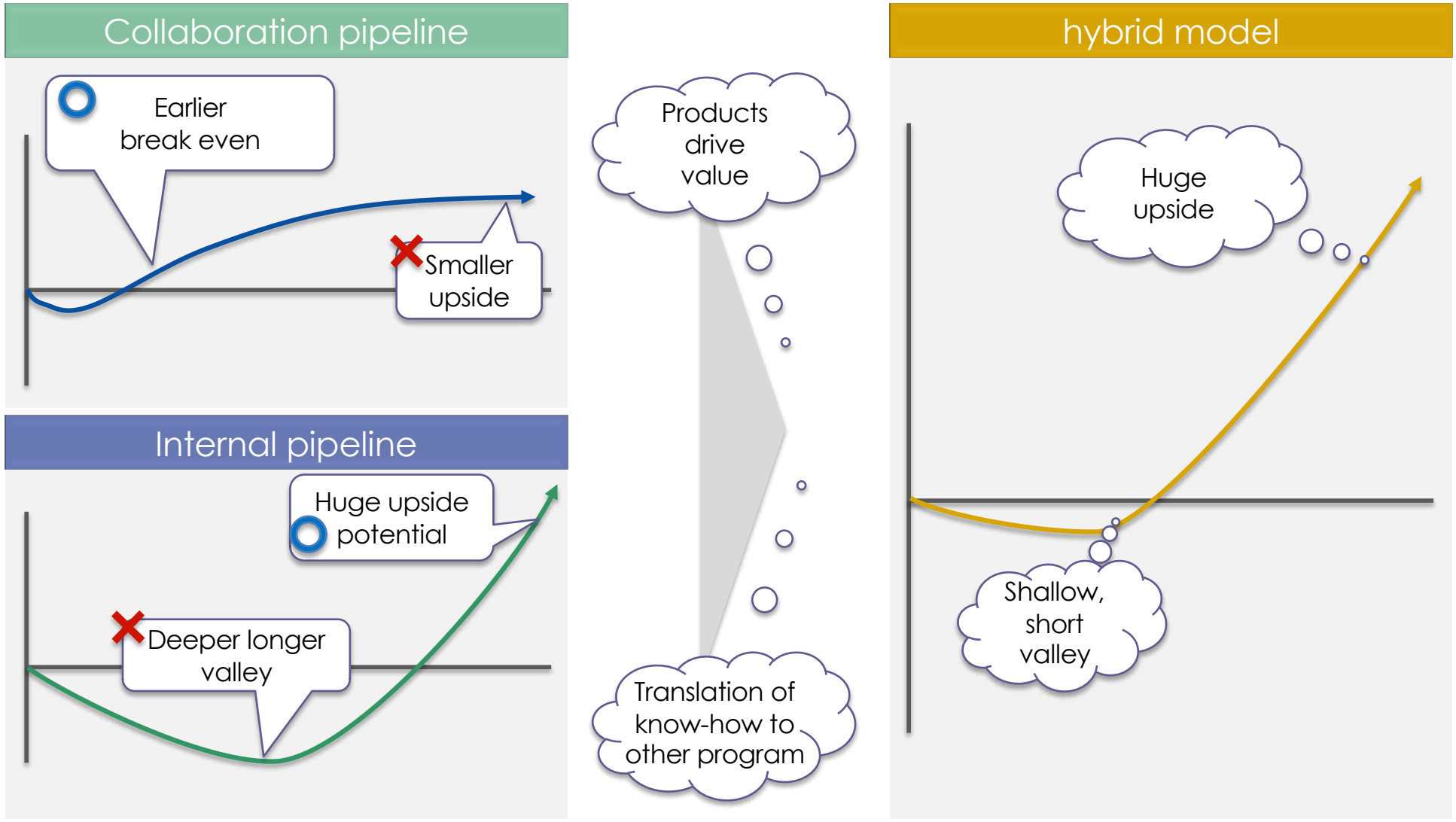


* future plan

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Modalis is pursuing a hybrid model

Combination of upside from internal pipelines and earlier cash stream from collaboration pipelines



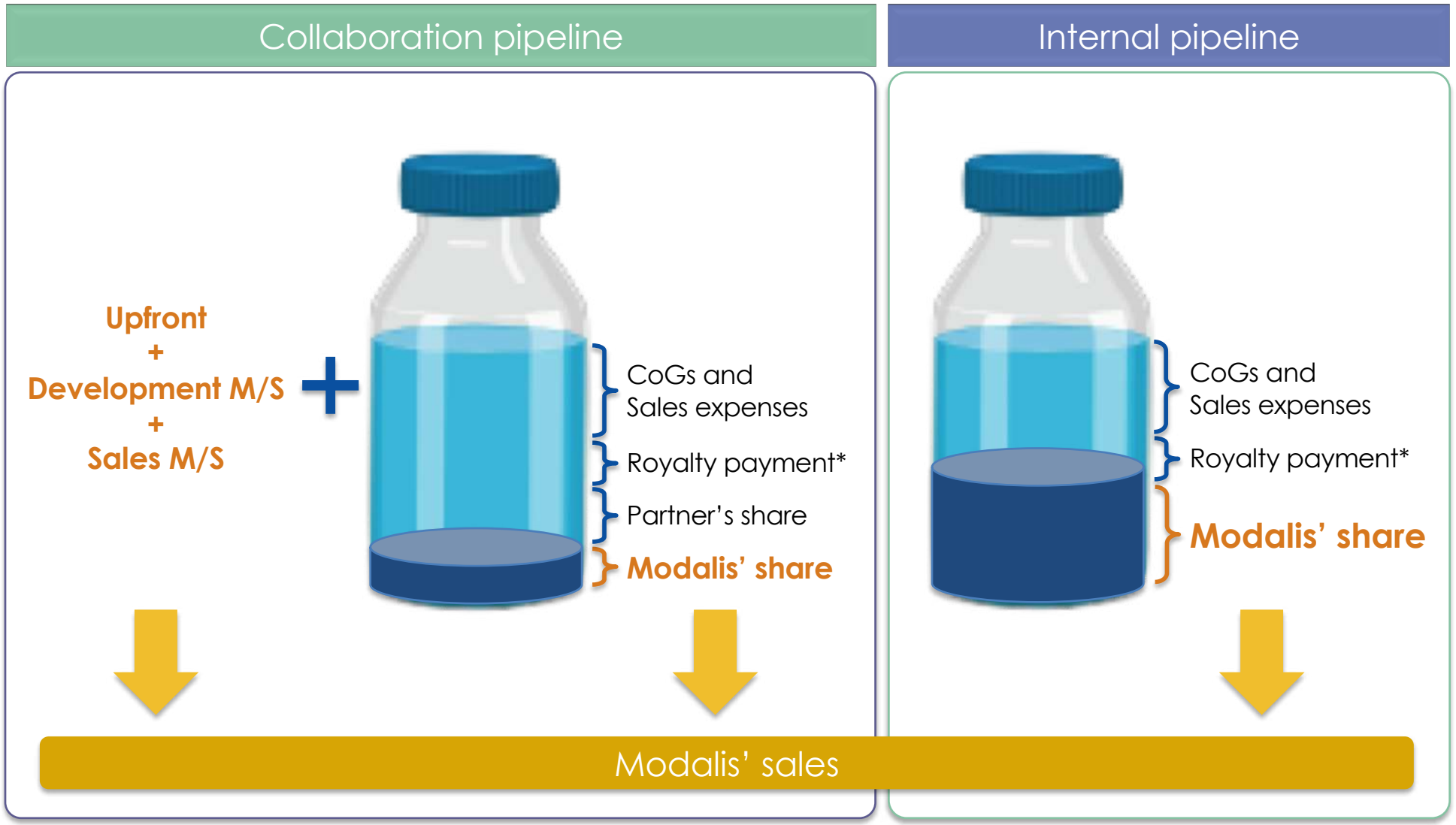
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Risk - profit share model

While collaboration model brings earlier cash, internal pipeline has higher profit with higher risks

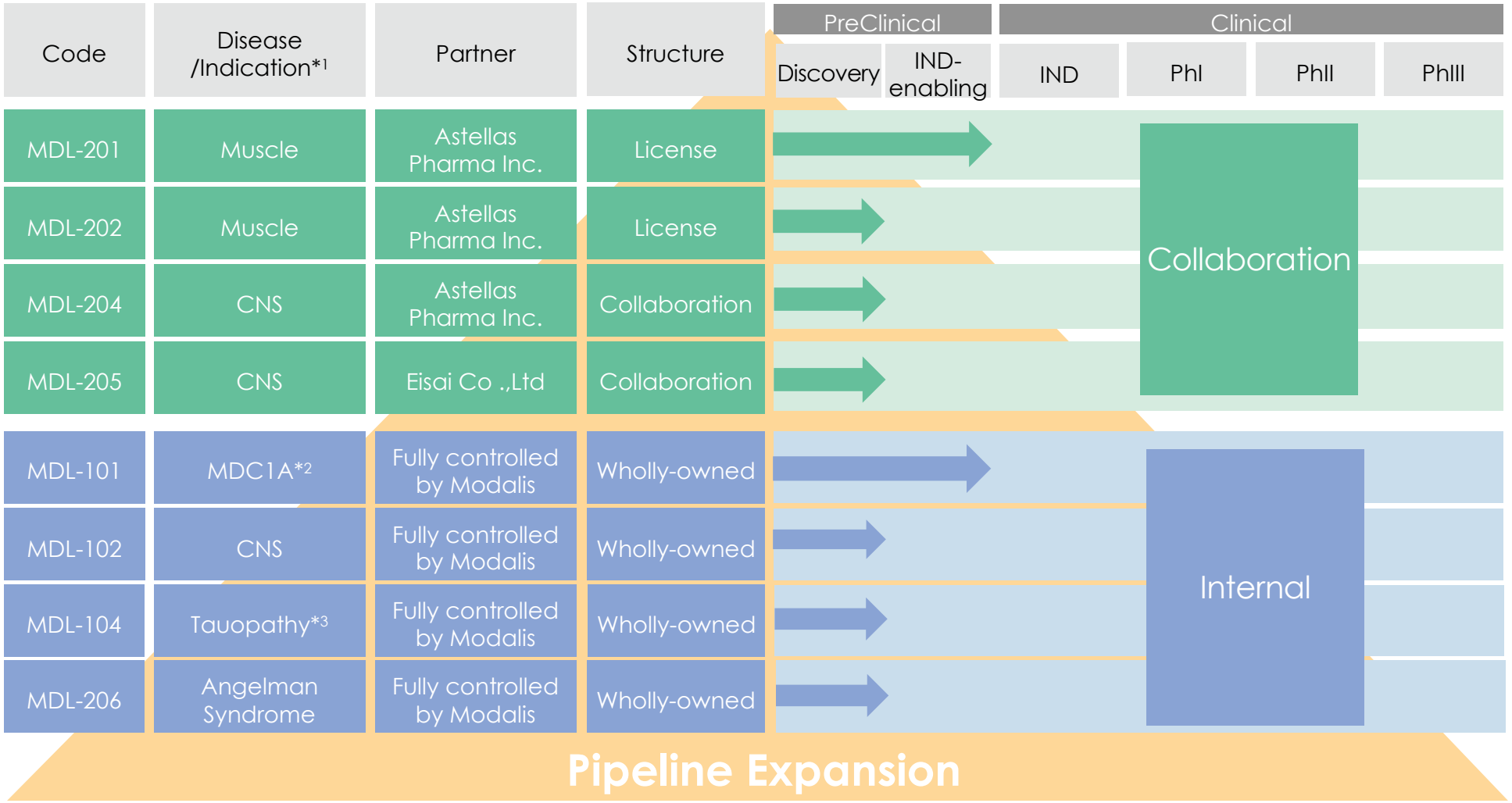


* : As a consideration for the licensed in intellectual property, a certain percentage of sales after market launch is paid to the intellectual property holding organization.

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Pipeline

Code	Disease /Indication*1	Partner	Structure
MDL-201	Muscle	Astellas Pharma Inc.	License
MDL-202	Muscle	Astellas Pharma Inc.	License
MDL-204	CNS	Astellas Pharma Inc.	Collaboration
MDL-205	CNS	Eisai Co .,Ltd	Collaboration
MDL-101	MDC1A*2	Fully controlled by Modalis	Wholly-owned
MDL-102	CNS	Fully controlled by Modalis	Wholly-owned
MDL-104	Tauopathy*3	Fully controlled by Modalis	Wholly-owned
MDL-206	Angelman Syndrome	Fully controlled by Modalis	Wholly-owned



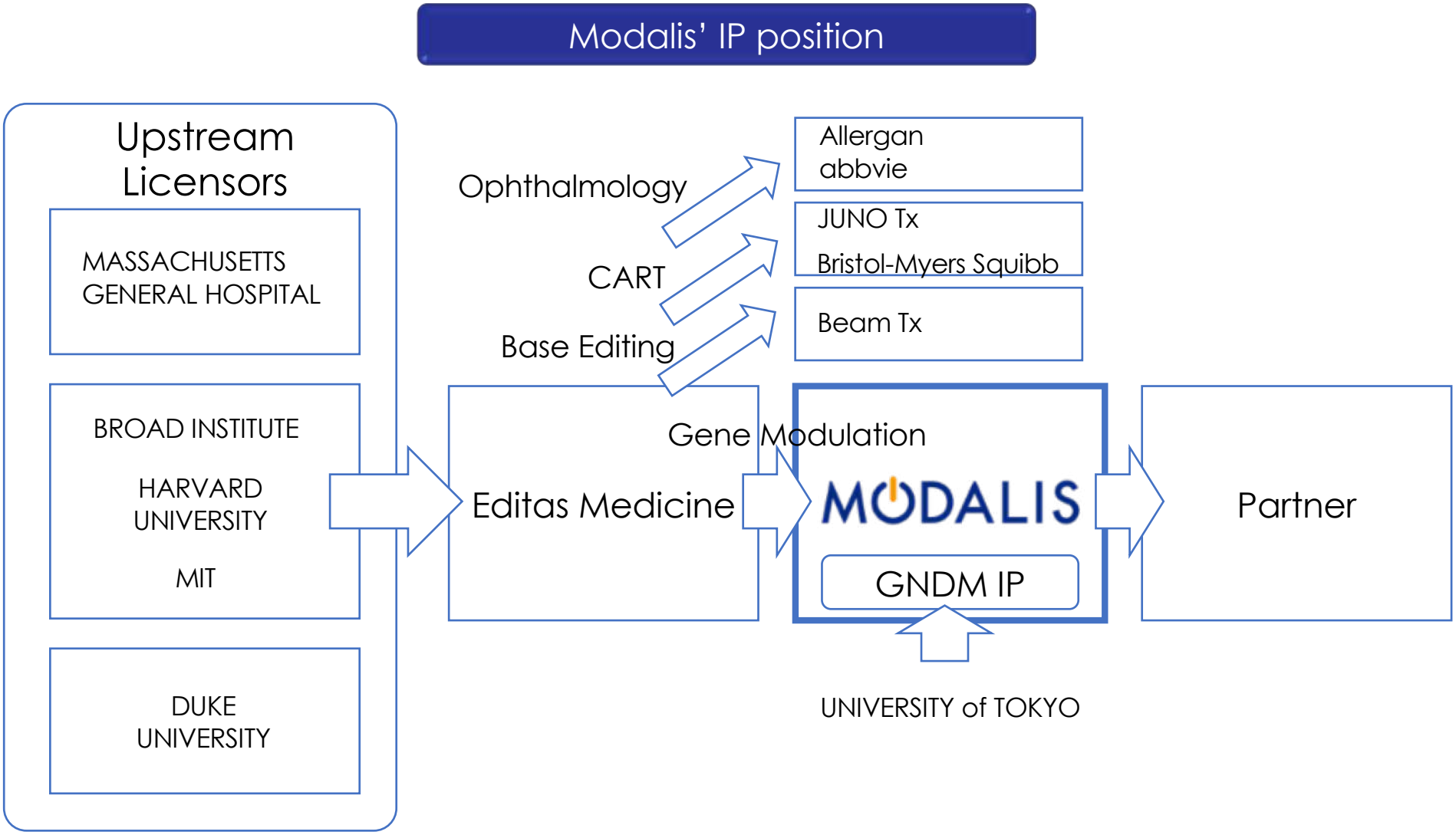
*1: We have adopted a strategy of withholding specific indications until the patent application is published for competitive reasons.
*2: MDC1A=Merosin-deficient congenital muscular dystrophy type 1A
*3: Tauopathy belongs to a class of neurodegenerative diseases involving the aggregation of tau protein. Correlation with Alzheimer's disease has been suggested.

