R&D Meeting 2021

October 15, 2021
Nippon Shinyaku Co., LTD.

NIPPON SHINYAKU CO., LTD.

What we aim for

Launch one or more products each year on average

Work on R&D with more speed

PLCM | **In-house development** | **In-licensing**

Acceleration of global development

Head Quarter（Japan）

NS Pharma, Inc.（U.S.）

Europe

China

Japan

U.S.

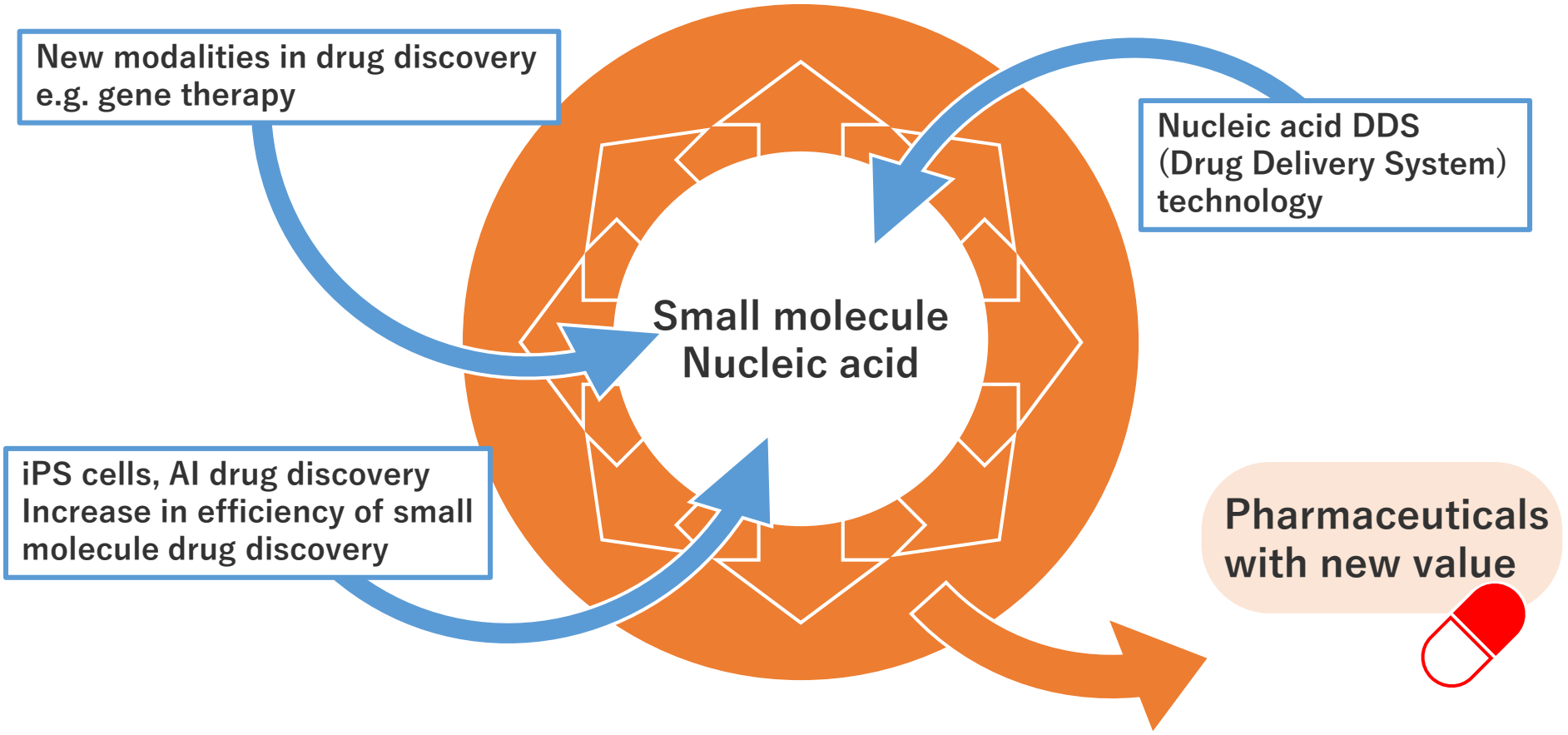
Beijing Representative Office

Led by viltolarsen, we will accelerate our global development.

Recalled from FY 2019
6th Five-Year Medium-term Management Plan presentation material (partially fixed)

Pharmaceutical R&D strategy

Expand the range of drug discovery to create new value by adding new modalities and technologies to our drug discovery platform where we created a small molecule drug Uptravi and a nucleic acid drug Viltepso.



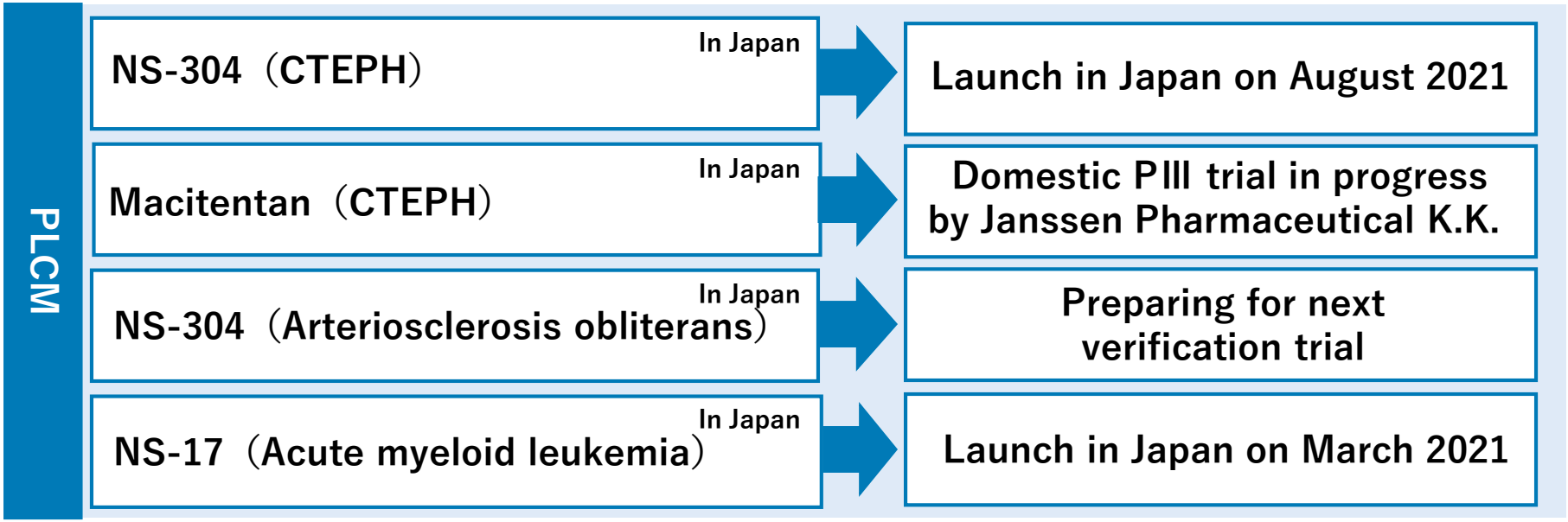
Progress of products to be launched during the 6th Five-year Mid-term Management Plan

Progress of products planned for launch during the 6th Five-Year Mid-Term Management Plan (FY2019 to FY2023)

In-house	NS-065／NCNP-01（DMD）	In Japan and overseas	Launch in Japan on May 2020 Launch in U.S. on August 2020
	NS-089／NCNP-02（DMD）	In Japan and overseas	Investigator initiated clinical trial in progress by National Center of Neuroloogy and Psychiatry
	NS-018（Myelofibrosis）	Overseas	Preparation for global P II trial
In-licensed	ZX008（Intractable epilepsy）	In Japan	Domestic P III trial in progress
	NS-73（SOS・Treatment）	In Japan	Launch in Japan on September 2019
	NS-73（SOS・Prevention）	In Japan	Termination of development
	NS-32（Iron deficiency anemia）	In Japan	Submitted NDA on March 2021 in Japan

DMD: Duchenne muscular dystrophy
SOS: Sinusoidal obstruction syndrome

Progress of products to be launched during the 6th Five-year Mid-term Management Plan



The products scheduled for launch During the mid-term management plan (FY2019 to FY2023), are generally on track

CTEPH: Chronic thromboembolic pulmonary hypertension

Products added to pipeline after the start of 6th Five-year Mid-term Management Plan

New	NS-304（Pediatric PAH）	In Japan	Domestic P II trial in progress
	NS-229（Inflammatory diseases）	In Japan	Domestic P I trial in progress
	NS-401（BPDCN）	In Japan	Preparing for clinical development

In addition to these products,
we will continue to expand our pipeline

PAH: Pulmonary arterial hypertension
BPDCN：Blastic plasmacytoid dendritic cell neoplasm

Progress of development
Nucleic acid products

Pre clinical trial	Clinical trial	Launch
Exon 50 Skipping (DMD)	NS-065／NCNP-01 Exon 53 Skipping (DMD)	NS-065／NCNP-01 Exon 53 Skipping (DMD)
Exon 51 Skipping (DMD)	NS-089／NCNP-02 Exon 44 Skipping (DMD)	
Exon 45 Skipping (DMD)	NS-035 Exon Trapping Inhibitor (Fukuyama congenital muscular dystrophy)	
Exon 55 Skipping (DMD)		
Novel coronavirus infection		

: Investigator initiated clinical trial

～To establish new technology platforms～

Aim to become an essential company in the world's healthcare field

【Next generation modalities】

- Peptide-conjugated phosphorodiamidate morpholino oligomer
- Stereo-controlled phosphorodiamidate morpholino oligomer
- Gene therapy

【Existing modalities】

- Morpholino oligonucleotide
- Small molecule drugs

R&D organization and activities

NIPPON SHINYAKU CO., LTD.