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IP position

Established IP with foundational CIRPSR IP from Broad and engineered Cas9 from Univ of Tokyo

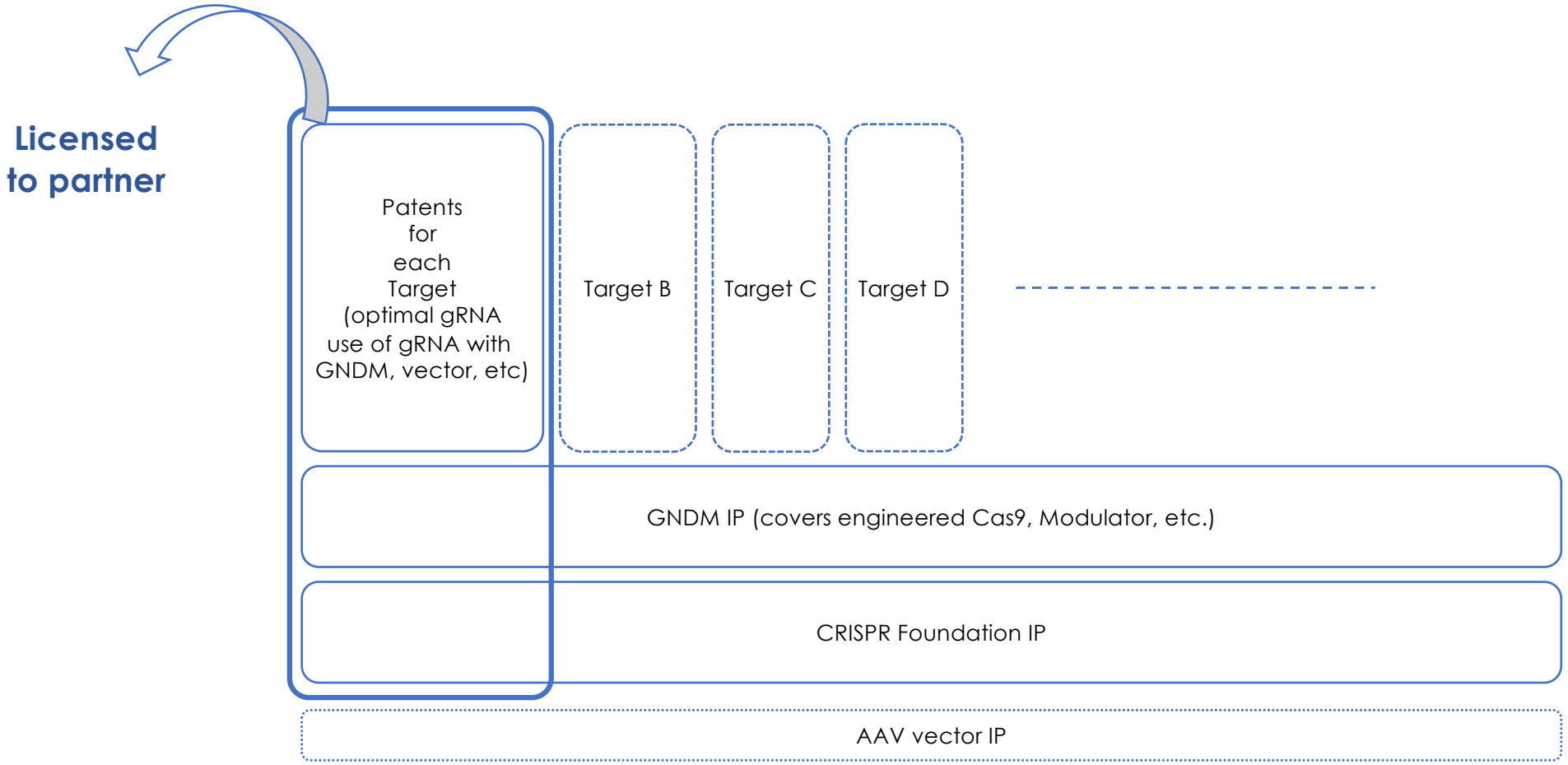


Source : disclosed information by each company

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Each product will be protected by multiple layers of IP



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Management Team and Board of Directors

Seasoned team

Executive Officers



SVP, Chief Technology Officer

Tetsuya Yamagata, M.D. Ph.D

- Glaxo Smith Kline, Tempero Pharmaceuticals
- Joslin Diabetes Center, Harvard Medical School



VP, Chief Financial Officer

Naoki Kobayashi, MBA

- Former CFO at Oncolysbiopharma, Hatena, and Argens
- Deloitte Tohmatsu, Daikyo Real estate



Co-founder, President, CEO, and Chair of the board

Haru Morita

- REGiMMUNE, Founder, President and CEO
- Y's Therapeutics, Booz Allen and Company, Kyowa-KIRIN

Board of Directors



Board member

Hideki Takeda

- President, Medical Patent Research
- Healios KK former president, Fujisawa (merged into Astellas)



Board member

Joseph S. McCracken, DVM

- Roche Head of Global license, Genentech, Sanofi

Board member, Audit committee

Miyuki Shimane

- Chugai Pharma

Board member, Audit committee, CPA

Teruhisa Tajima

- President Tajima CPA office
- Corporate Auditor (OncoTherapy,
- Prism Bioscience)

Board member, Audit committee, Attorney at Law

Toshio Furuta

- Representing attorney, Clair Law Firm
- Corporate Auditor (NetYear Group, Canbas, Zenrin DataCom)

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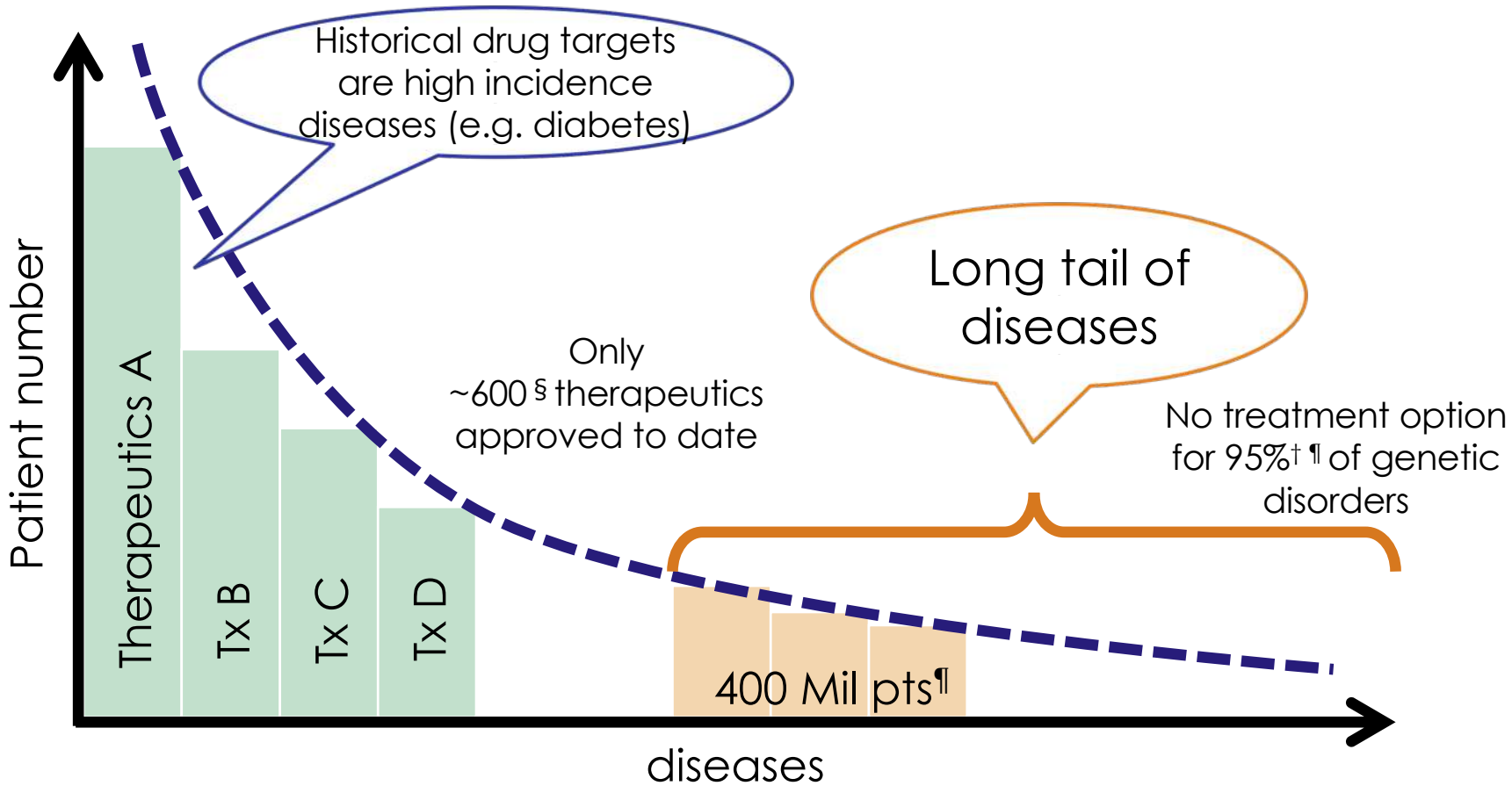
2. Gene Therapy and Gene Editing

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To target "long tail" of diseases, innovation is needed

Among 10,000* human disorders ~7,000#are orphan disease and 80%†are genetic disorders



Scalable efficient approach is required to tackle the divided population

Source: *21st Century Cure Act, #NIH GARD †innovation.org ¶GlobalGenes.org
§Active therapeutics of 491 NME, 106 BLA, 17 cellular and gene therapy products @FDA as of 2019.7.22 Source from KEGG

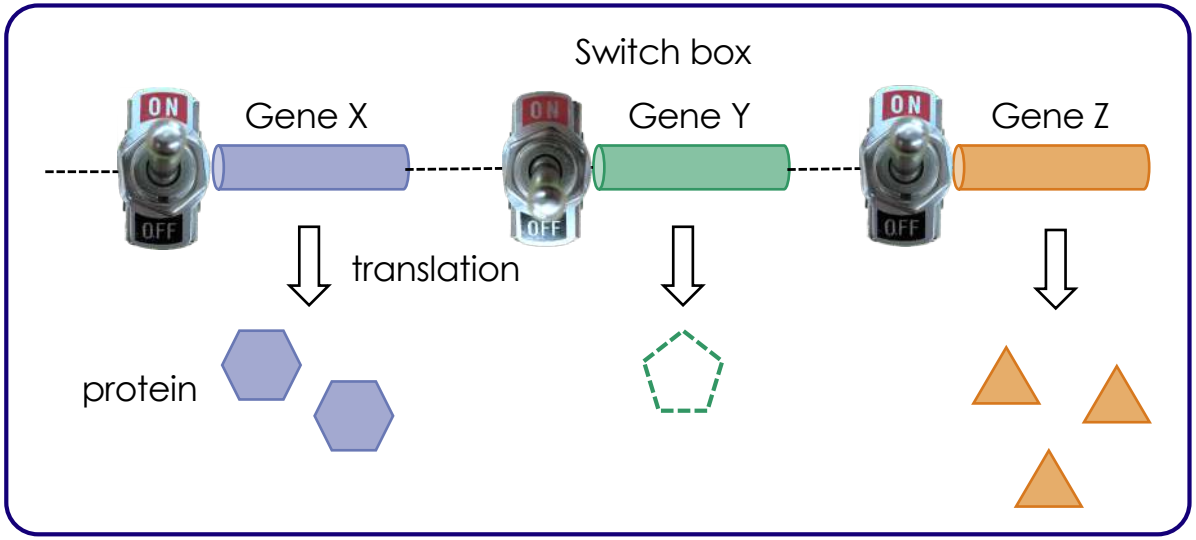
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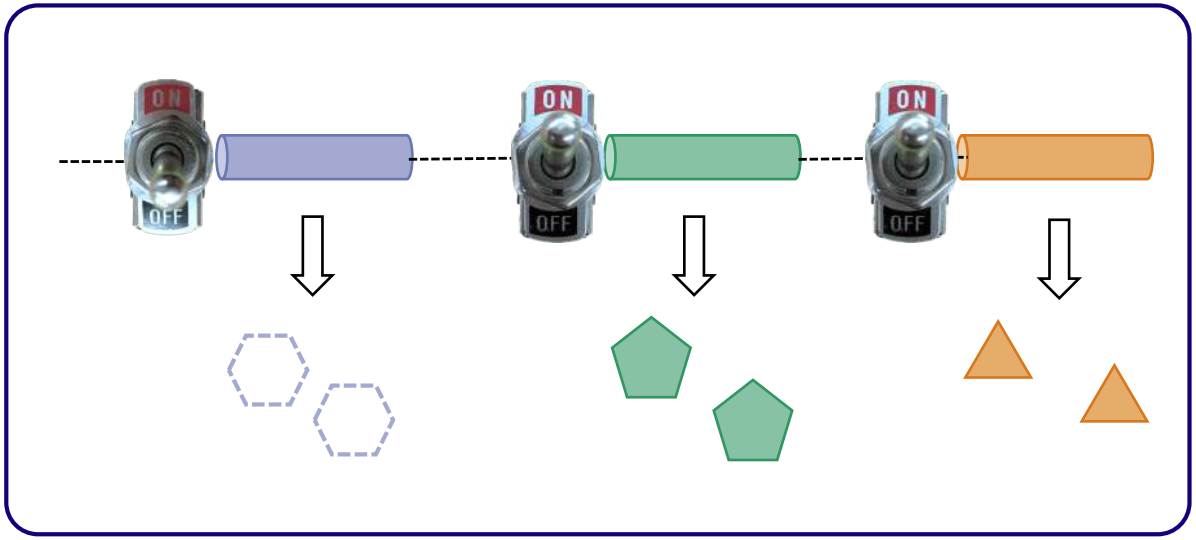
How multiple cell types are created from the same DNA code

Each of 20,000 genes have ON/OFF switches that control cell type specific expression

Cell A



Cell B



- There are **37.2 Trillion cells** in our body
- **200 cell types** in our body have the same DNA code despite differences in appearance and function
- Differences in cell types and their states are controlled by ON / OFF switches of the expression of **20,000 genes** coded by **3 billion bases of DNA**

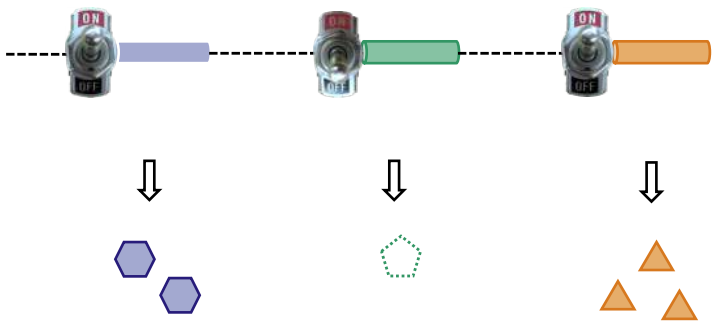
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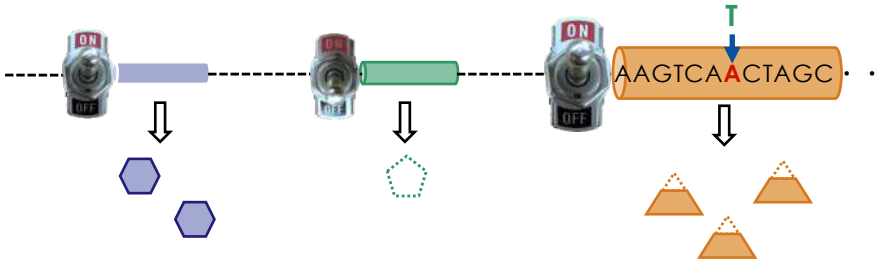
3 types of genetic disorders

An error in the code or in switching can cause disorders

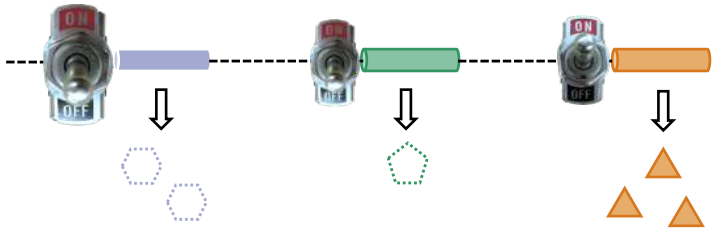
Normal state



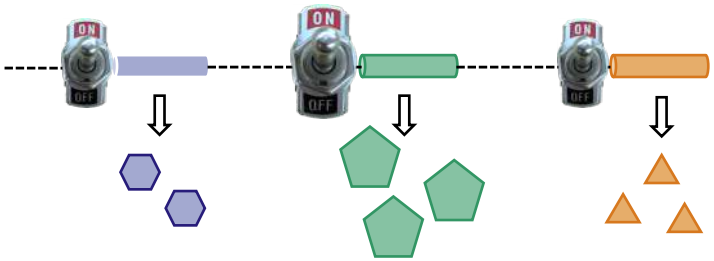
Error in the code results in a **non-functional protein**



A **required protein** is not supplied due to being witched OFF due to a switching error



An **un-necessary protein** is produced by a switching error



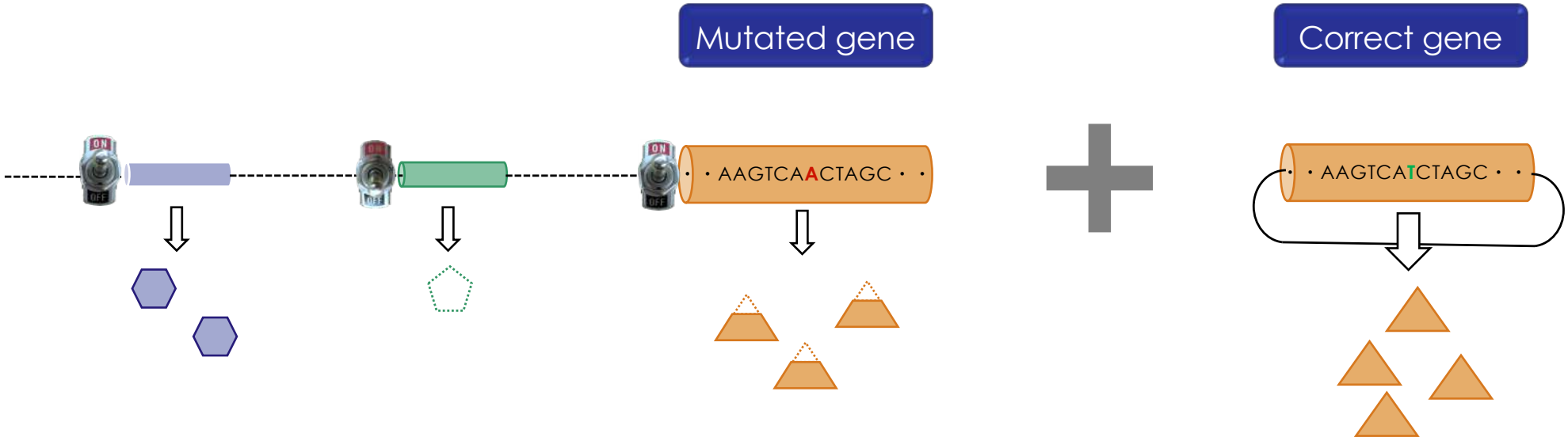
Switches control which, when and how much protein is expressed

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Classical gene therapy

Replaces a mutated gene by inserting a correct gene exogenously

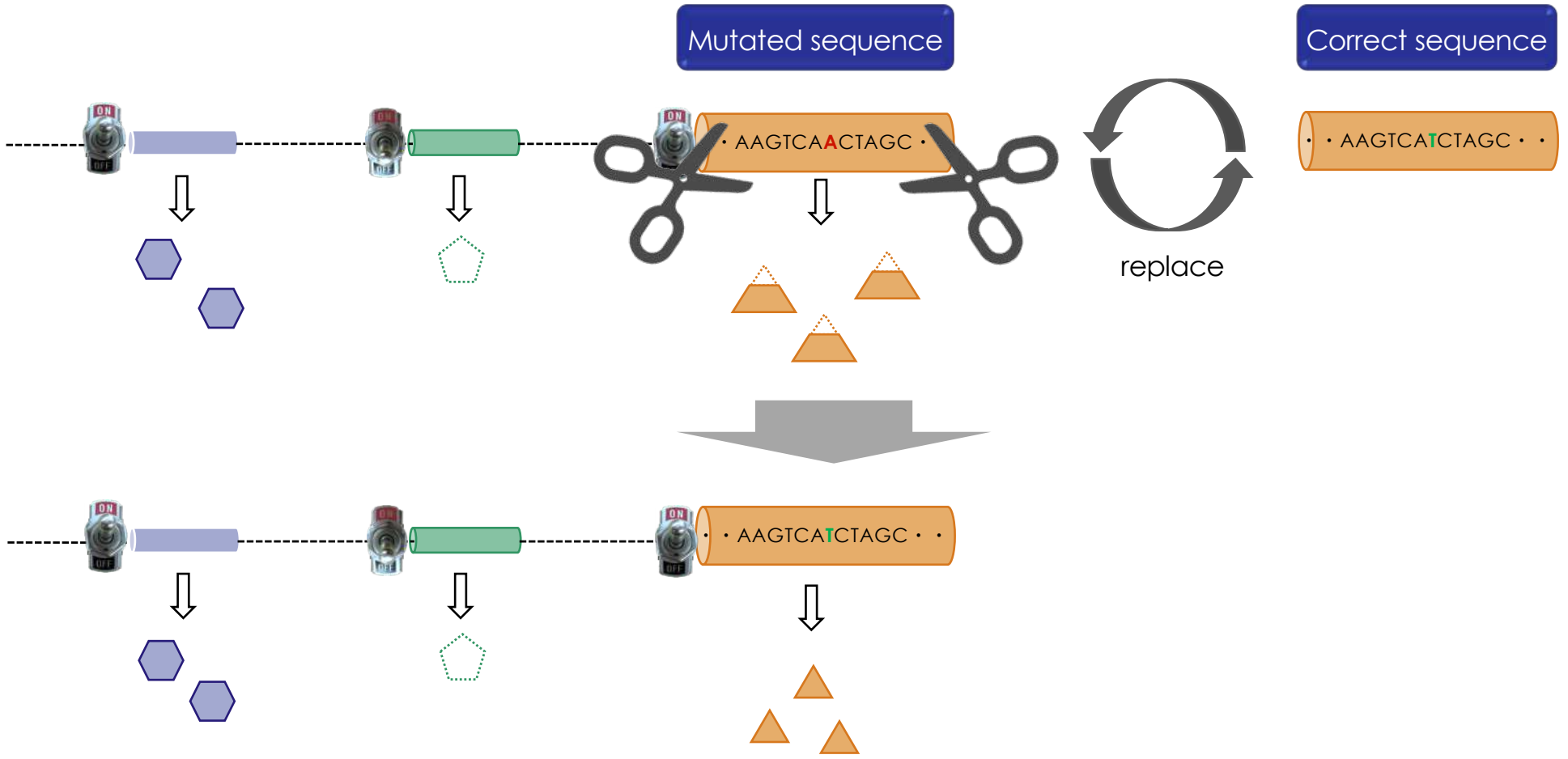


Overwrite of missing gene

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Gene Editing

Replaces mutated DNA with correct DNA by cleaving DNA



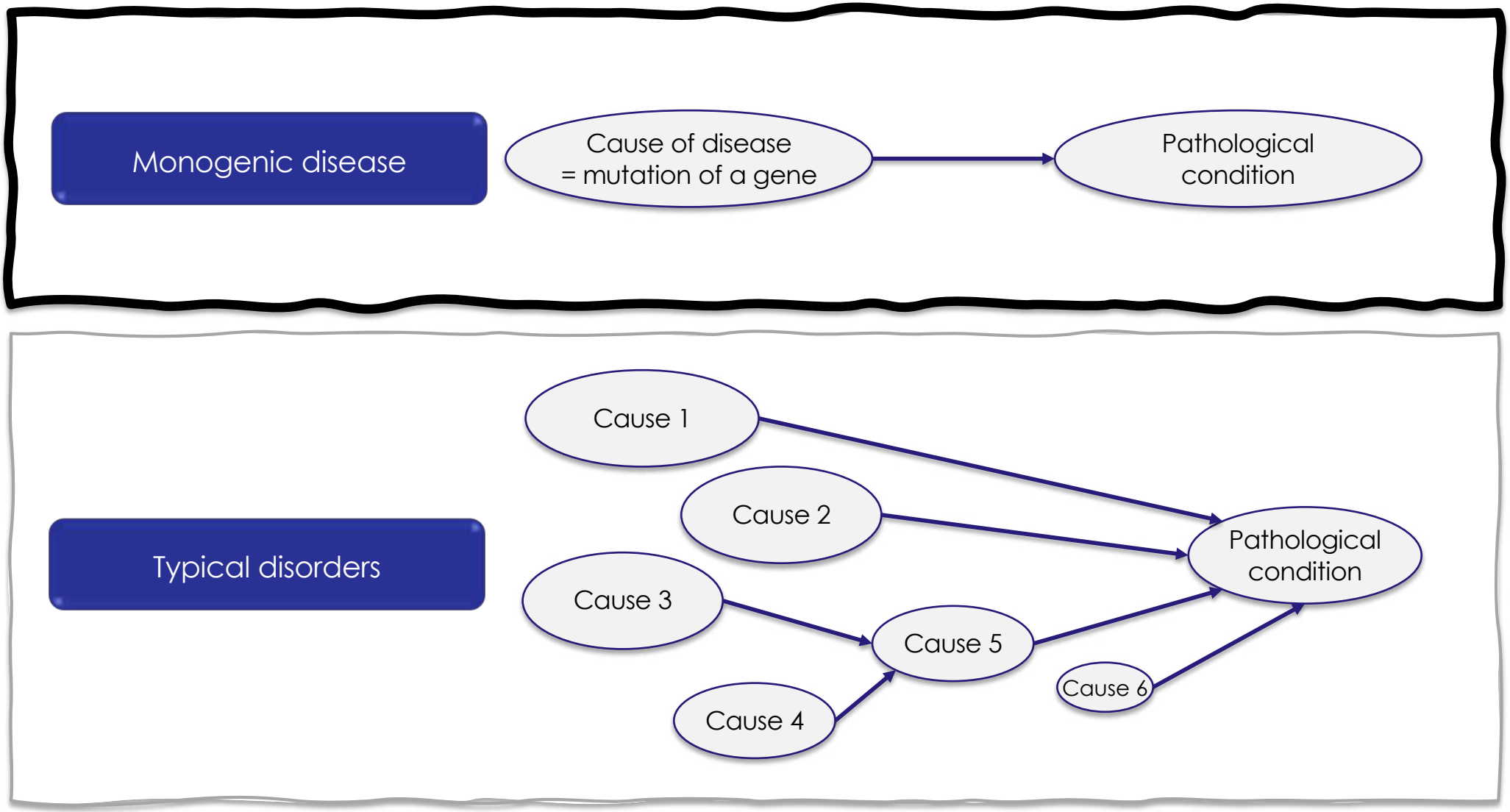
However, cleaving DNA increases risk of cancer

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Monogenic Diseases

Gene therapies for monogenic disorders are expected to have higher probability of success due to simplicity of mechanism



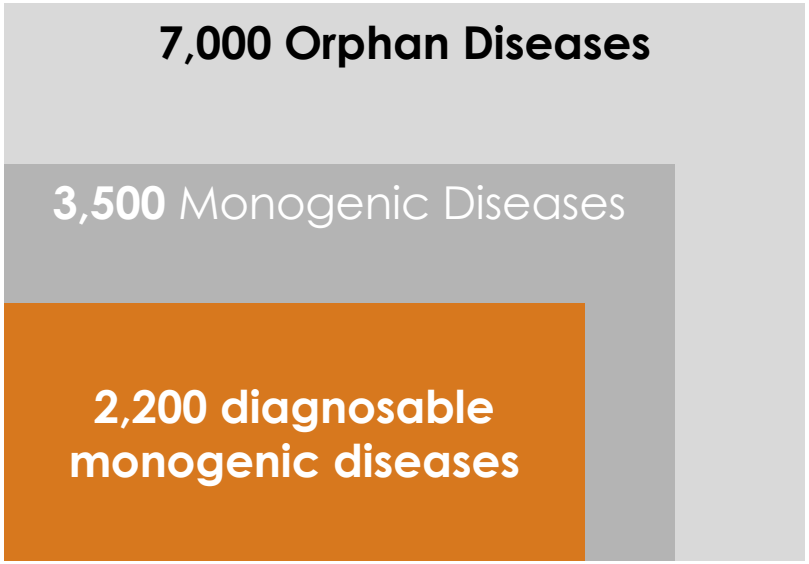
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Untapped opportunities in monogenic disorders

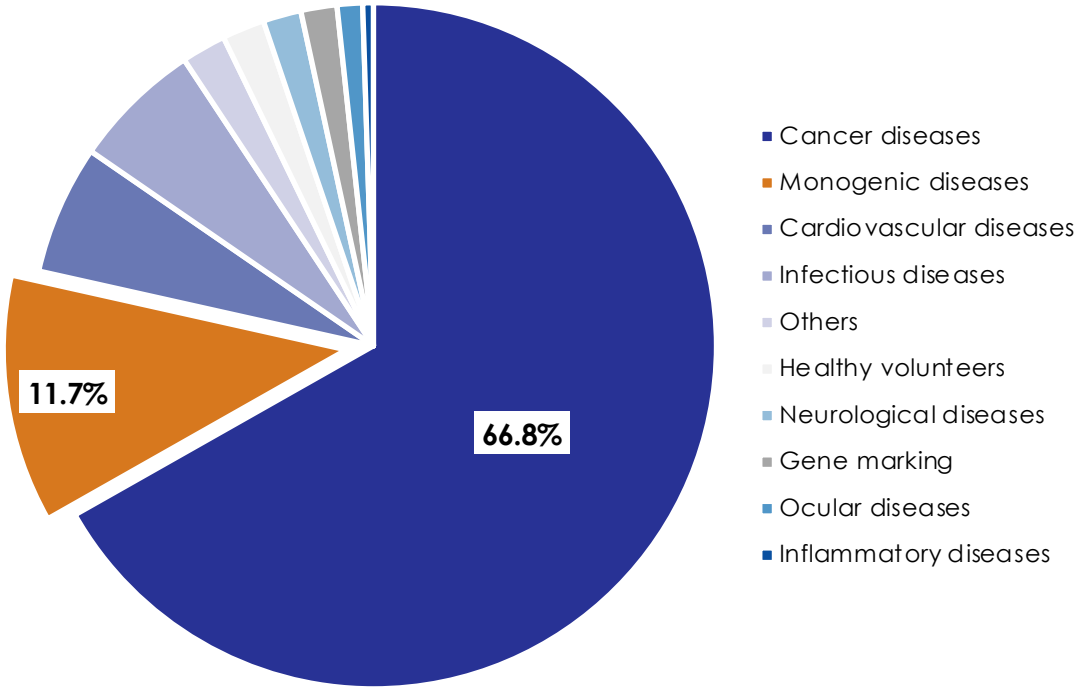
Limited number of drugs are approved or in clinical development for monogenic disorders

Monogenic Disease



Source: Discovery Medicine

Breakdown of GTx clinical trials (1989~ Worldwide)



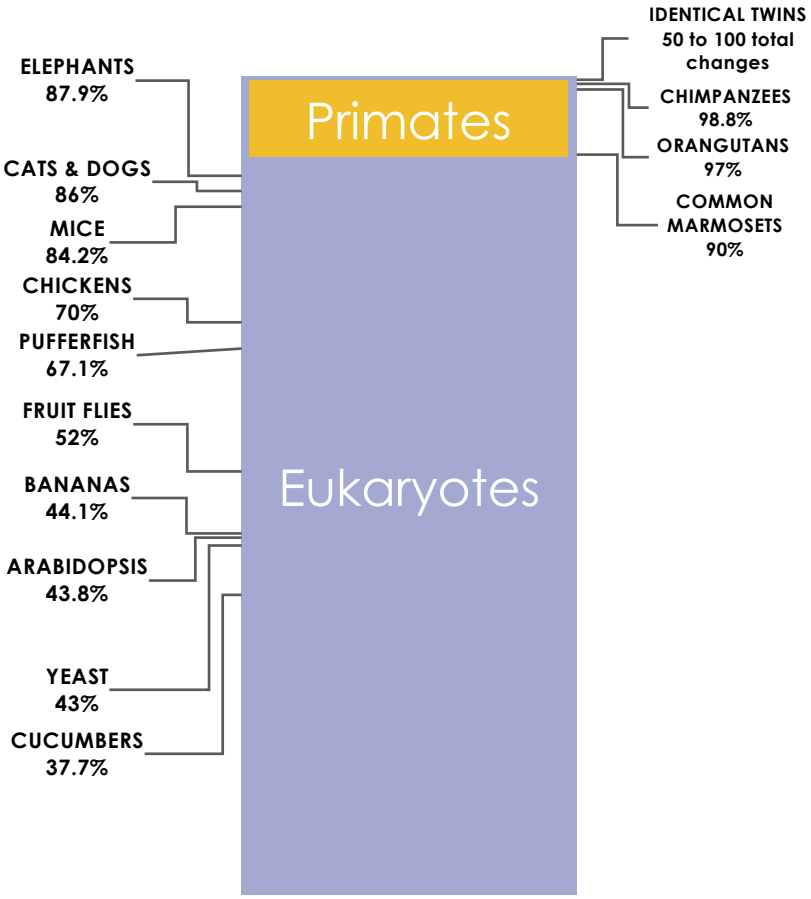
Source: The Journal of Gene Medicine (2019)

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Why GTx outcome is predictable?