R&D policy

As a slogan for our R＆D division, we aim for "The creation of new drugs to be used worldwide". We will strive to contribute to the society through creating highly unique and distinctive drugs in the pharmaceutical field of intractable disease where small number of patients are suffering and awaiting for new treatments. Our goal is to create new drugs which becomes a ray of hope for patients awaiting for new treatments.

In order to achieve this goal, we will proceed with three approaches: in-house drug discovery, in-licensing, and PLCM*.

*Product Life Cycle Management
Maximize product value by considering new indications, dosage forms, etc. for existing and developed products.

R&D approach

➢Approach towards drug discovery modalities

In addition to our two pillars of drug discovery modalities in our R&D; nucleic acid and small molecule, we will continue to work on new modalities such as gene therapy, that are suitable for targeting certain diseases.

➢Promote data-driven drug discovery

We will improve the quality and quantity of data and utilize internal and external big data to promote research and development not only based on experience and intuition but also through data analysis using AI and IT, to speed up and improve the probability of success.

➢Encourage open innovation

We will continue to cooperate with top-class research institutions and venture companies to develop research themes and collect information on new technologies. In specific research areas, we aim to build strategic networks with academia and ventures.

R&D organization

R&D Administration Dept.

Intellectual Property Dept.

R&D Operation Dept.

NS Pharma R&D Division

R&D bases and in-house development

R&D expenditure (FY2020): 16.1 billion yen (13% of net sales)

Discovery Research Laboratories (Kyoto)

Discovery Research Laboratories in Tsukuba

Research and development for drug discovery in pursuit of high added value

In addition to small molecule drug discovery which we have cultivated over the years, we will continue to incorporate new technology related to drug discovery and promote the creation of new drugs which responds to the increase of functional sophistication.

Innovative and advanced R&D

With our strengths in nucleic acid research, we are able to lead the field of nucleic acid drugs. In addition, by developing next-generation nucleic acid drugs, we will promote the development of treatments for diseases that have been difficult to cure with existing modalities.

Clinical development

Domestic development (As of August 10, 2021)

Development phase	Code No. (Generic name)	Mechanism of action	Therapeutic field	Indications	Origin	Development
Launch P III	NS-065 / NCNP-01 (viltolarsen)	Exon 53 Skipping	Intractable diseases/ Orphan disease	Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku
NDA filing	NS-304 (selexipag)	Selective IP receptor agonist	Intractable diseases/ Orphan disease	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Janssen Pharmaceutical K.K.
NDA filing	NS-32 (ferric derisomaltose)	Iron	Gynecology	Iron-deficiency anemia	Licensed-in from: Pharmaosmos A/S	Nippon Shinyaku
P III	ZX008	Serotonin agonist	Intractable diseases/ Orphan disease	Dravet syndrome Lennox-Gastaut syndrome	Commercial rights from: Zogenix, Inc.	Zogenix, Inc.
P II	NS-304 (selexipag)	Selective IP receptor agonist	Cardiovascular	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku
P II	NS-304 (selexipag)	Selective IP receptor agonist	Orthopedics	Lumbar spinal canal stenosis	Nippon Shinyaku	Nippon Shinyaku
P II	NS-304 (selexipag)	Selective IP receptor agonist	Cardiovascular	Pediatric pulmonary arterial hypertension	Nippon Shinyaku	Co-development: Janssen Pharmaceutical K.K.

Clinical development

Domestic development (As of August 10, 2021)

Development phase	Code No. (Generic name)	Mechanism of action	Therapeutic field	Indications	Origin	Development
P II	NS-580	mPGES-1 Inhibitor	Gynecology	Endometriosis	Nippon Shinyaku	Nippon Shinyaku
P I / II	NS-87	Liposomal combination of cytarabine and daunorubicin	Hematologic malignancies	Secondary acute myeloid leukemia	Licensed-in from: Jazz Pharmaceuticals plc	Nippon Shinyaku
P I	NS-229	JAK1 inhibitor	Inflammatory diseases	Inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku
Preparation for P I	NS-917	DNA stand-break by incorporating itself into DNA	Hematologic malignancies	Relapsed/refractory acute myeloid leukemia	Licensed-in from: Delta Fly Pharma	Nippon Shinyaku
Preparation for development	NS-401 (tagraxofusp)	Targeting cancer cells expressing CD123	Hematologic malignancies	Blastic plasmacytoid dendritic cell neoplasm	Licensed in from: The Menarini Group	Nippon Shinyaku

mPGES-1: membrane-associated prostaglandin E synthase-1

Clinical development

Overseas Development (As of August 10, 2021)

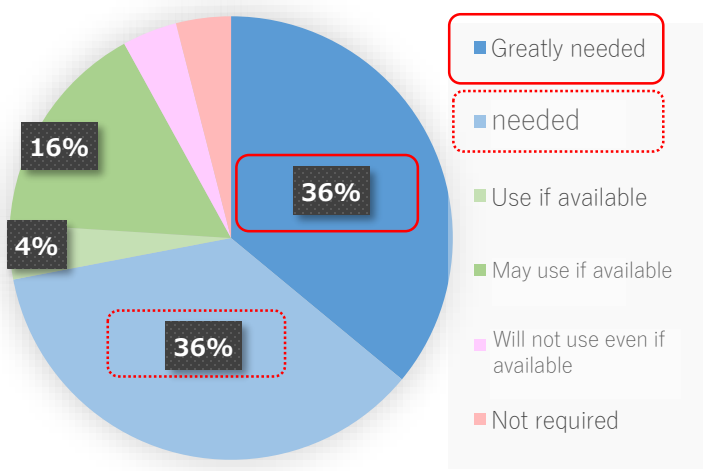
Development phase	Code No. (Generic name)	Mechanism of action	Therapeutic field	Indications	Origin	Development
Launch P III	NS-065 / NCNP-01 (viltolarsen)	Exon 53 Skipping	Intractable diseases/ Orphan disease	Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku
P III	NS-304 (selexipag)	Selective IP receptor agonist	Cardiovascular	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Licensed-out to: Johnson & Johnson
Preparation for P II	NS-018 (ilginatinib)	JAK2 inhibitor	Hematologic malignancies	Myelofibrosis	Nippon Shinyaku	Nippon Shinyaku

NS-018
- Treatment for myelofibrosis -

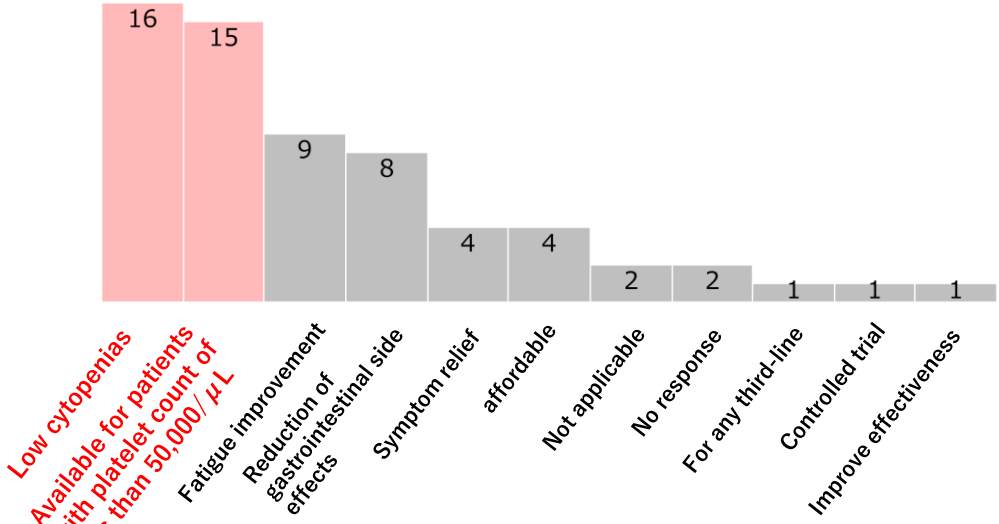
Needs for new JAK inhibitors for patients with myelofibrosis (MF)

Survey of 25 U.S. hematologists

Q. Is a new JAK inhibitor needed for patients with MF?



Q. What are the requirements desired for future JAK inhibitors?



Unmet need for indications for patients with platelet count of less than 50,000/μL