Genetic machinery (OS) is common in eukaryotes while genetic codes differ





Humans share 40% of their genes with cucumbers

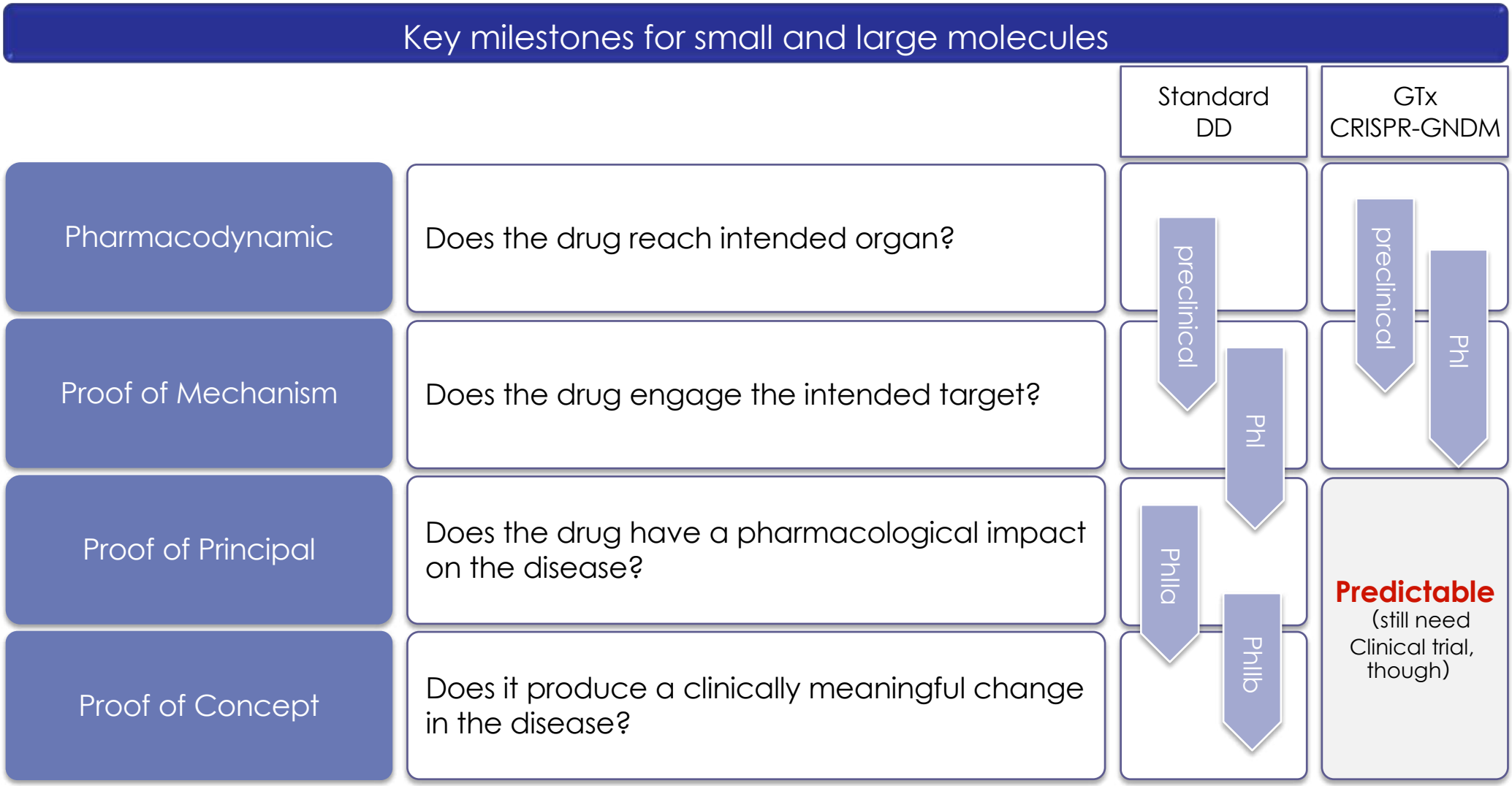
Source : Datascope

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Major hurdles in drug development

PoP and PoC are predictable in GNDM prior to human testing



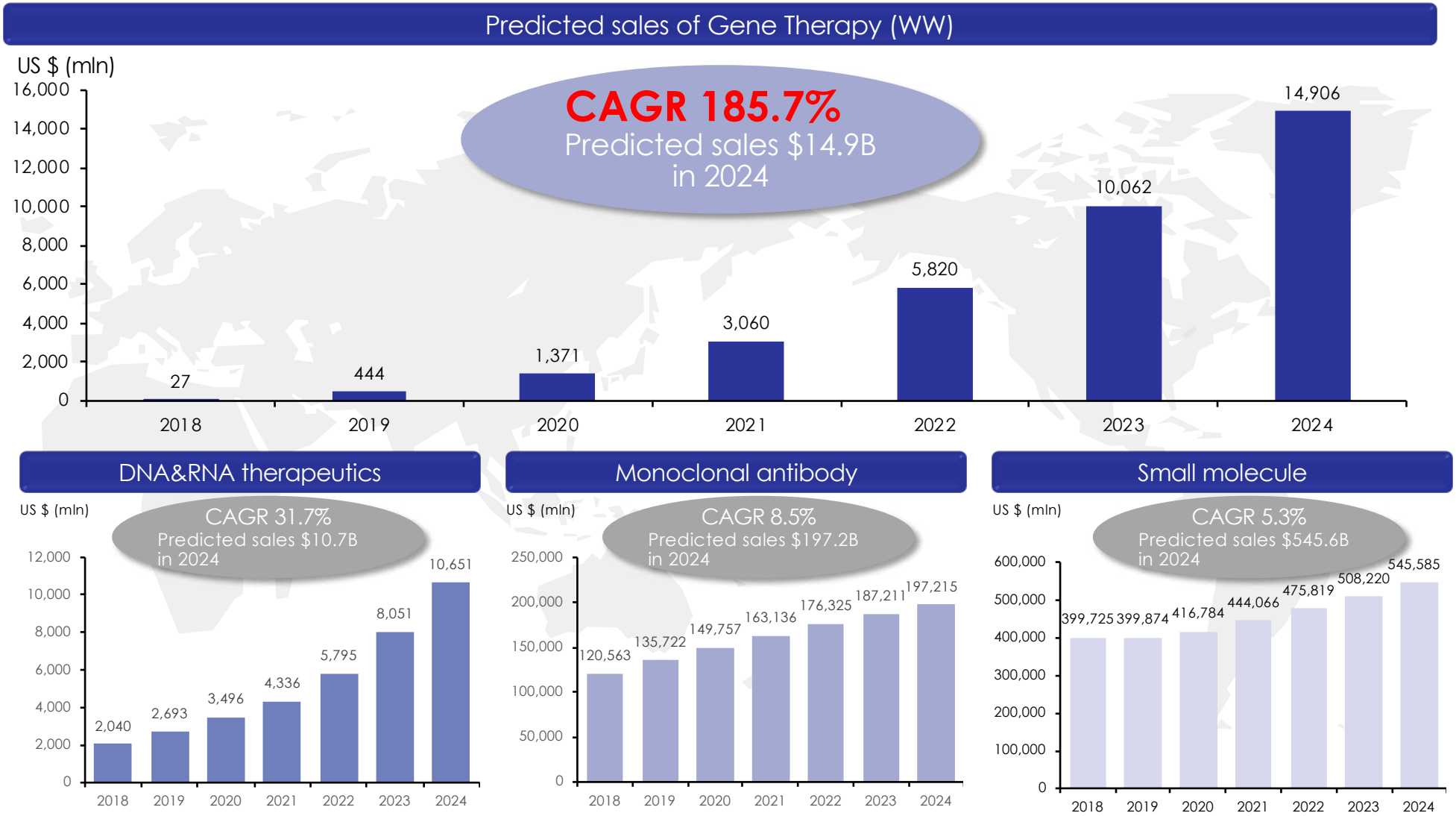
Source : Nature Biotechnology volume 30, p596–599 (2012)

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Sales growth of pharmaceutical modalities

GTx is growing faster than other modalities



Source : Evaluate Ltd (in Aug 2019 data) *CAGR=2018 to 2024. 2019 to 2024 are predicted sales

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CRISPR is a novel gene editing technology

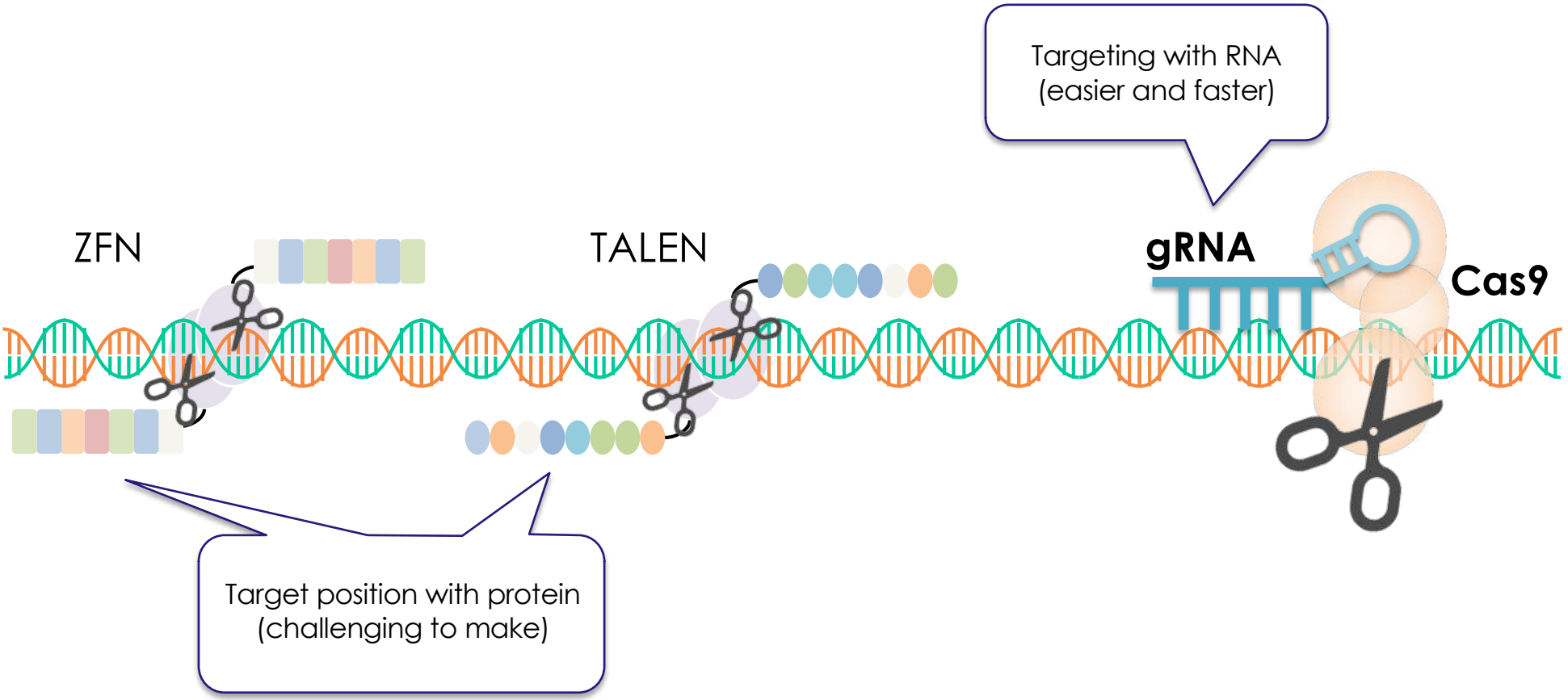
Faster and higher throughput due to limited variable region which is easily synthesizable as gRNA

Old gene editing technologies

ZFN

TALEN

CRISPR

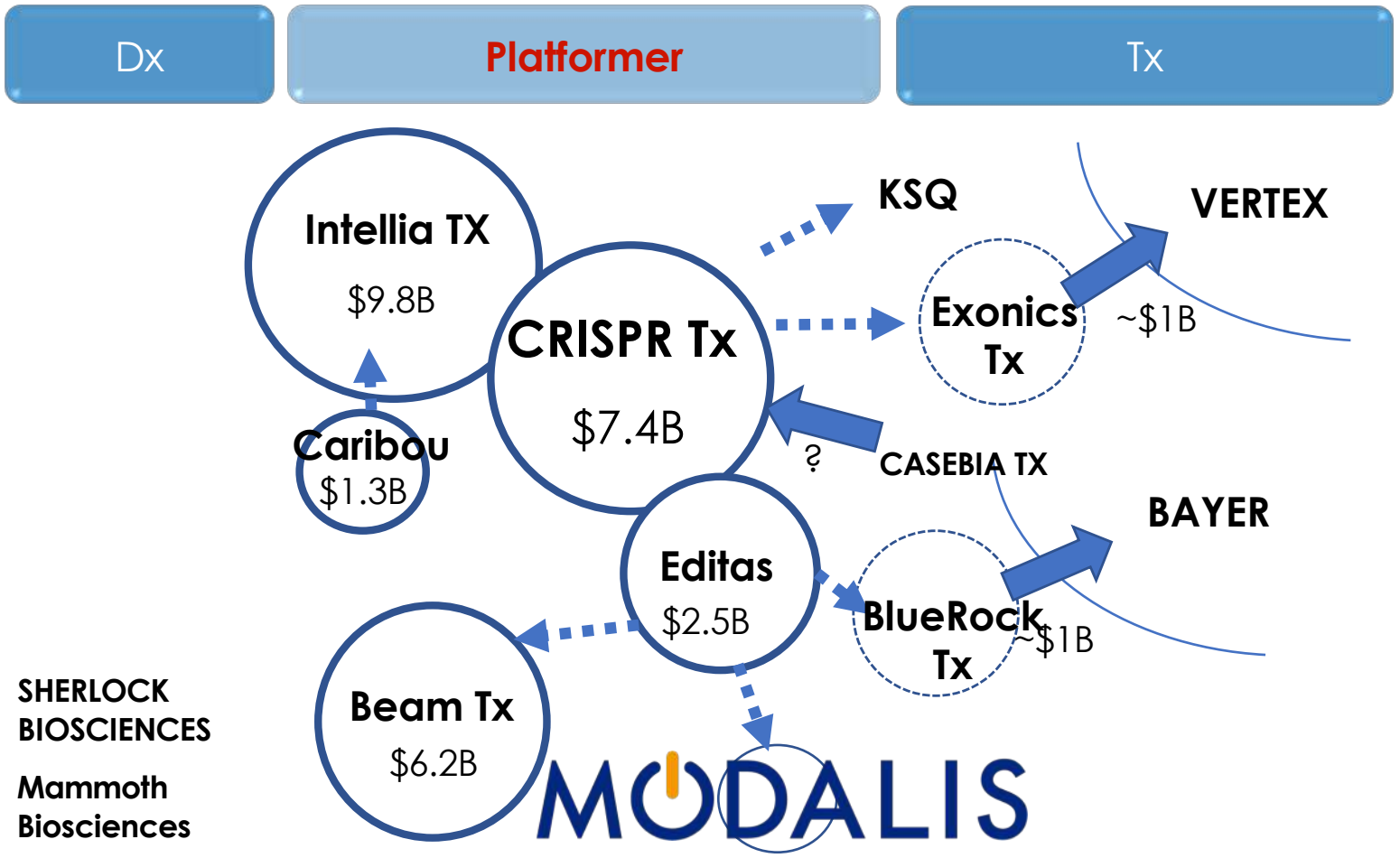


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Major players in CRISPR field

Modalis established unique position in CRISPR companies, most of which reached >$1B



Source: stock info. The figures represent market cap as of Nov 4th ,2021 or value at the time of acquisition.
Dotted circle represent acquired companies

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Market size

Drug price and patient number of marketed gene therapies

Trade Name (proper name)	cost	Indication	Manufacturer	Patient Population	US market size (mil USD)*
Kymriah (tisagenlecleucel)	$475k	B-ALL	Novartis	1.6 per 100,000 (6500 new cases per yr in US)	<3000
Yescarta (axicabtageneciloleucel)	$373k	NHL	Kite Pharma (Gilead)	3.8 per 100,000 (7500 new cases per yr in US)	<2800
Lxturna (voretigeneneparvoec-rzyl)	$850k	RPE65	Spark Therapeutics	2 per 100,000	<1700
Strimvelis (GSK2696273)	$648k	ADA-SCID	GSK	0.5-0.1 per 100,000	<324
Glybera (alipogene tiparvovec)	$1.2M	LPLD	uniQure	0.1 per 100,000	<120

*estimated from prevalence



market size = Drug price x patient number
As drug price is hard to be estimated until we see its clinical benefit, it is hard to estimate market size, which is the function of drug price
On the other hand, it is possible to go beyond $1B in US or $2B in WW unless it is ultra orphan

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3. CRISPR-GNDM® and its advantages

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Gene modulation is the next big advance in CRISPR

Jennifer Doudna, who was awarded Noble prize in chemistry in 2020, mentioned about CRISPR based gene modulation as follows.

Q: "What do you think is going to be the next big CRISPR advance?"

Doudna: "I think one interesting possibility is that **we'll see CRISPR being used not to edit genomes, or at least not to make permanent changes to genomes, but instead to regulate them, to control levels of human proteins that are produced from different genes.** This is a newer way of using the CRISPR technology. I think it has a lot of potential to allow control of cells that doesn't require actual permanent chemical changes being made to the DNA."

That's exactly what Modalis do with CRISPR-GNDM®

*Source: Interview on Future Human "Fresh Off Her Nobel Prize Win, Jennifer Doudna Predicts What's Next for CRISPR"

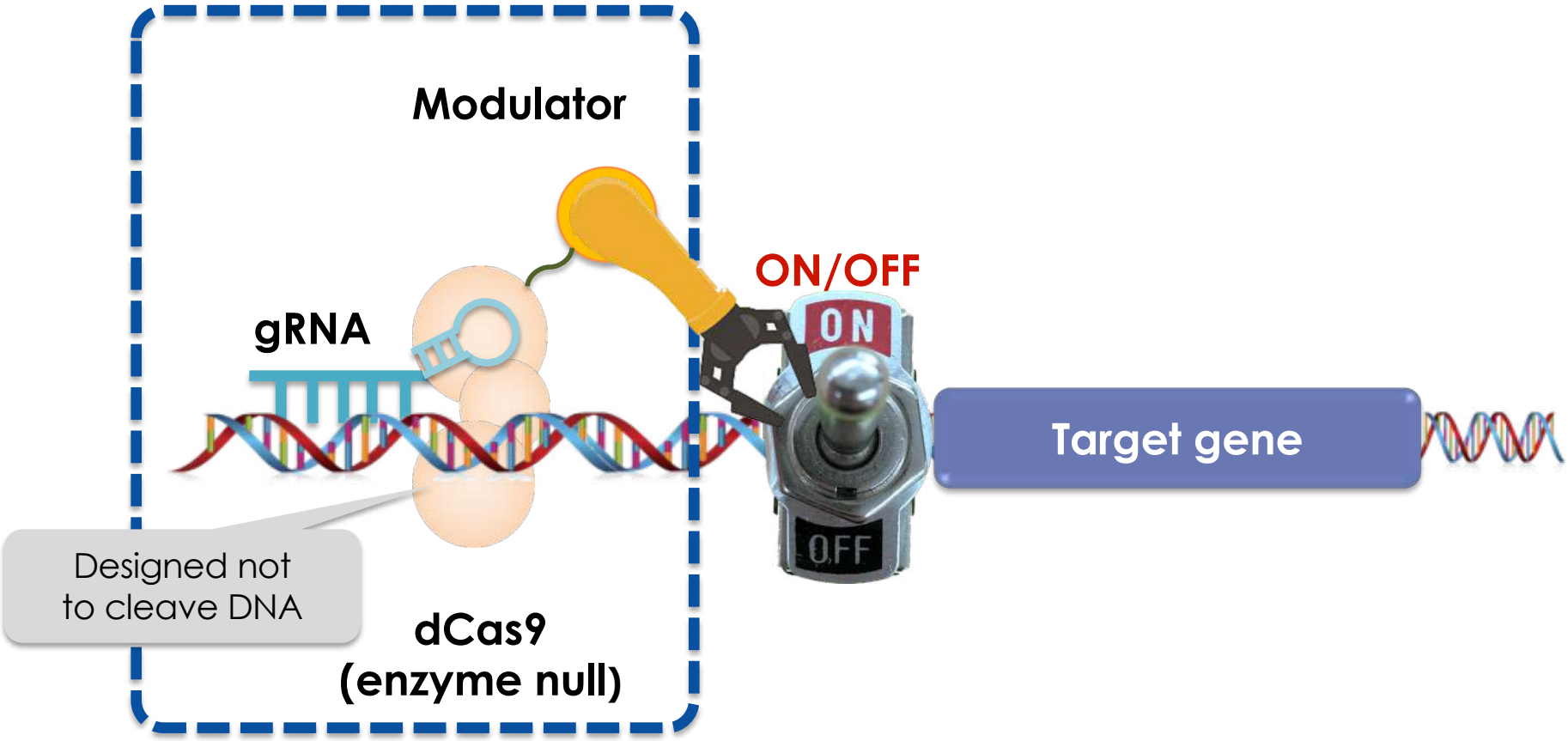
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Non-cleaving CRISPR = CRISPR-GNDM®

Enables treatment of genetic disorders by controlling ON/OFF switch

CRISPR-GNDM® (Guide Nucleotide-Directed Modulation) platform

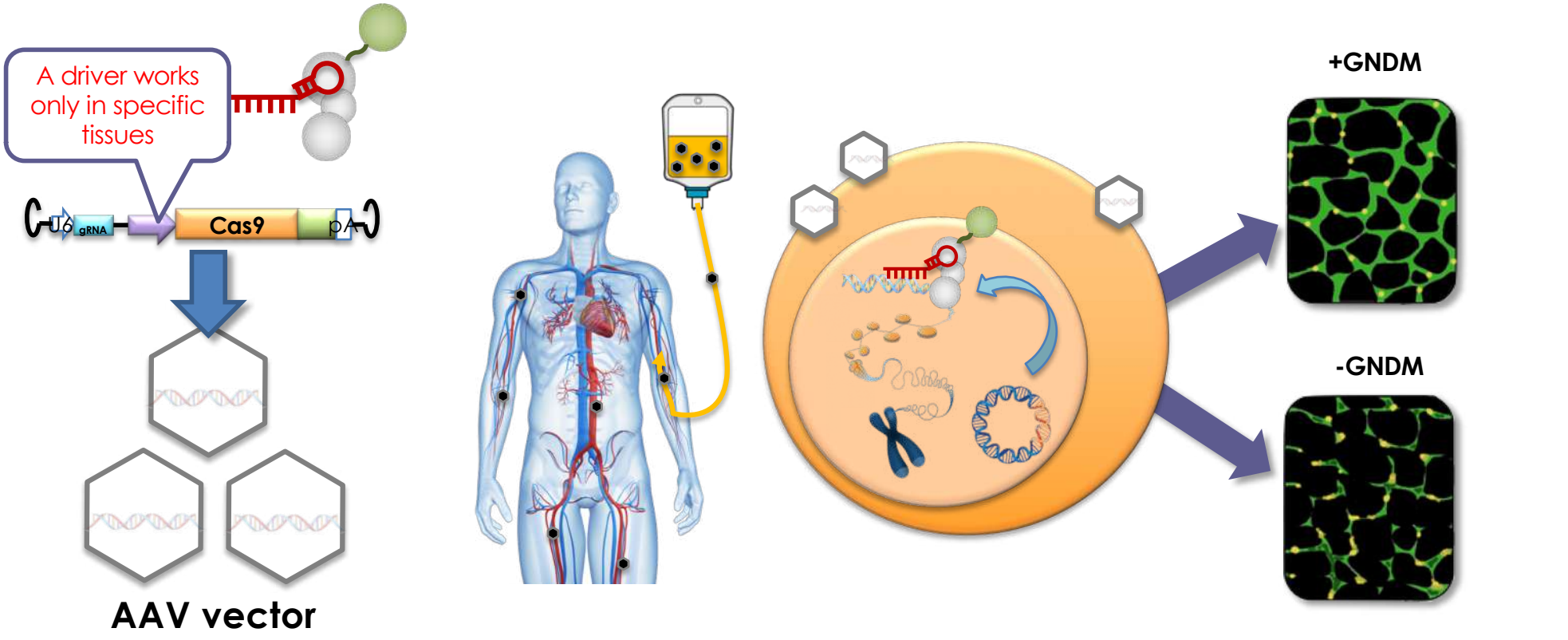


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Delivery of CRISPR-GNDM® to target

Use AAV vector to deliver GNDM to target cell

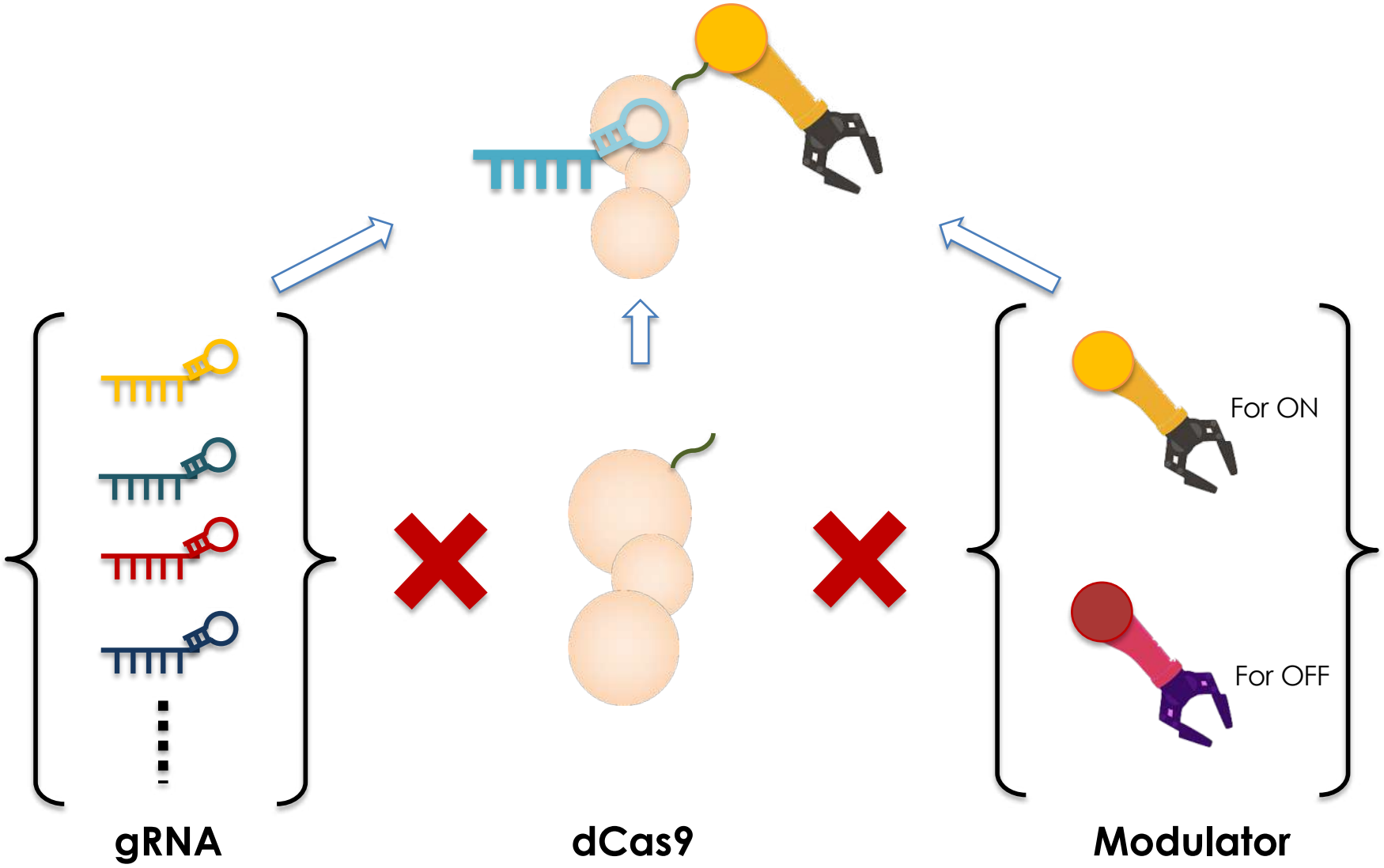


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Scalability of GNDM

gRNA is the only variable which is unique for each target. Other components are off-the-shelf to assemble.

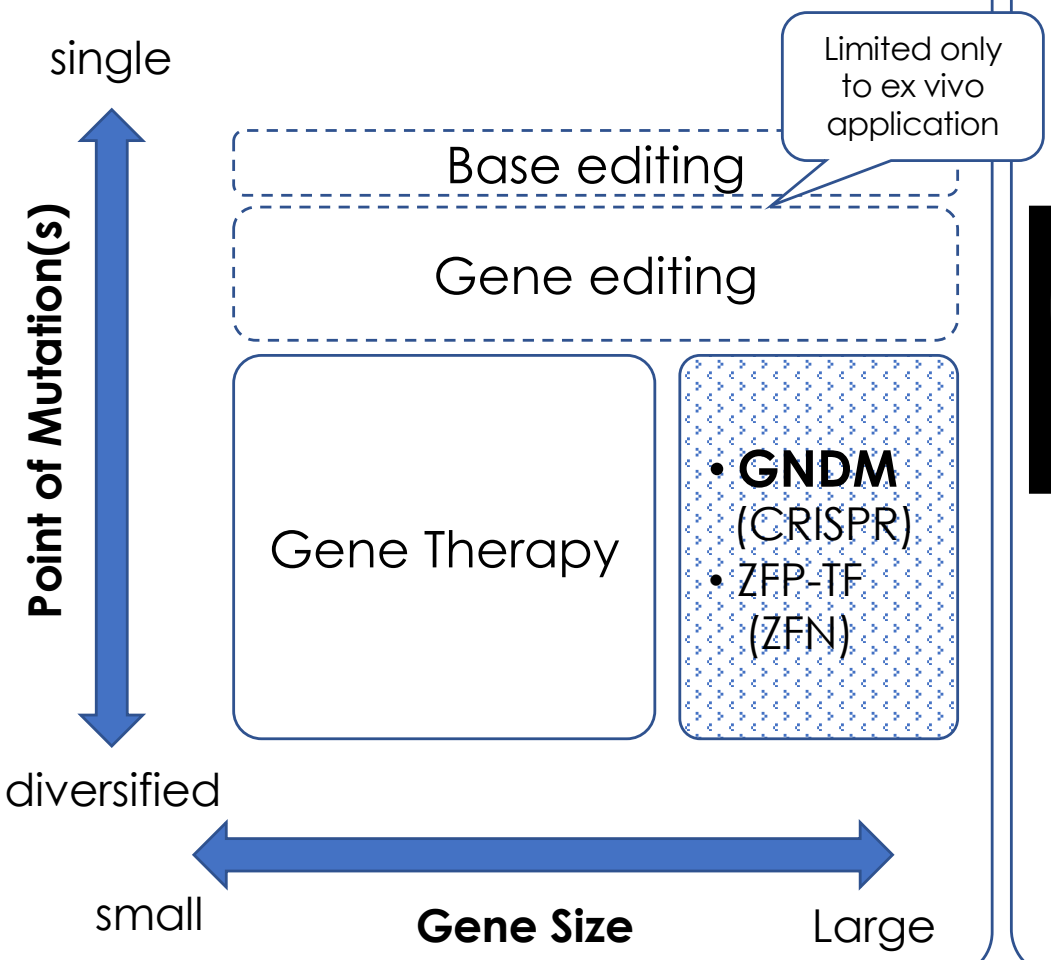


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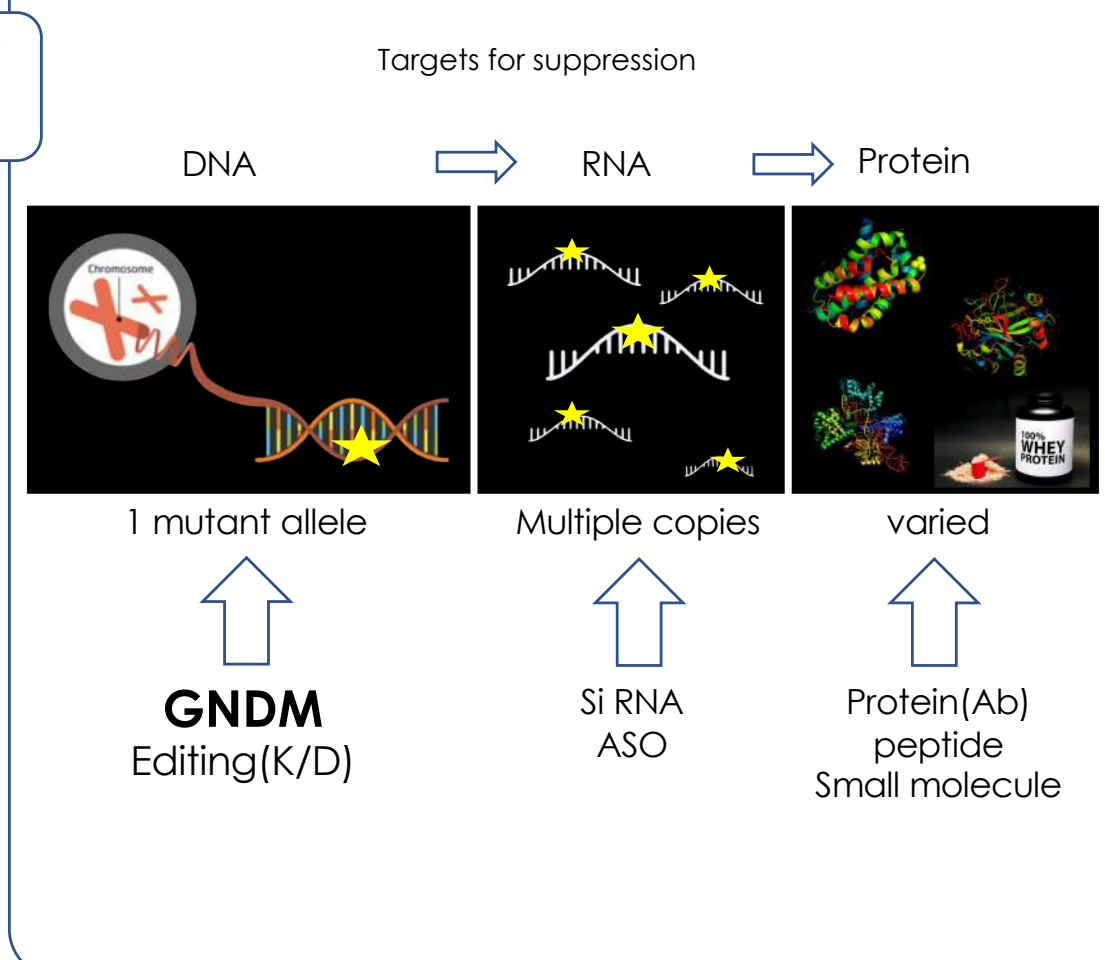
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GNDM is efficient approach both for LoF and GoF mutation