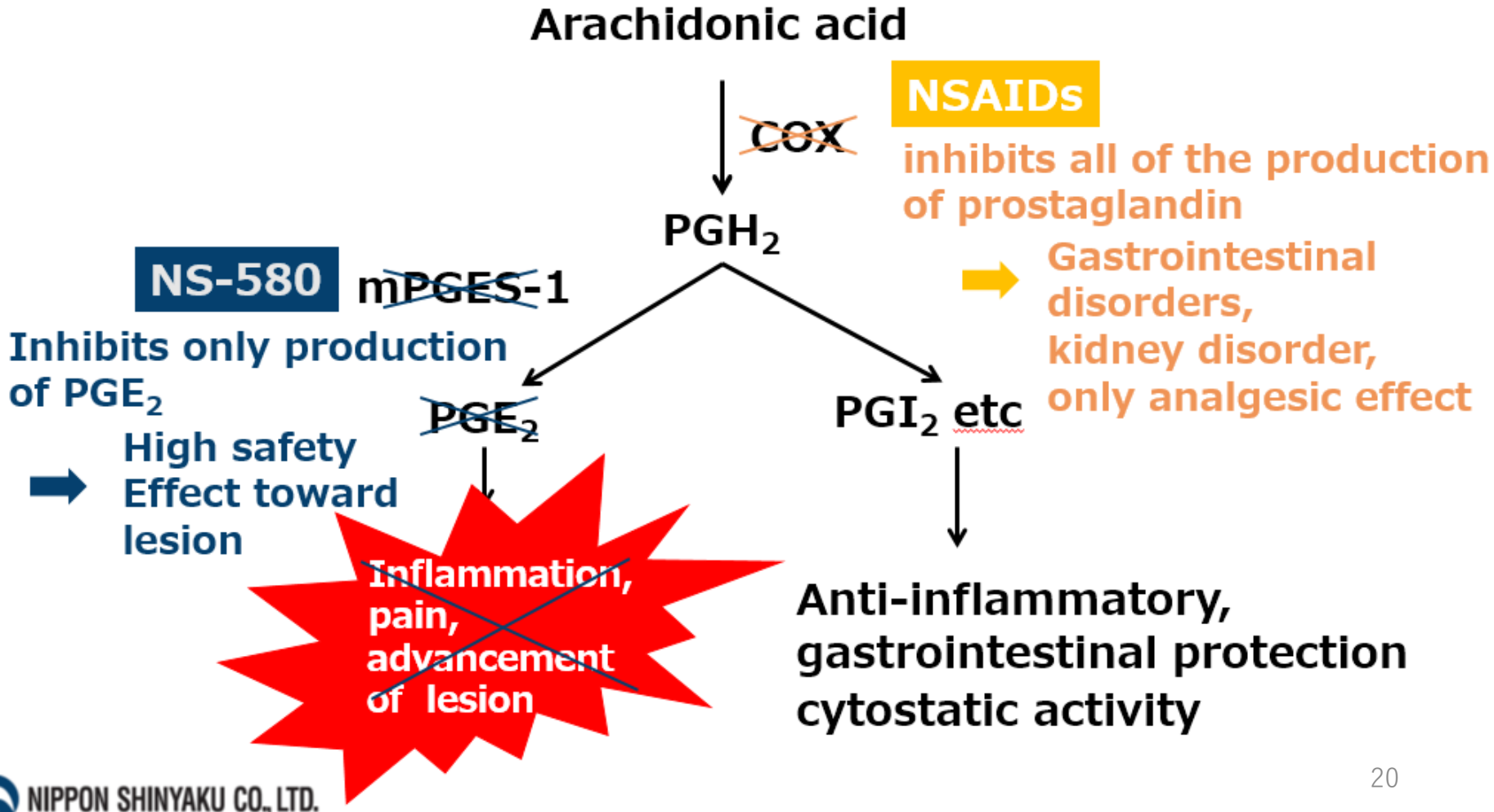
NIPPON SHINYAKU CO., LTD.

NS-018
- Treatment for myelofibrosis -

Development phase	Preparing overseas PII
Origin	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indications	Myelofibrosis
Dosage form	Tablet
Feature	✓ Potent and highly selective JAK2 inhibitor ✓ High efficacy and safety are expected for myelofibrosis patients with low platelet count, for whom QOL improvement can't be obtained because no treatment is available
Development strategy	We will aim for 1st line treatment for myelofibrosis patients with platelet count of less than 50,000/μL, which is an unmet medical need, by utilizing the efficacy and safety profile characteristic of this drug

NS-580
- Treatment for endometriosis -

By inhibiting mPGES-1 selectively, inhibits the production of PGE_2



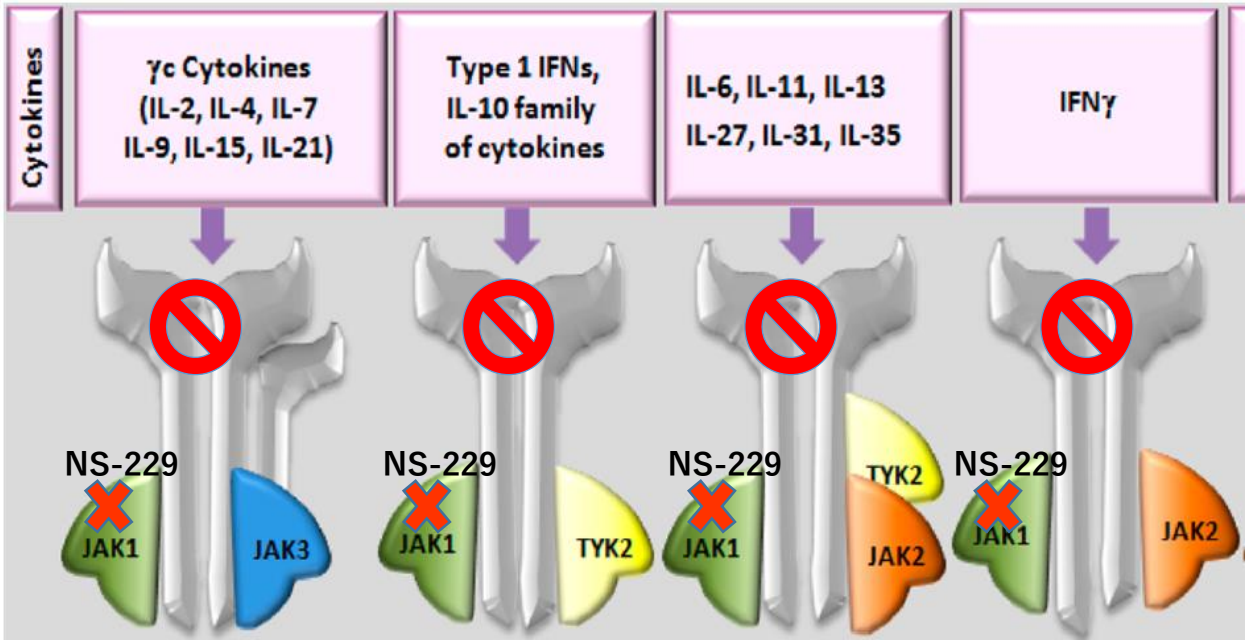
NS-580
- Treatment for endometriosis -

Development phase	PII trial
Origin	Nippon Shinyaku
Mechanism of action	Membrane-bound prostaglandin E synthase-1 (mPGES-1) inhibition
Indications	Endometriosis
Dosage form	Oral agent
Feature	✓ Treatment for endometriosis without hormonal effect and with possible analgesic potency ✓ It is expected to be safe and can be taken over a long term

NS-229
- Treatment for inflammatory diseases -

Selective inhibitory effect on JAK1 compared to existing drugs

- The JAK family consist of four members (JAK1-3 and TYK2).
- JAK1 involves pathogenesis of inflammatory diseases through various cytokine signals
- JAK1 inhibitors launched for rheumatoid arthritis and atopic dermatitis



Adapted from Clark JD et al., al. J Med Chem, 2014, 57 (12), 5023-5038.

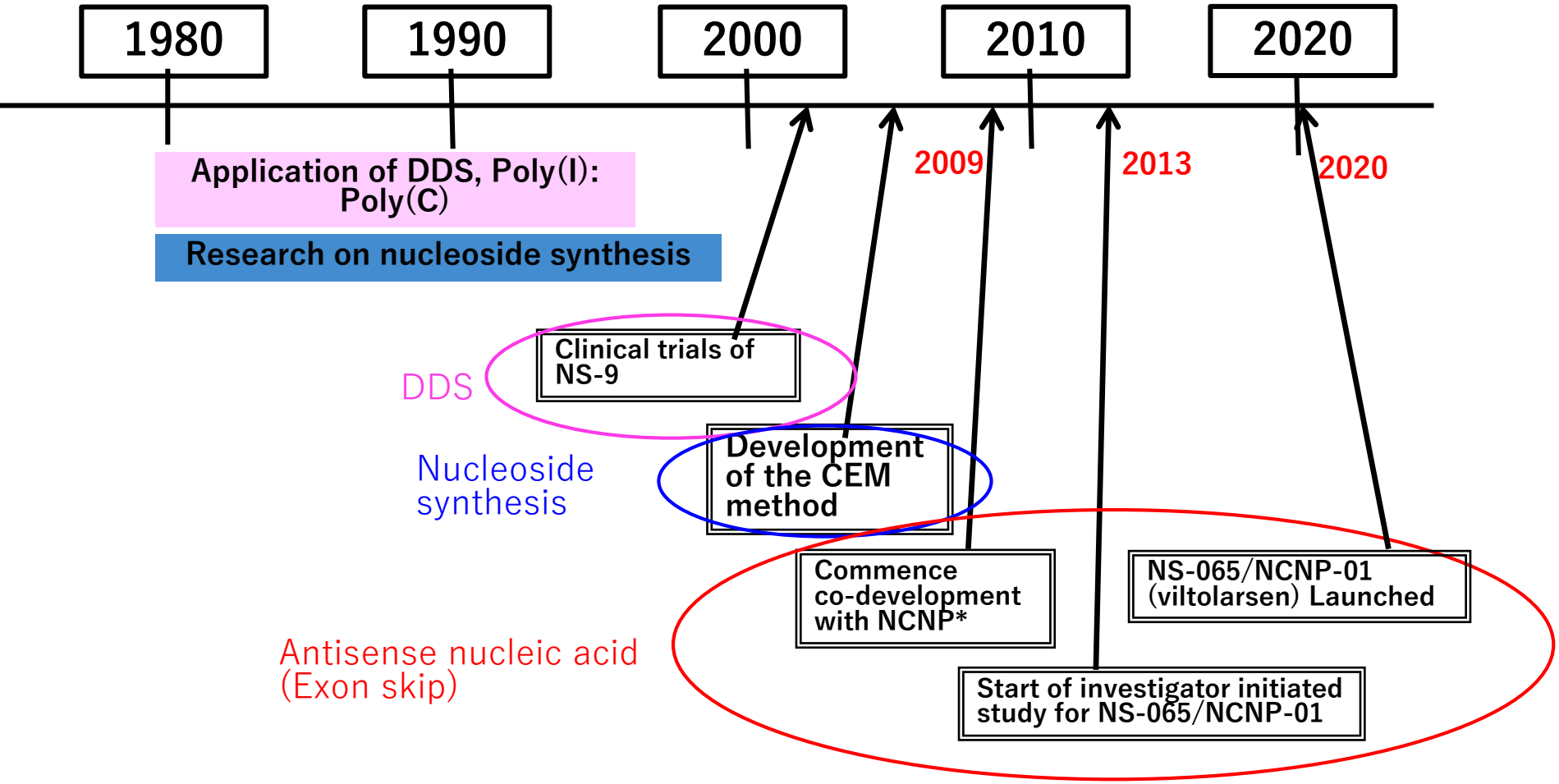
NS-229
- Treatment for inflammatory diseases -