In LoF disorders



In GoF disorders



LoF: Loss of function
GoF: Gain of (mal)function

K/D: Knock-down

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Uniquely positioned even in the CRISPR field

Positioning in CRISPR and Editing Company

	Editing (Gene)	Editing (base)	Modulation (epigenetic editing)
CRISPR	Editas Intellia CRISPR	Beam	MODALIS
Other (e.g. ZFN)		Sangamo	

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4. MDL-101 for MDC1A
MDL-104 for Tau
MDL-206 for Angelman Syndrome

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MDL-101 for MDC1A

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MDC1A

Severe muscular dystrophy caused by loss of function mutation in LAMA2 gene

- Frequency: **1 in 30,000***
- Inheritance Pattern: **Autosomal Recessive**
- Early onset: apparent at birth or within the **first few months of life**
- Symptoms:
  Severe muscle weakness;
  Lack of muscle tone (hypotonia);
  Little spontaneous movement;
  Joint deformities (contractures);
  Heart problems and seizures.
- Life expectancy:
  Because of the serious health problems that occur in this form of the disorder, many affected individuals **do not survive past adolescence**.
- Genetic cause: **LAMA2** mutation

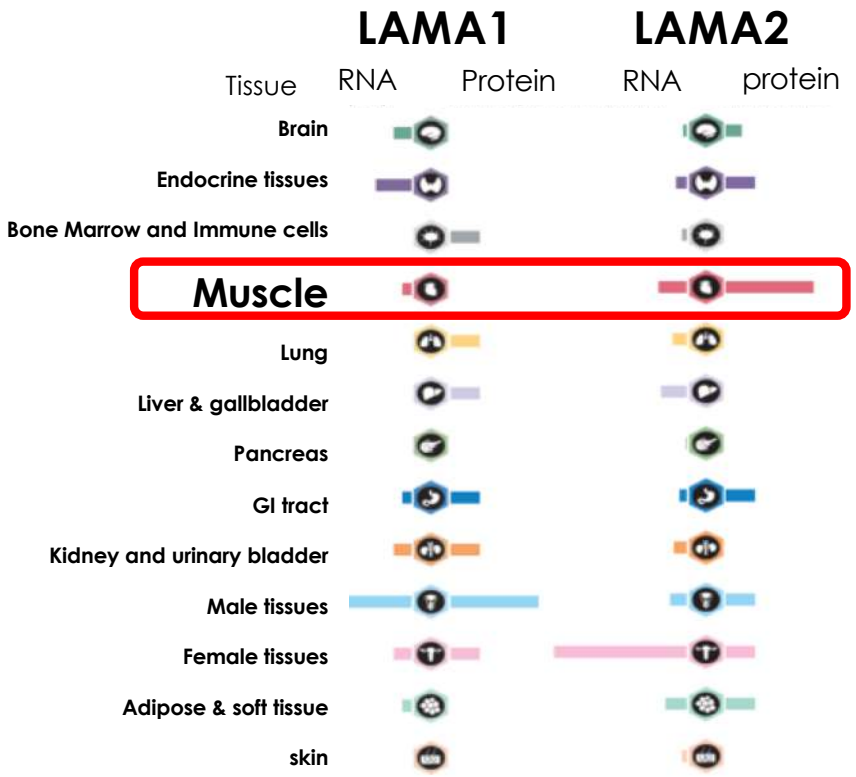
MDC1A: merosin- deficient congenital muscular dystrophy type 1A
*Orphanet

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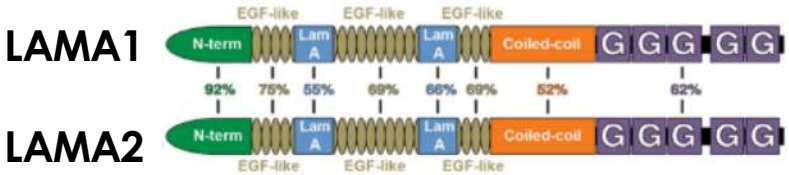
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By activating the sister gene, LAMA1, GNDM compensates missing function of LAMA2

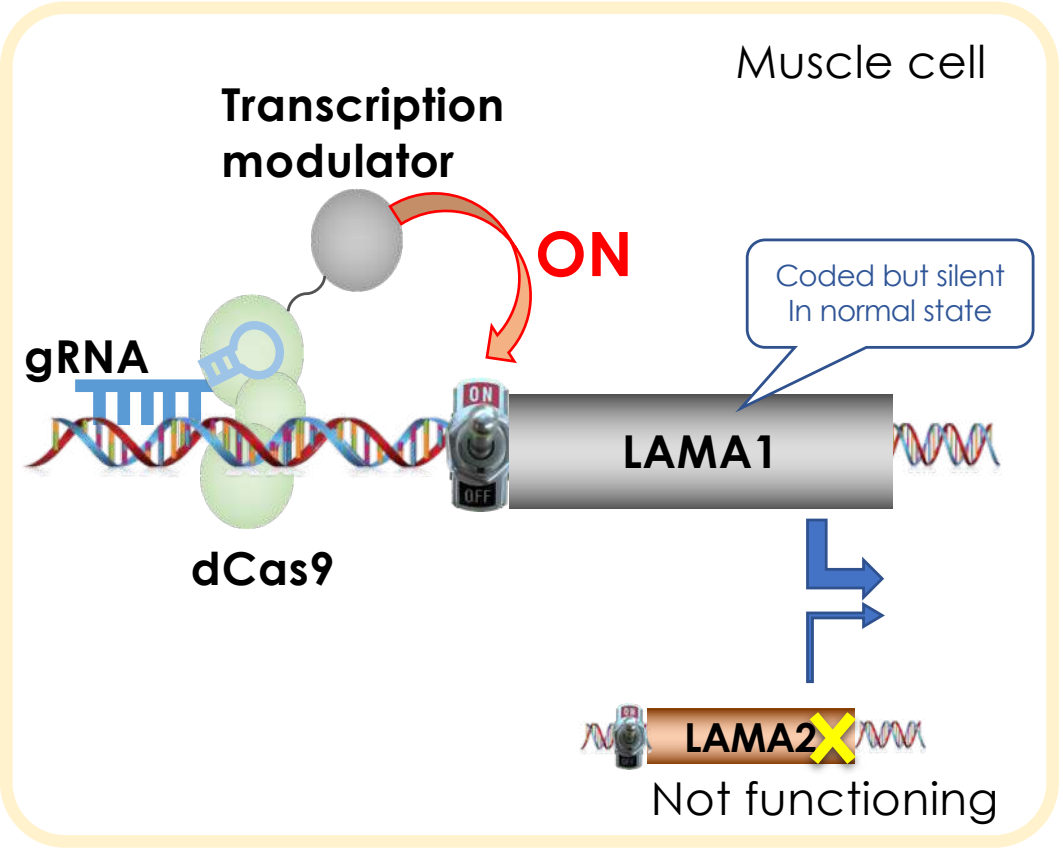
Exspression pattern of LAMA1and LAMA2 by tissues



Protein structure of LAMA1 and 2



CRISPR-GNDM® targeting LAMA1

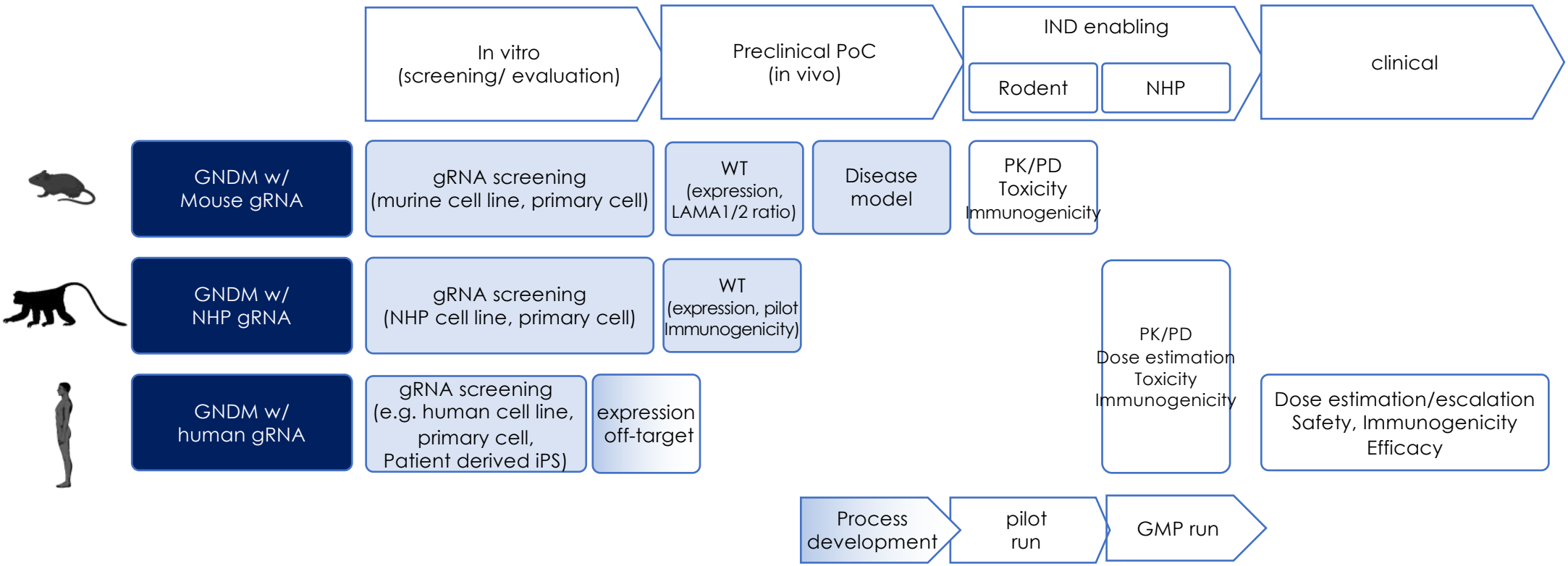


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Having convincing animal data both in 2 species, moving forward to IND enabling studies with establishing manufacturing process

Path to clinic for CRISPR-GNDM®



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In vivo study Summary

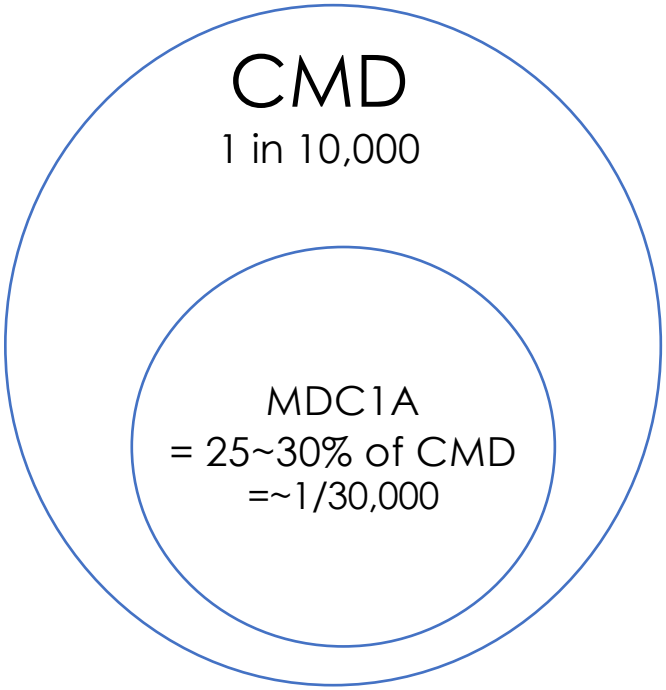
- Mouse
  - in vivo upregulation of LAMA-1 in skeletal and cardiac muscles using a Lama-1 specific gRNA
    - Strong GNDM mRNA expression
    - LAMA-1 mRNA expression induced up to 50% of endogenous LAMA-2 mRNA
    - GNDM/Cas9 protein expression detected by IHC
    - LAMA-1 protein broadly expressed in muscle tissues by IHC
  - Efficacy study in MDC1a disease models completed
    - **Confirmed significant improvement in dyW and dy2J disease models**
      - **GNDM expressed in muscle tissues**
      - **LAMA-1 expressed in various muscle tissues**
      - **No significant toxicity observed**
      - **Muscle related score significantly improved**
      - **Body weight (dyW)**
      - **Grip (dy2j and dyW)**
      - **Blood Chemistry (dy2J and dyW)**
- Cyno
  - NHP studies with AAV-cyMDL-101
    - Mild anti-Cas9 immune reaction elicited in AAV injected animals
    - No obvious lymphocytes infiltration nor tissue destruction observed in muscle tissues
    - Persistent GNDM expression detected in muscle tissues in high dose group up to the end the study(20wks)

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Prevalence of MDC1a

- Exact prevalence of MDC1A is still unknown but...
  - The prevalence of congenital muscular dystrophies (CMD) has been estimated between
    - 1-9/100,000
  - MDC1A is about ~30% of CMD:
    - **~1/30,000** with regional variation