Development phase	PI trial
Origin	Nippon Shinyaku
Mechanism of action	JAK1 inhibition
Indications	Inflammatory diseases
Dosage form	Oral agent
Feature	✓ Potent and highly selective JAK1 inhibitor ✓ High efficacy and good safety profiles are expected in the treatment of inflammatory diseases
Development strategy	Planning to develop in Japan and in the U.S. for P2 and beyond, targeting diseases that are not expected to be sufficiently treated with existing JAK1 inhibitors

R&D progress in nucleic acid drug

NIPPON SHINYAKU CO., LTD.

History of research on nucleic acid drugs



*NCNP: National Center for Neurology and Psychiatry

Characteristics of nucleic acid drugs

(1) Activates toward targets which were difficult to approach with exisiting modalities

Direct linkage to genetic information

(2) Highly selective

Precise targeting to the target gene sequence

(3) Development requires expertness

Sequence design, nonclinical evaluation, clinical trials, and mass production

(4) Shortening drug discovery period

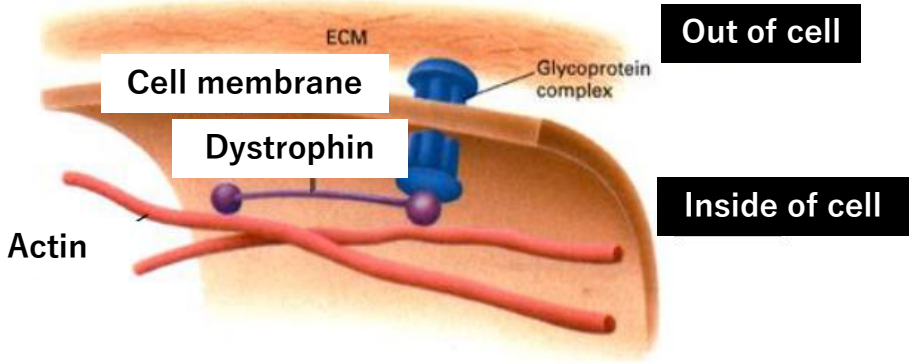
Improves the efficiency of new drug development

Treatment for Duchenne muscular dystrophy

NIPPON SHINYAKU CO., LTD.

Duchenne muscular dystrophy (DMD)

- Incidence: about 1/3,500 male births
- Number of patients:
  approximately 3,500-5,000/Japan
- Cause: dystrophin gene mutation
- Progressive muscular atrophy
- Onset around age 3 years
- Difficult to walk at age 11-13
- Respiratory failure in the 20s



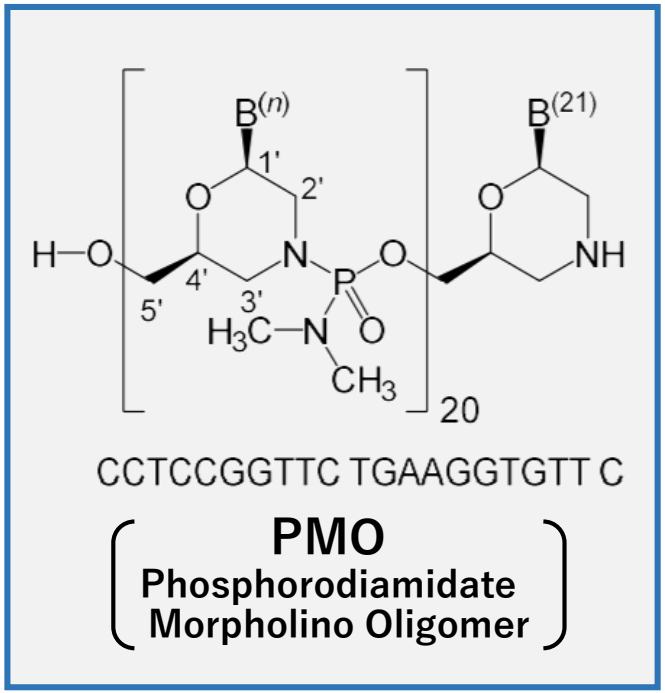
Adapted from H. Lodish *et al.*, in Molecular Cell Biology, p999

Viltepso (viltolarsen: NS-065/NCNP-01)

Origin: Nippon Shinyaku
National Center of Neurology and Psychiatry (co-development)

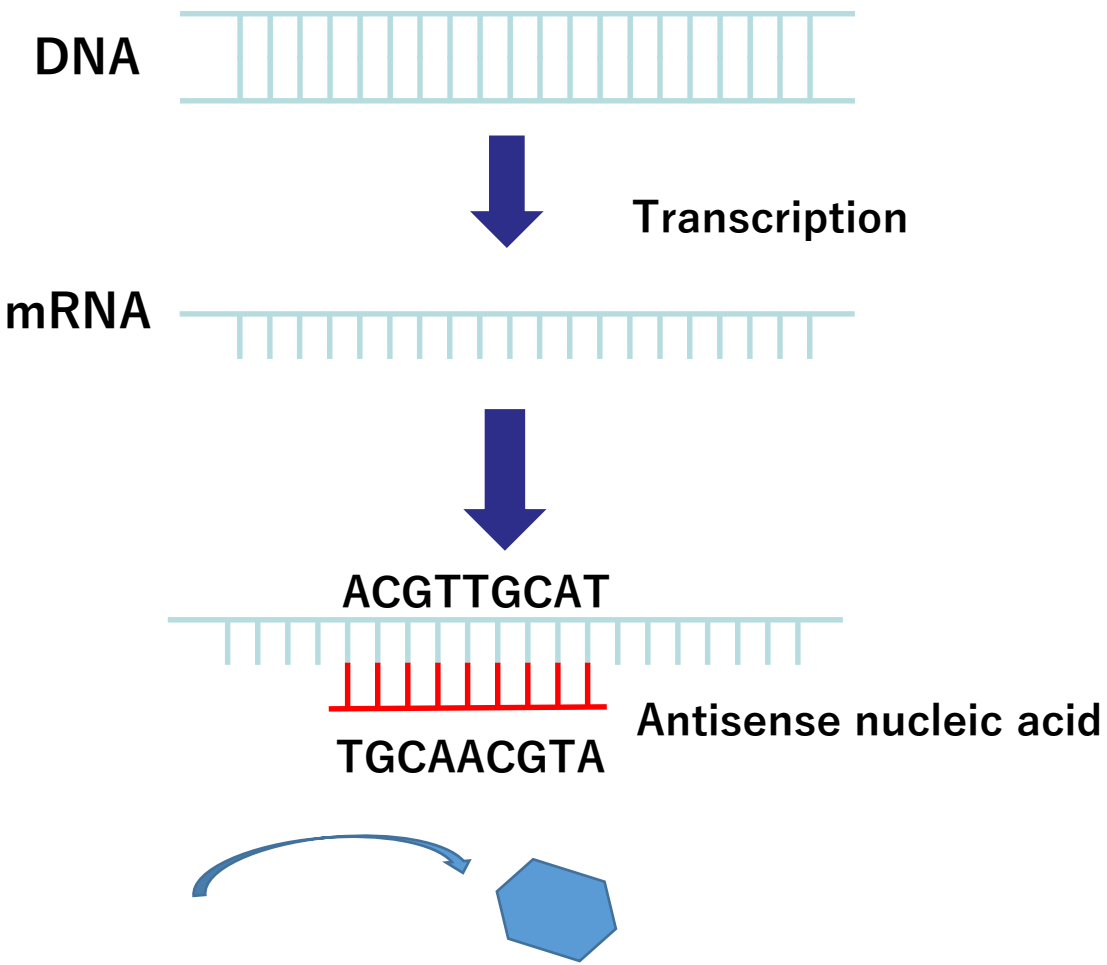
Feature:

- Antisense nucleic acids with morpholino oligomer structure
- High exon 53 skipping activity
- March 2020 manufacturing and marketing approval obtained in Japan
  August 2020 U.S. FDA approved
  (Dosage and administration: 80 mg/kg/weekly intravenous infusions)