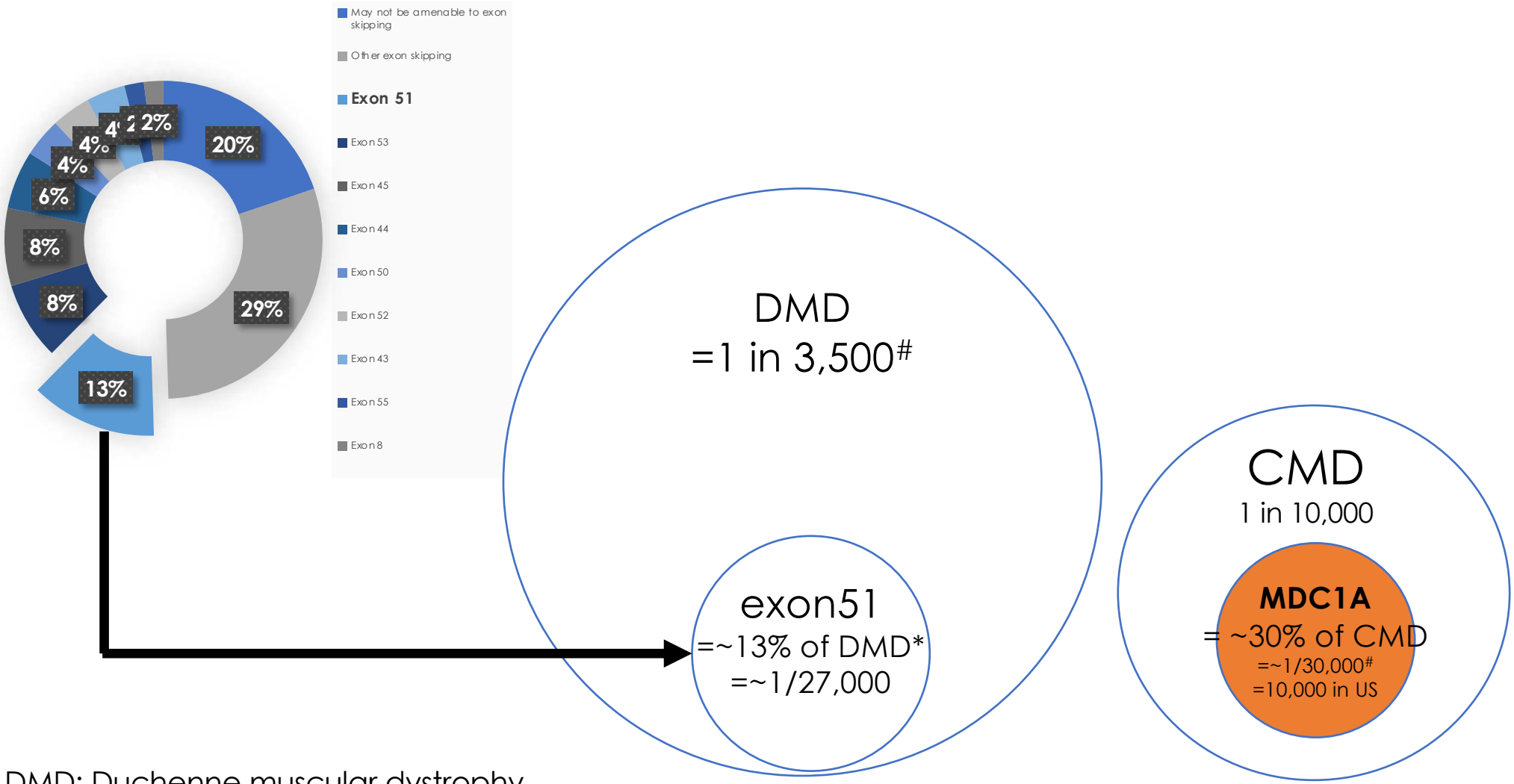
CMD: congenital muscular dystrophy

Source: orpha.net

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MDC1A is about the same size to exon 51 DMD



DMD: Duchenne muscular dystrophy

*https://www.cureduchenne.org/cure/exon-skipping/

#Source: www.orpha.net

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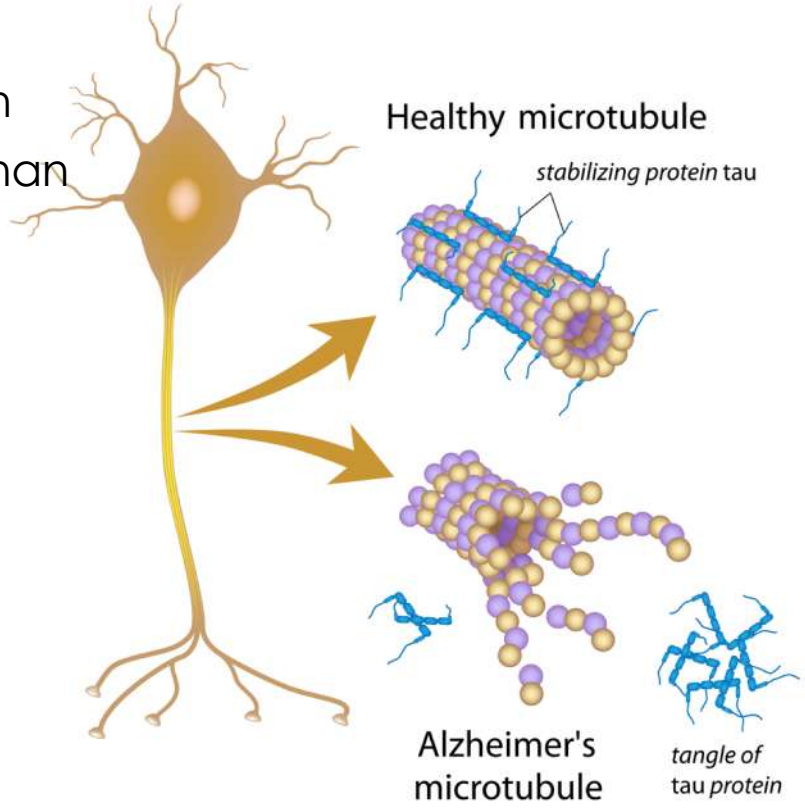
MDL-104 for Tau

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Tau is a center of attention in treating Alzheimer diseases

- Tau correlates with clinical symptoms and neuronal loss in Alzheimer's disease and other primary tauopathies.
  - Tau aggregates and tangles are thought to induce neuronal degeneration, synaptic loss and cell death
  - Tauopathies include a range of high value and orphan clinical diseases
    - AD (Alzheimer's Disease)
    - FTLD (Frontal Lobar Degeneration)
    - PSP (Progressive Supranuclear Palsy)
    - CBD (Corticobasal Degeneration)
    - Pick's disease
- Tau is likely to be a better target than Aβ because the tau burden correlates better with clinical impairments than does the Aβ burden
- Tau knockout has few adverse effects
- Therefore, reducing total Tau expression is a logical therapeutic strategy

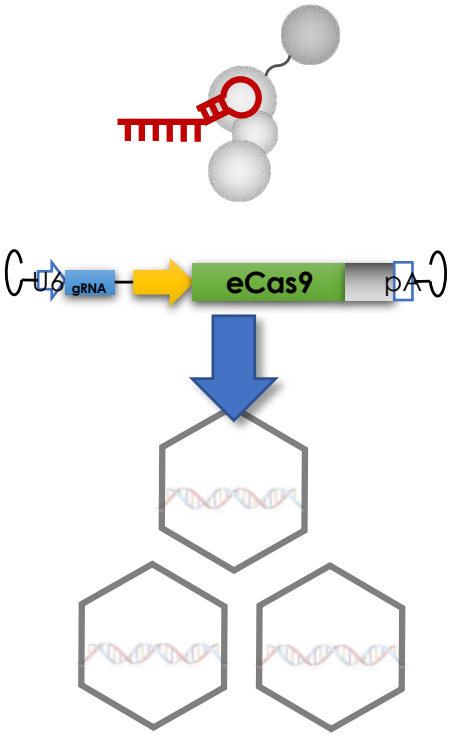


Source: Congdon EE, Nature Review Neurology 2018 "Tau-targeting therapies for Alzheimer disease"

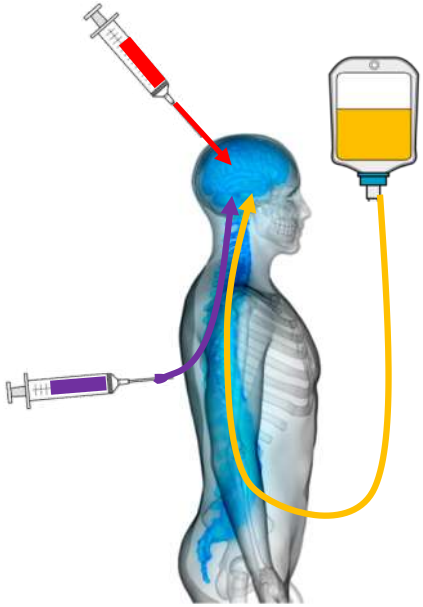
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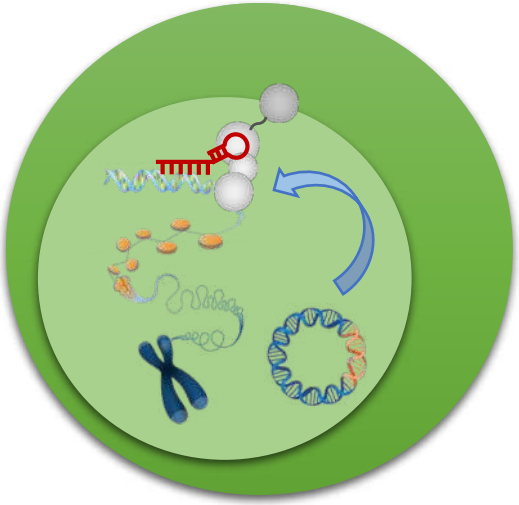
Single-administration of AAV - CRISPR-GNDM® to lower all tau forms at DNA level



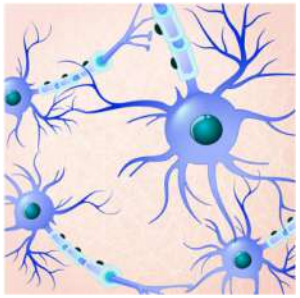
AAV vector



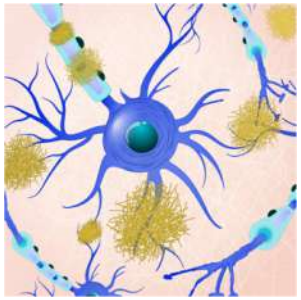
Non-integrating Virus vector



+GNDM



-GNDM (AD)



1 Packing into one AAV

2 Administration route Intracranial, Intrathecal or Intravenous

3 CRISRP-GNDM® reduce Tau at the DNA level

4 Reduce Tau Prevents Neuro-degeneration

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MDL-206 for Angelman Syndrome

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What is Angelman syndrome

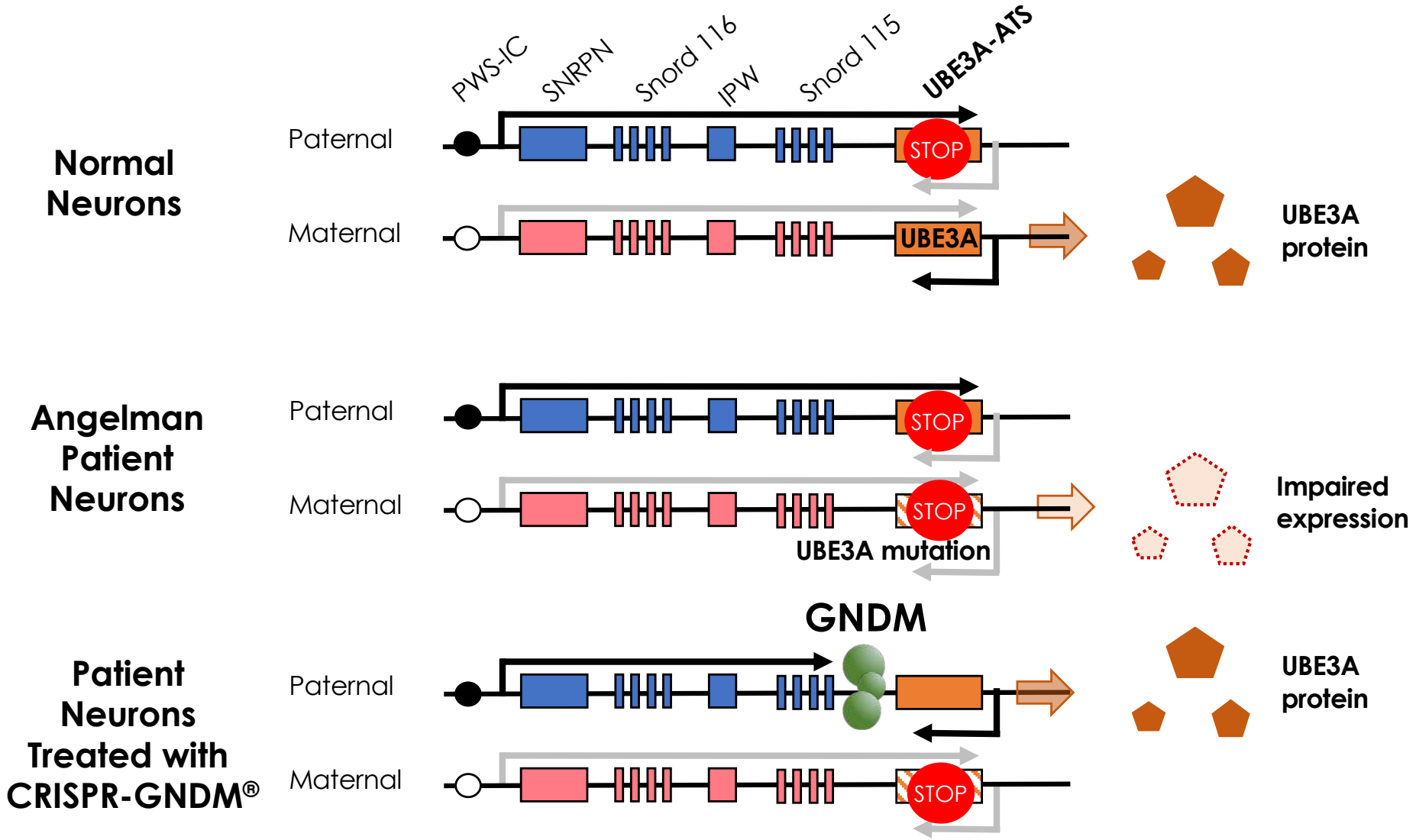
- Angelman syndrome (AS) is a rare neuro-genetic disorder that occurs in **one in 15,000 live births** or **500,000 people** worldwide.
- It is caused by a loss of function of the **UBE3A gene** in the 15th chromosome derived from the mother.
- Angelman syndrome shares symptoms and characteristics with other disorders including **autism**, **cerebral palsy** and **Prader-Willi syndrome**.
- People with AS have developmental problems that become noticeable by the **age of 6 – 12 months**. Other common signs and symptoms usually appear in early childhood like **walking and balance disorders**, **gastrointestinal issues**, **seizures** and **little to no speech**.

Source: Angelman Syndrome Foundation

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By blocking ATS transcript, GNDM un-silences UBE3A expression



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Summary of status and development plan

- Modalis has confirmed target engagement of CRISPR-GNDM® based molecule in disease model mice studies.
- While there are several molecules being studied in the field including ASO, Gene Therapy, and small molecule, no marketed drug nor late-stage product in development.
- Modalis continue to work on human version molecule to bring it into clinic.
- As Modalis regain its world-wide right to develop and commercialize the product, it will try to find partner for this product.