FDA: Food and Drug Administration

Mechanism of antisense nucleic acid - Block the target sequence -



Antisense nucleic acids: single-stranded nucleic acid with 20-30 bases
Targets mRNA
Work inside of cell

Inhibits binding of functional factors by binding against target sequences

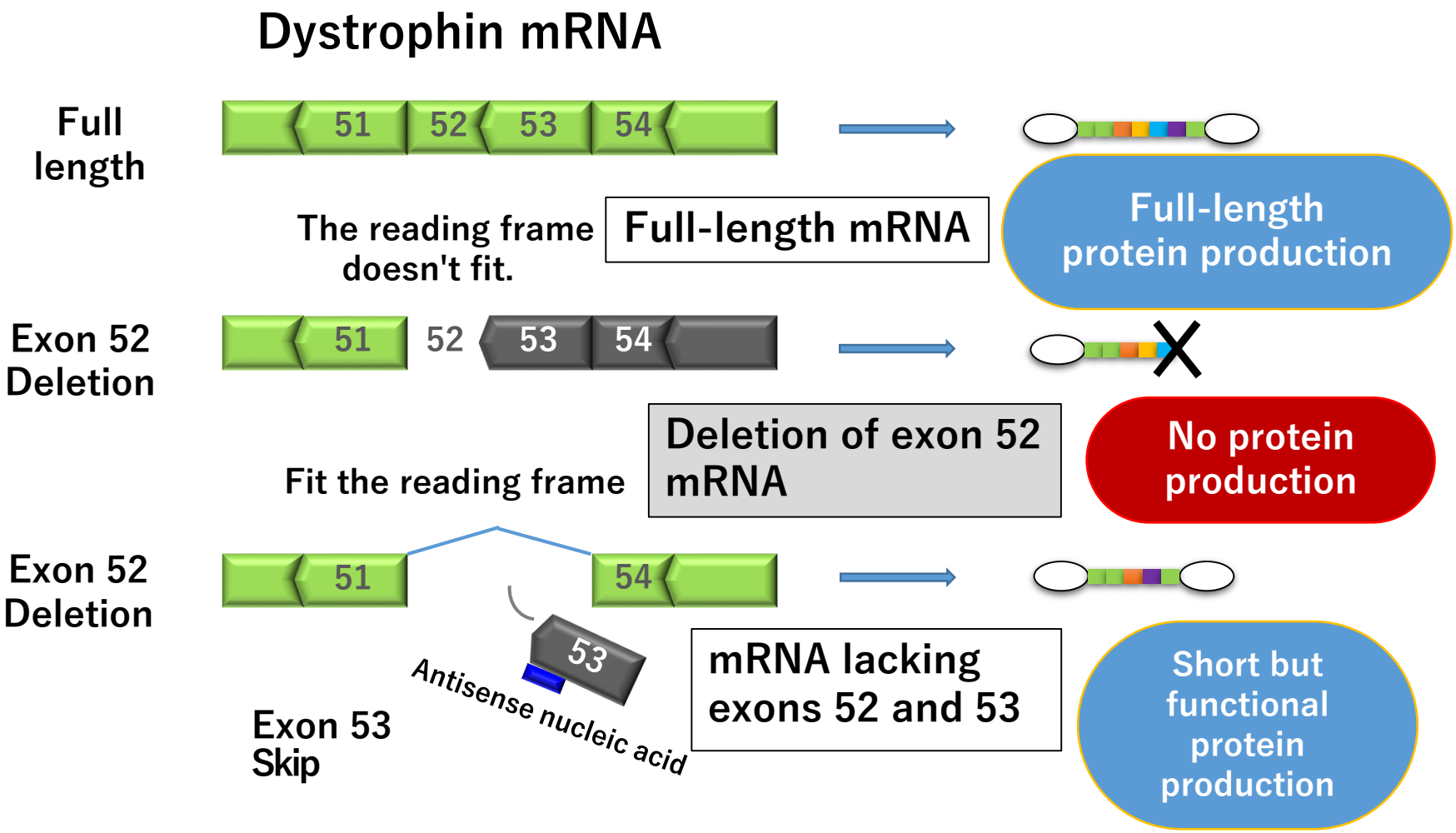
↓

Inhibits the work of functional factors

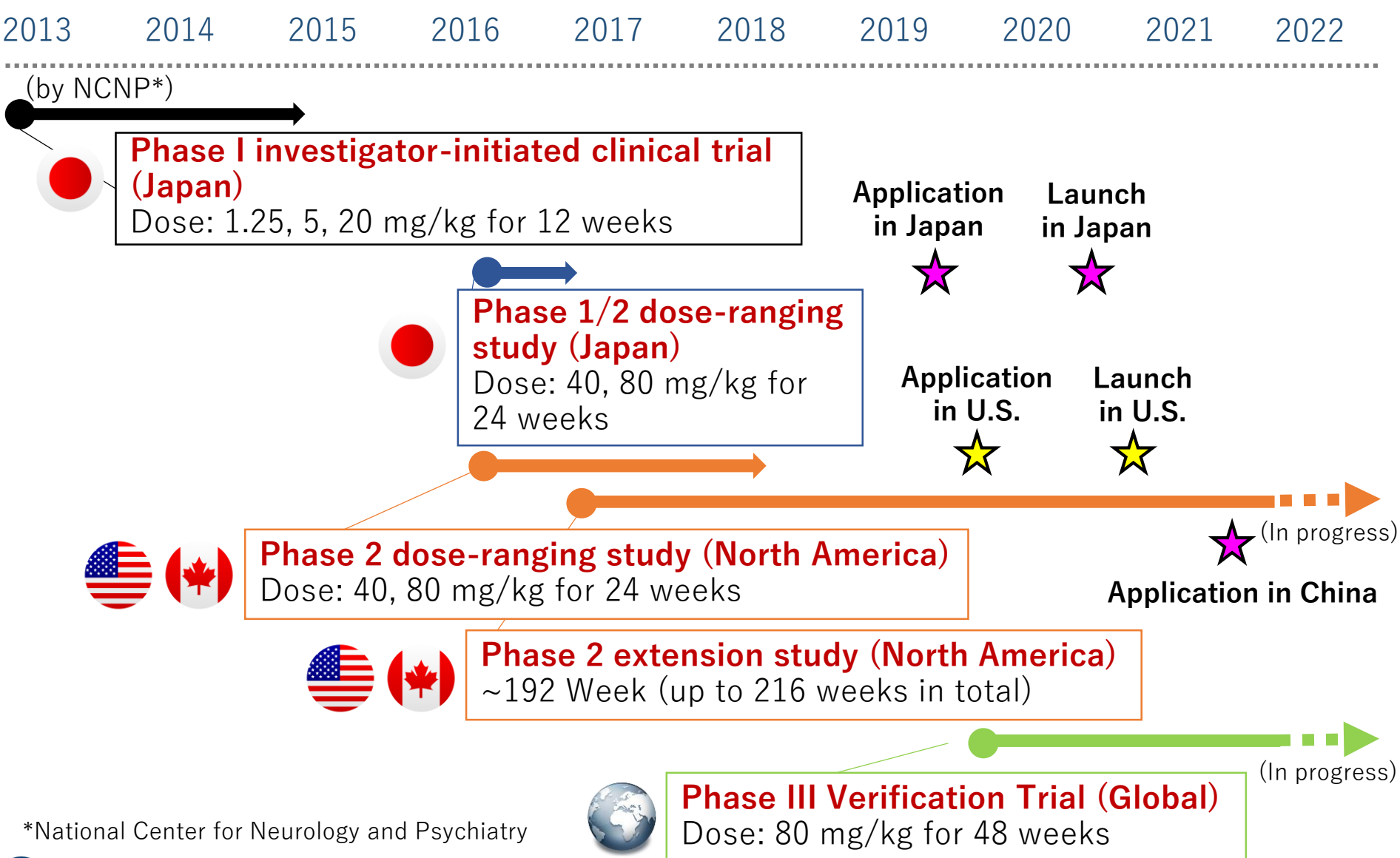
By blocking sequences involved in recognition as exons, it can be repressed from being taken into the mRNA.

→ Exon Skipping

Principles of DMD exon skipping therapy



Overview of the viltolarsen clinical trials



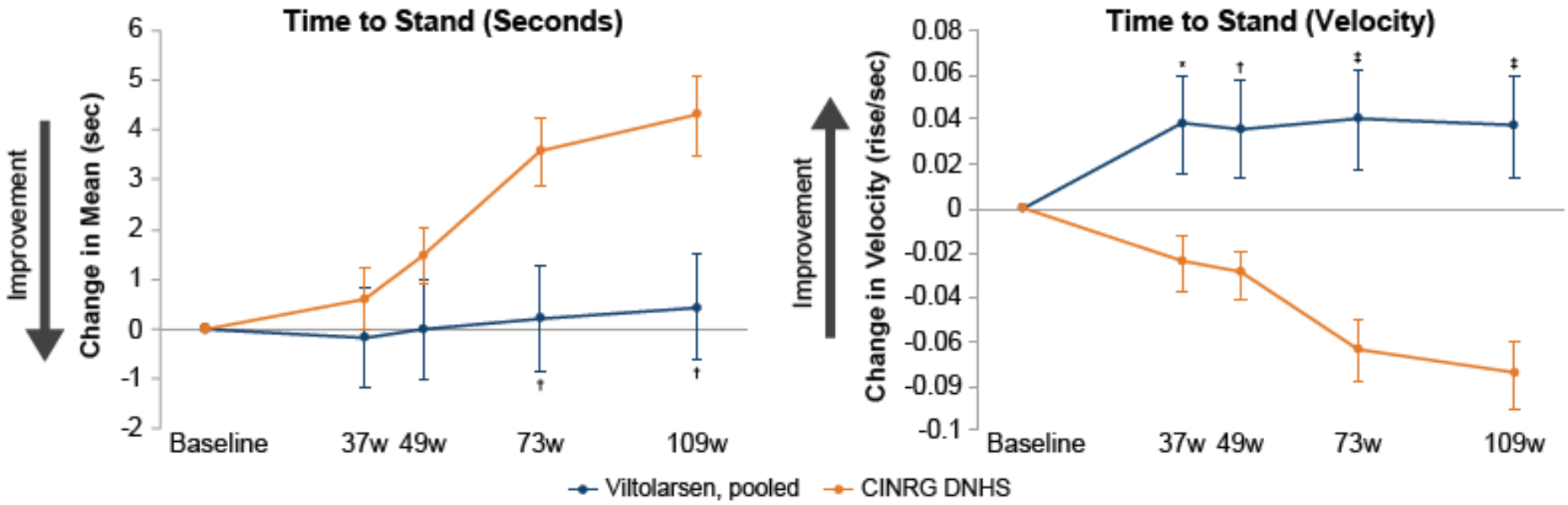
*National Center for Neurology and Psychiatry