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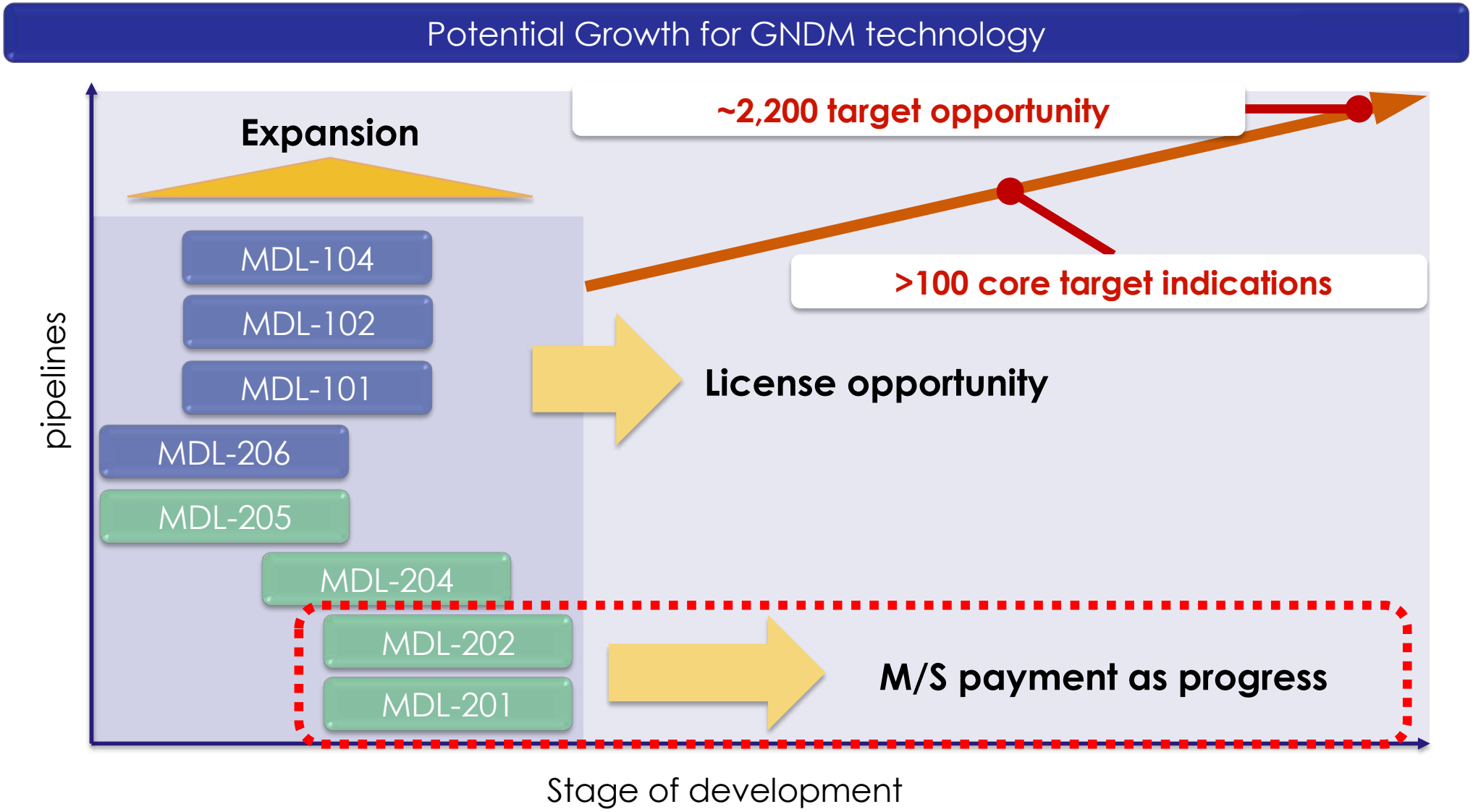
5. Growth Strategy

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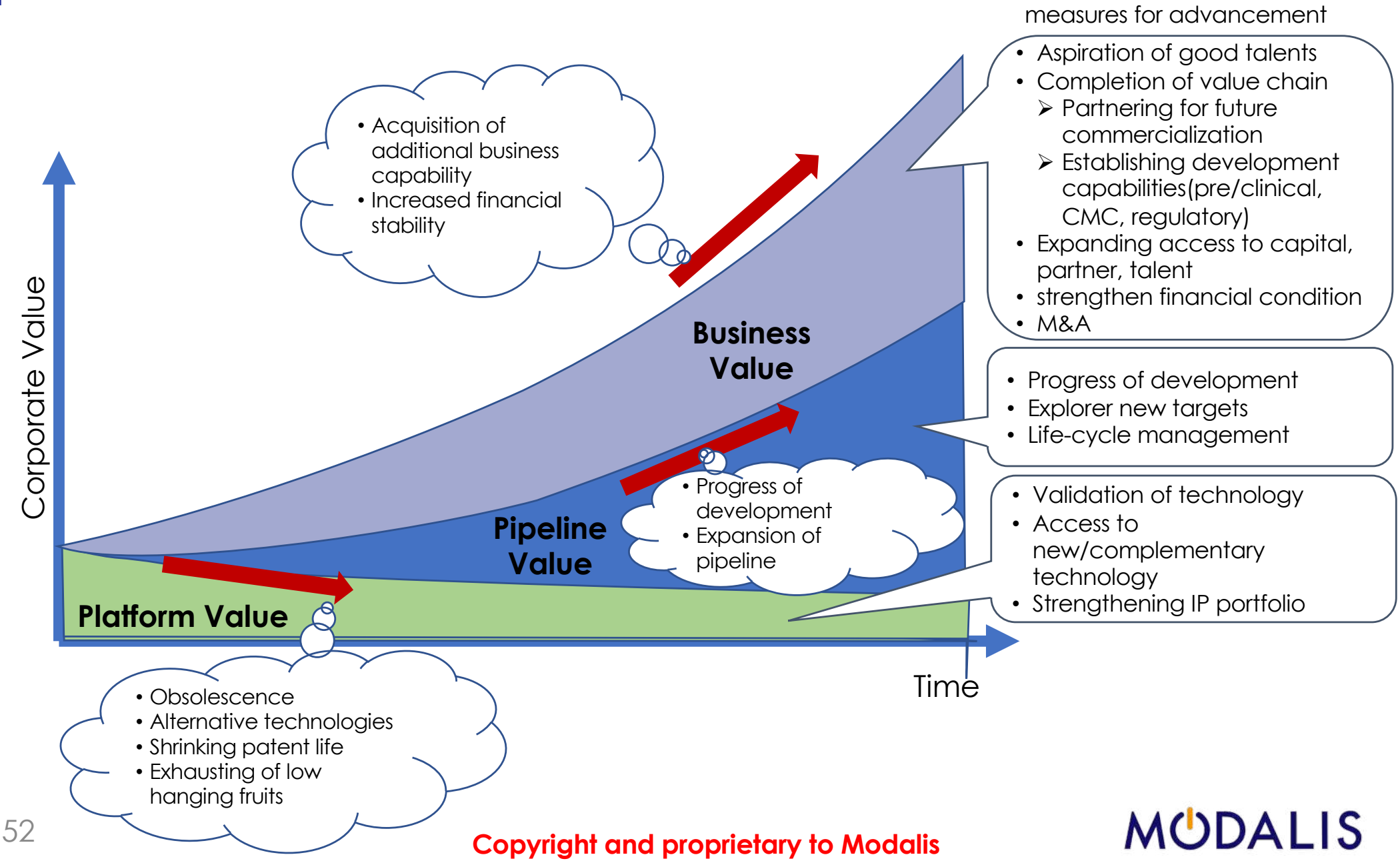
Growth Strategy

opportunity expands two dimensionally



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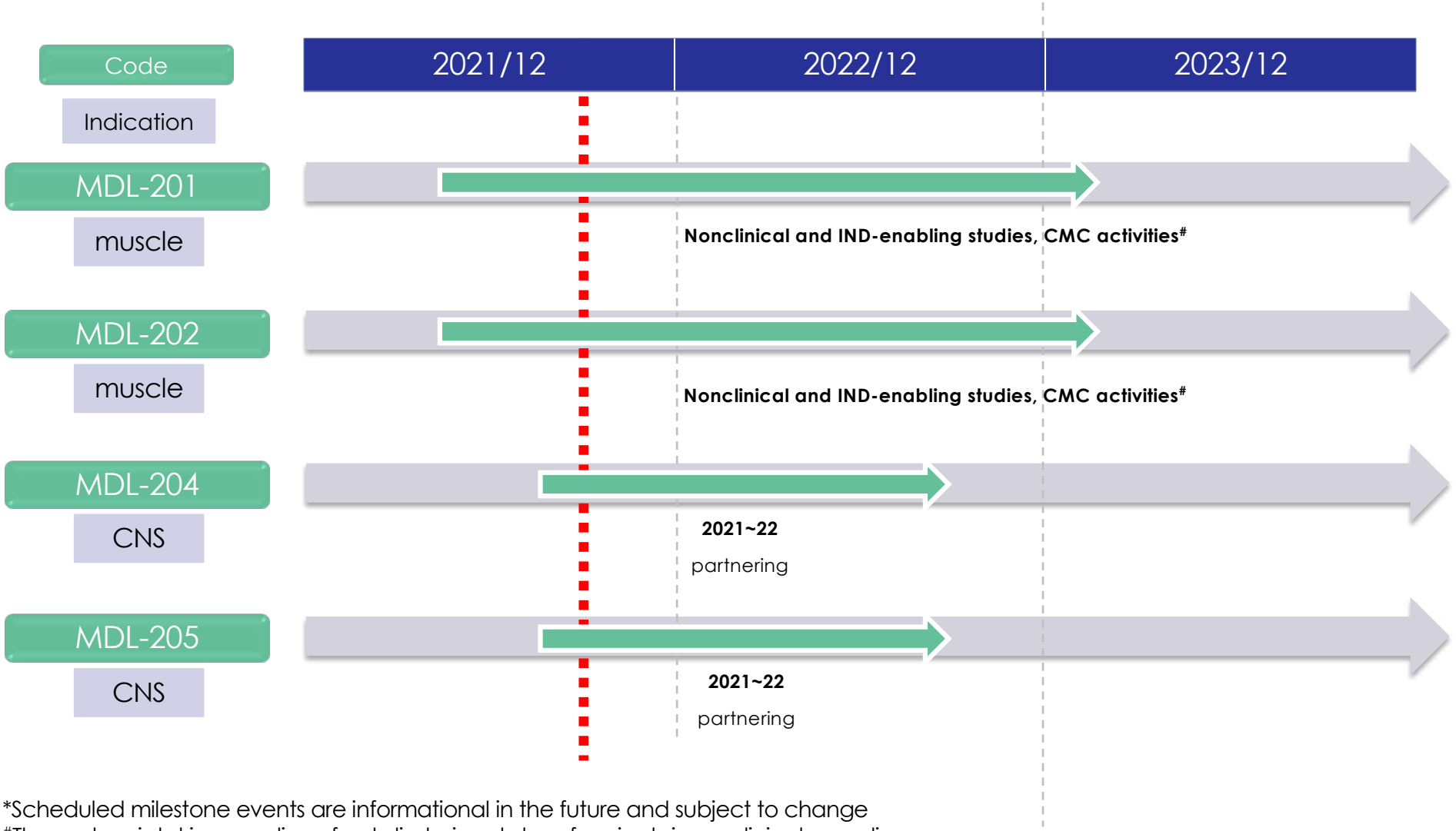
Composition of Modalis' value and measures for advance



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Collaboration pipeline

Achieved and expected Milestone events*

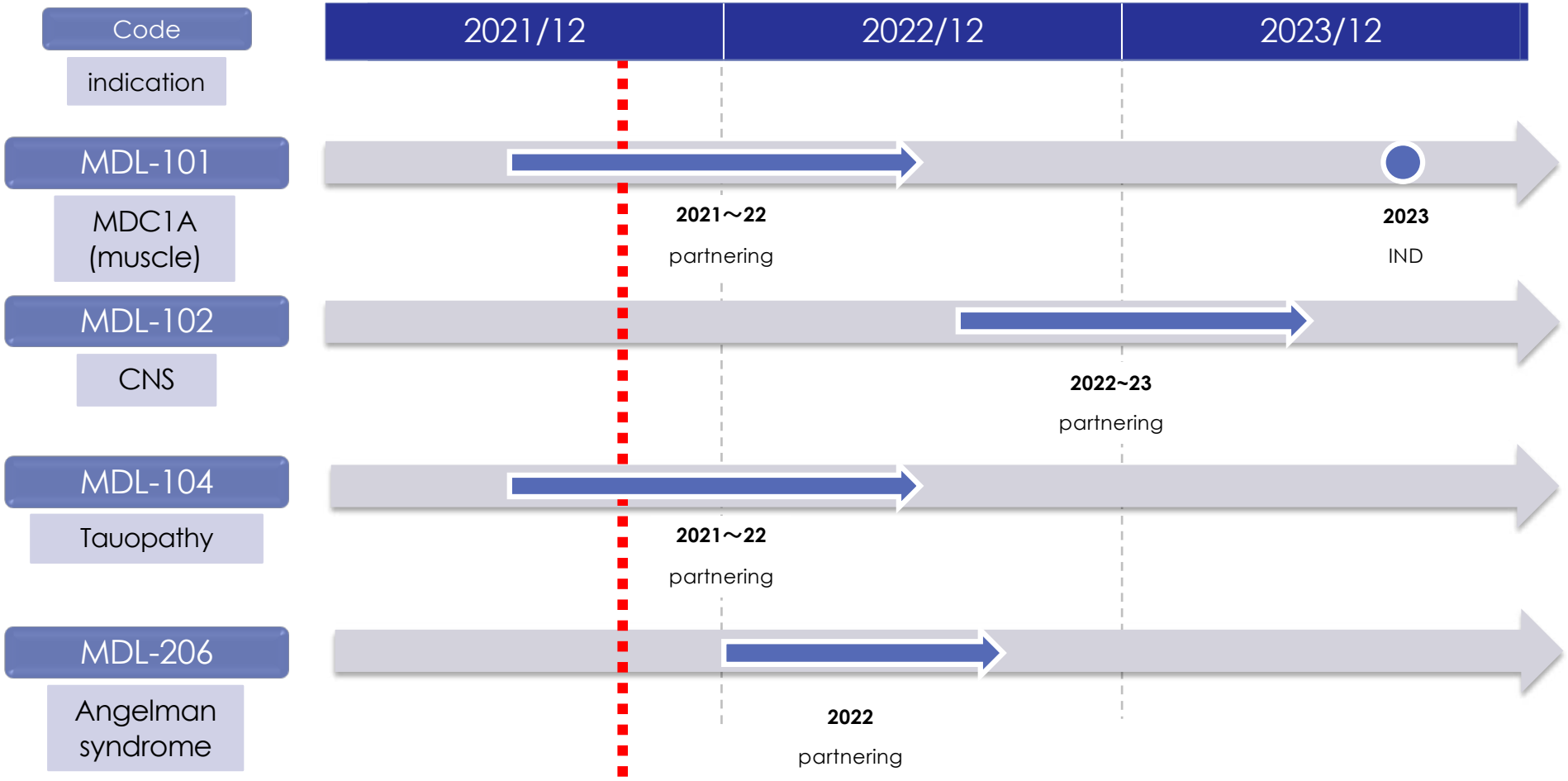


*Scheduled milestone events are informational in the future and subject to change
#The partner is taking a policy of not disclosing status of projects in preclinical or earlier

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Internal pipeline

Expected milestones by end 2023*



* Scheduled milestone events are informational in the future and subject to change

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Status summary

Collaboration pipeline

- MDL-201 and MDL-202: Astellas, which took over the whole development, has policy of not disclosing status until it becomes clinical program
- MDL-204: research collaboration is on going
- MDL-205: research collaboration is on going

Internal pipeline

- MDL-101:initiated 1) IND-enabling studies, 2) prep for FDA communications, and 3) process development for coming GMP manufacturing. At the same time, partnering discussion with multiple pharma/biotech on going.
- MDL-102: under the lead optimization
- MDL-104: additional animal studies on going while discussing potential partnering with multiple companies.
- MDL-206: Took over the whole right from Astellas to further develop by ourselves. Also exploring a new partner

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Advantages of GNDM in our business

- Unlimited upside potential
  - >100s potential indication that GNDM is superior to the other technologies
- Bye-bye, one-in-millions
  - Predictable result and timeline based on experience and streamlined research process
- Scalable
  - Experience in one indication is easily transplanted into the other

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6. Risk Information

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Known Risks and Preventative Measures（1）

Topic	Main Risks	Probability	Level of Impact	Preventative Measure(s)
(1) Risks related to the research and development of gene therapies	The risk of unforeseeable problems developing due to working with cutting-edge experimental medical treatments	Low	High	Constantly monitoring cutting-edge scientific technologies and related businesses, making pertinent judgements, taking appropriate actions
	Due to gene editing technology being a field with steady progress and rapid advancement, there is a possibility of new technologies appearing and risk of competing with other modalities	Low	High	Ensuring we are using the most up-to-date version of the underlying technologies in our research and subsequently monitoring new trends in technologies, and adopting necessary technologies as needed
(2) Risks related to the pharmaceutical industry	The risk of failure or decision to suspend development caused by a certain product or technology used in pharmaceutical development	Moderate	High	Regularly reviewing risk mitigation measures and making appropriate modifications to our portfolio when collaborating with partner companies and adding pipelines to our portfolio
(3) Risks related to execution of business activities	Due to the fact that execution and related decisions are driven by our partners, there is a possibility development is suspended and the risk of contract cancellation even if there are no failures during development	Moderate	High	Aiming to stabilize for the future and maximize profits through the stratification of our pipelines and strategically adding to our portfolio
	The risk of delays in the timeline if appropriate business coordination measures are not made regarding production that is entrusted to external parties, preclinical experiments, etc.	Low	High	Performing appropriate project management, concurrently negotiating with various candidate service providers, and securing a slot to prevent delays in the timeline

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Known Risks and Preventative Measures（2）

Topic	Main Risks	Probability	Level of Impact	Preventative Measure(s)
(4) Risks related to intellectual property rights	The risk that patents other than the originally introduced license will be required while the basic patent is in a disputed state.	Low	High	Striving to secure patents for each project (including the Company's own patents) and concurrently investigating the introduction of necessary patents
(5) Risks related to business performance, financial condition, etc.	The risk that recorded profits will not be stable, since profit is strongly influenced by the license agreements, milestones, etc.	Moderate	High	Using a hybrid model to stabilize for the future and maximize profits through the stratification of our pipelines and strategically adding to our portfolio
(6) Risks related to the company structure	The risk that we are unable to secure talented individuals who possess technical knowledge or skills for scientific research and development	Low	High	To attract talent, we are engaged in R&D that appeals to potential candidates and creating a favorable working environment in addition to adopting of a restricted stock unit system to recruit competitively
	The risk that negative gossip or rumors influence the public credibility of the Company group	Low	Moderate	Misinformation and rumors are taken seriously, and the Company maintains their position by the equitable, fair, and timely disclosure of information

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