From the presentation of the PPMD Annual Meeting (23-26 June, 2021)

PPMD: Parent Project Muscular Dystrophy

NIPPON SHINYAKU CO., LTD.

Extension Study (Interim; ～109 week)
Time to Stand from the floor (change from baseline)



w: week

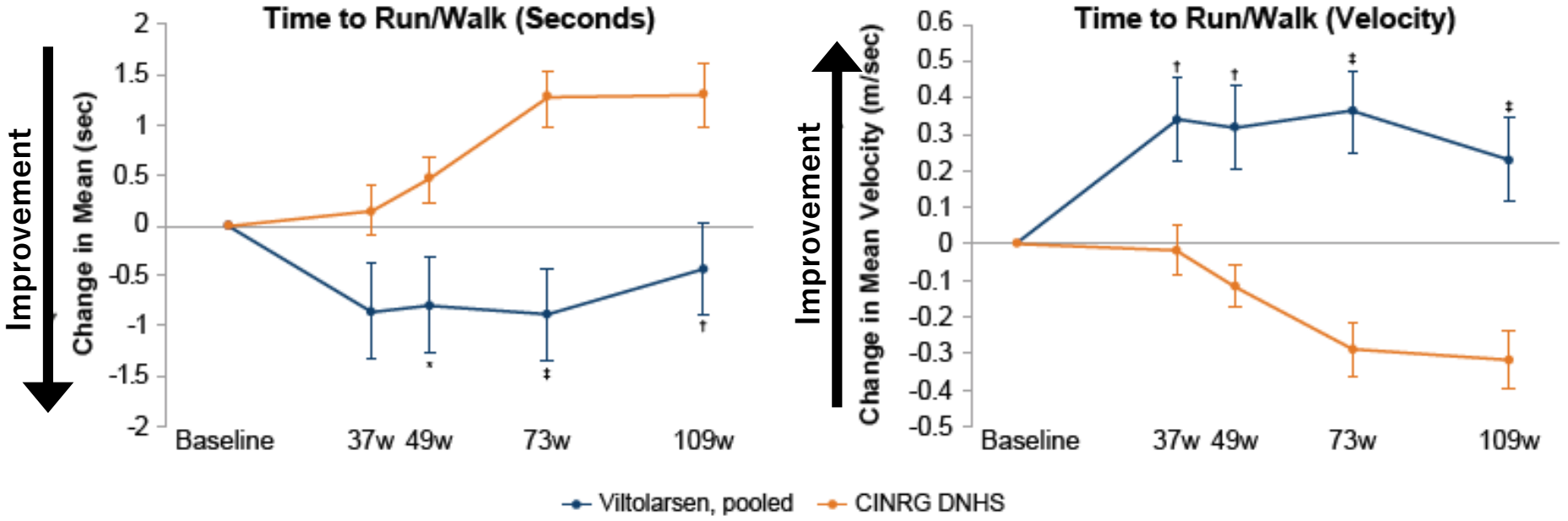
Calculation of TTSTAND velocity: rise/sec * $P < 0.05$; ($P < 0.01$; ± $P \leq 0.0001$)

The viltolarsen-treated group showed significant improvement in time to stand from the floor compared with the natural history control group.

CINRG: Cooperative International Neuromuscular Research Group
DNHS: Duchenne Natural History Study
TTSTAND: Time To Stand

PPMD Annual Meeting (June 23-26, 2021)

Extension Study (Interim; ～109 week)
10m run/walk time (change from baseline)



w: week

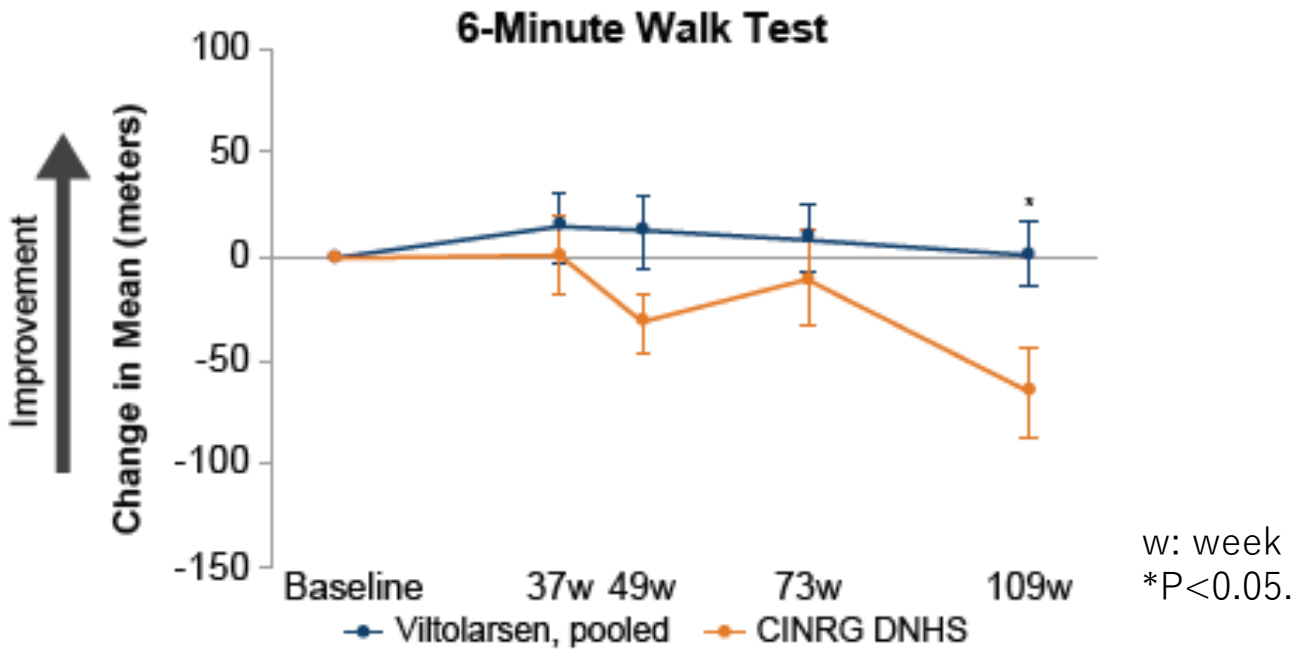
Calculation of TTRW speed: meter/sec * $P < 0.05$; $P < 0.01$; $P \pm 0.0001$

The viltolarsen-treated group showed significant improvement in time to 10m run/walk compared with the natural history control group.

TTRW: Time To Run/Walk

PPMD Annual Meeting (June 23-26, 2021)

Extension Study (Interim; ～109 week)
6-Minute Walk Test (change from baseline)



w: week
*P<0.05.

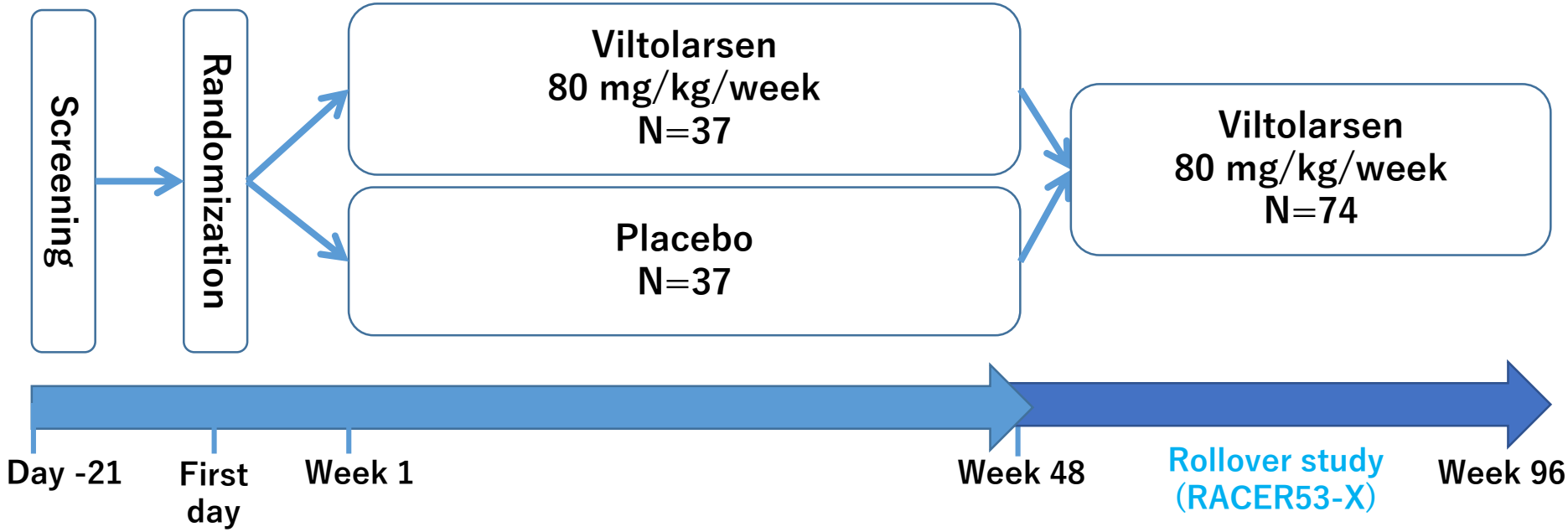
The viltolarsen-treated group showed significant improvement in walking distance compared with the natural history control group.

PPMD Annual Meeting (June 23-26, 2021)

Summary of the presentations at PPMD Annual Meeting (June 23-26, 2021)

- viltolarsen was well tolerated. All adverse events were mild or moderate.
- All 16 patients treated with viltolarsen showed significant dystrophin expression by Western Blot.
- The exon skipping effect demonstrated by RT-PCR method showed clear evidence for the exon 53 skip of viltolarsen.
- Time to Stand from the floor, 10m run/walk and 6-Minute Walk showed significant improvement in viltolarsen-treated patients compared with CINRG natural history data statistically.
- Time to Stand and 10m run/walk were improved compared to baseline in viltolarsen-treated patients.

Phase III Confirmatory Trial (Global)
Design and evaluation items



Study population

- DMD patients who can be treated with exon 53 skipping
- 4 to 8 years
- Ambulatory
- Stable therapies of glucocorticoids

Primary endpoint

- Change in time to stand from floor

Secondary endpoints

- 10m run/walk time, 6-Minute Walk, North Star Ambulatory Assessment, Change in 4-step ascent/descent time and hand-held dynamometer

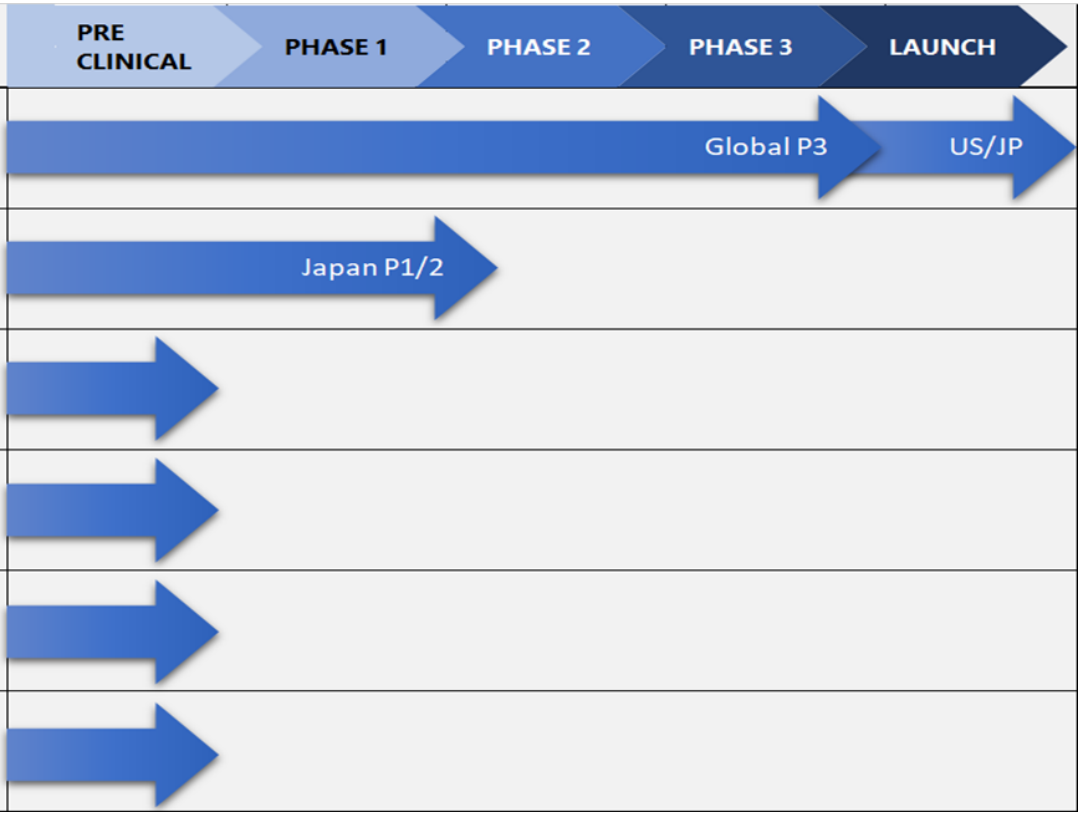
ClinicalTrials.gov: NCT04060199, NCT04768062

DMD pipeline

NIPPON SHINYAKU CO., LTD.

DMD pipeline

PROGRAM	TARGET	Patient % out of DMD
NS-065/NCNP-01 (viltolarsen)*	Exon 53	8%
NS-089/NCNP-02	Exon 44	6%
NS-050	Exon 50	4%
NS-051	Exon 51	13%
NS-045	Exon 45	8%
NS-055	Exon 55	2%



*Approval on August 12, 2020 in the United States(Priority Review), Approval on March 25, 2020 in Japan (Conditional Early Approval System) , application on June 25, 2021 in China (priority review)

NS-owned DMD pipeline can cover approximately 40% of all DMD patients.

NCNP: National Center of Neurology and Psychiatry

NS-089/NCNP-02

Development phase	NCNP: Investigator initiated study in progress NS: Preparing PII trial in Japan and U.S.
Mechanism of action	Exon 44 skipping
Feature	✓ High skipping activity with a new sequence design method developed by NS ✓ High safety confirmed in pre-clinical ✓ Expect remarkable effect by increased dystrophin protein expression in shorter time

Expect to become a treatment that can manage disease progression for DMD Patients in lifetime

Treatment for Fukuyama congenital muscular dystrophy

NIPPON SHINYAKU CO., LTD.

Fukuyama congenital muscular dystrophy (FCMD)

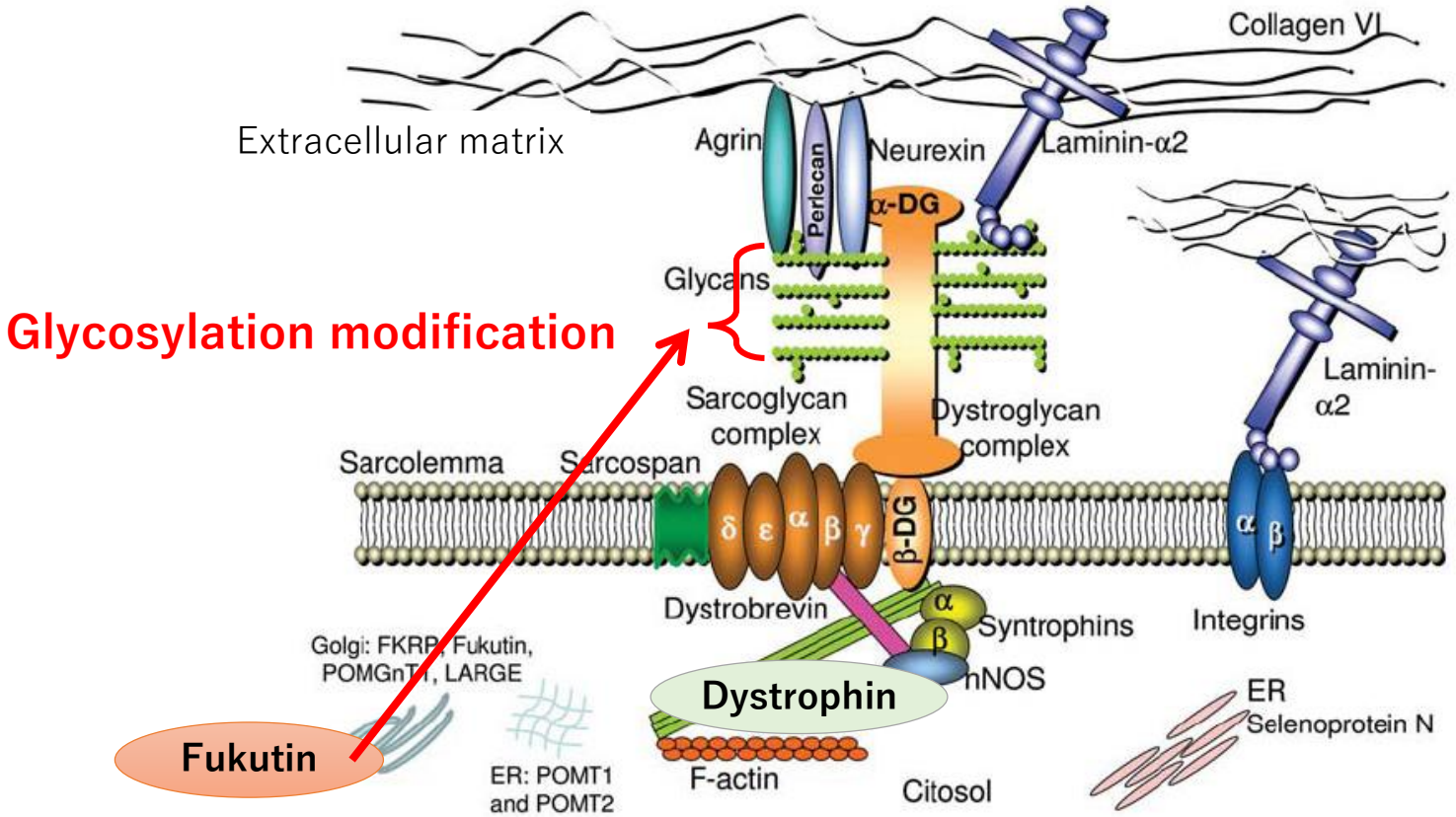
Characteristics

- Congenital muscular dystrophy
- 1,000-2,000 patients
- Hereditary disease common in Japan
- Muscle atrophy and CNS abnormalities

Symptoms

- Average age for sitting: 2 years
- Many patients are unable to walk and are more serious than DMD.
- Average life expectancy: around 12 years

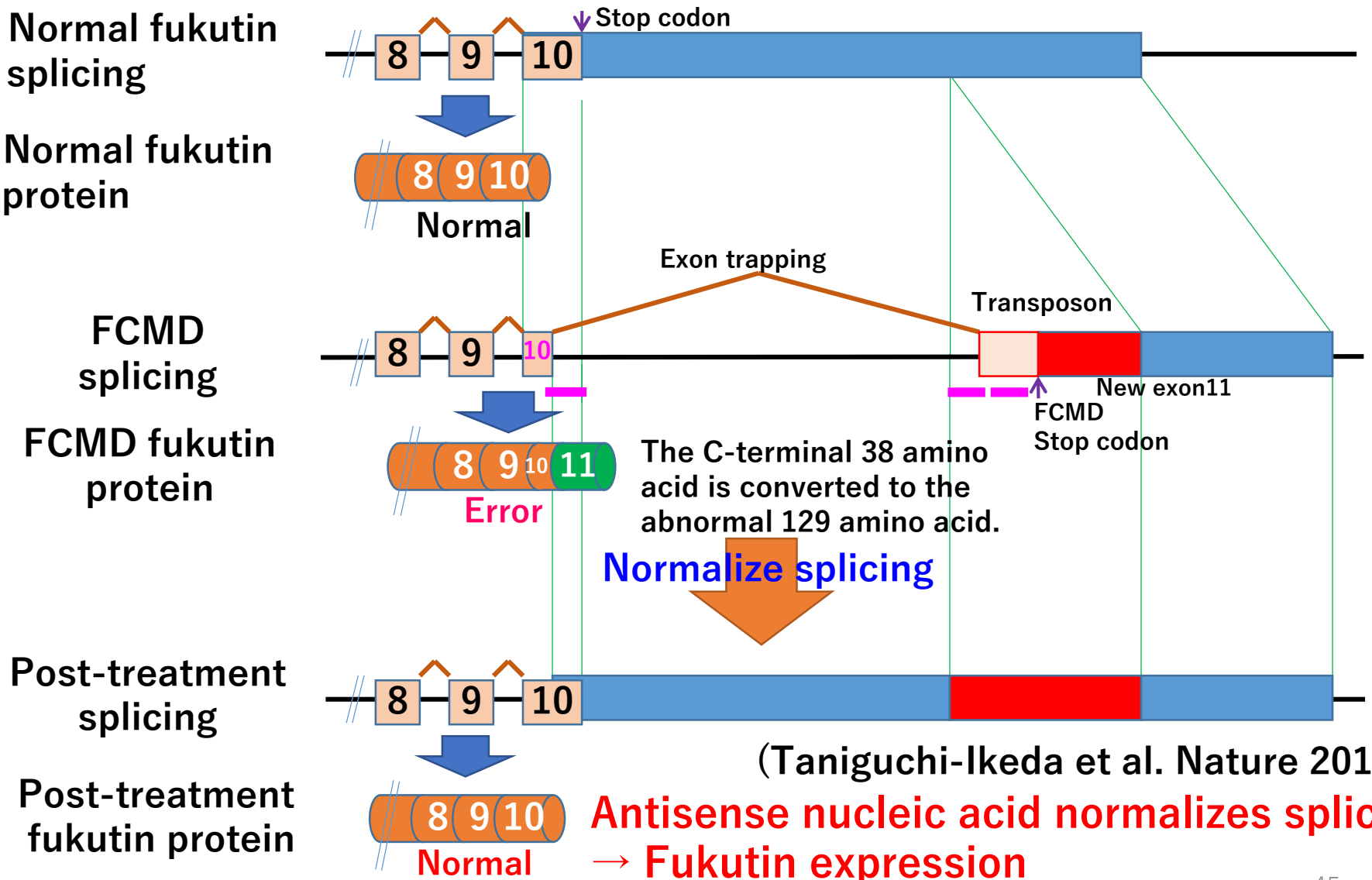
Fukuyama congenital muscular dystrophy - Abnormalities in the causative gene (fukutin) -



Arq Neuropsiquiatr. 2009 Jun; 67(1):144-168

Abnormalities in the fukutin gene ▶ Abnormal fukutin protein ▶ α-DG with no glycosy-lation ▶ Failure to fix muscle cells ▶ Vulnerable muscle cells

Fukuyama congenital muscular dystrophy - Exon trapping inhibition -



(Taniguchi-Ikeda et al. Nature 2011)

Antisense nucleic acid normalizes splicing.
→ Fukutin expression
→ Improvement of pathology

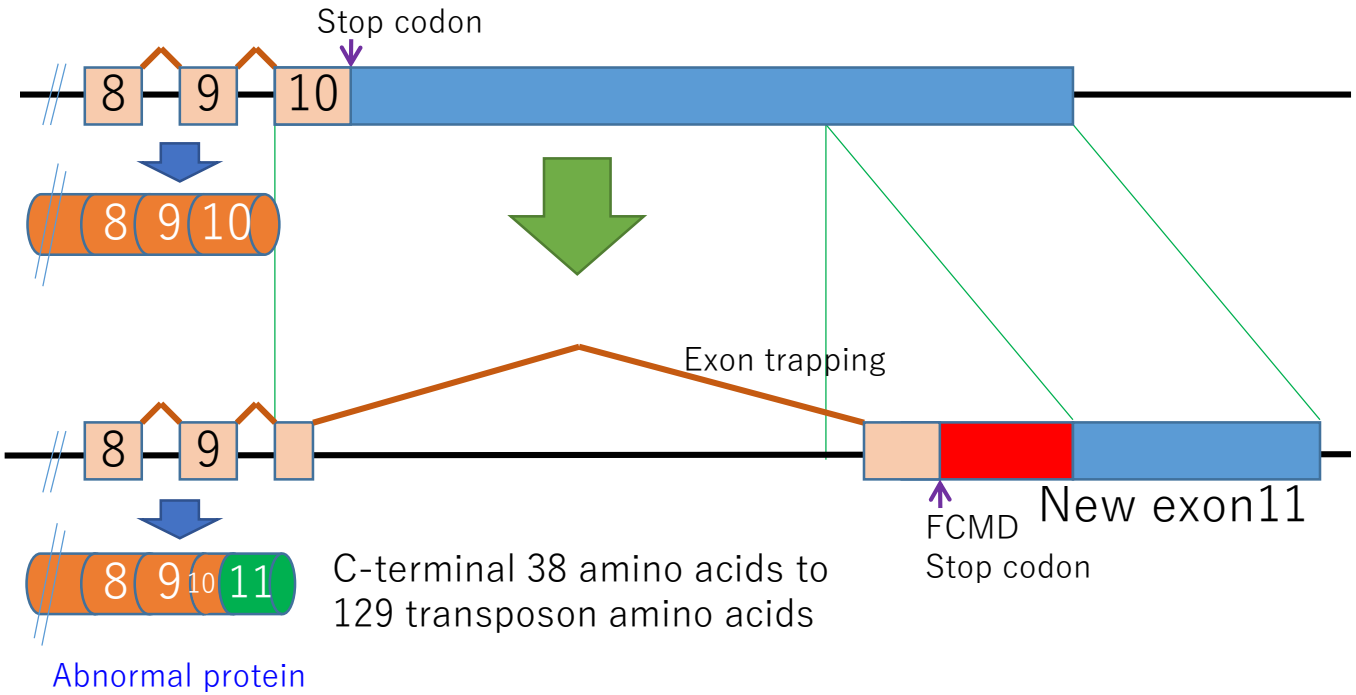
Fukuyama congenital muscular dystrophy - Exon trapping inhibition -

- **Multisequence antisense nucleic acid treatment suppressed aberrant splicing in patient cells and model mice, produced normal fukutin protein, and restored dystroglycan glycosylation. These results pave the way for the fundamental molecular targeted therapy of the FCMD.**
- **Through joint research with Kobe University and Nippon Shinyaku, we found the antisense nucleic acid sequence NS-035, which shows strong exon trapping inhibitory activity.**
- **A clinical trial at the University of Tokyo Hospital (principal investigator: Prof. Tatsushi Toda) was initiated in August 2021.**

Study	Study design	Intervention	Primary outcome
Phase 1 study	・Investigator initiated study ・Open label	・1.6, 6, 20, 40 mg/kg ・Intravenous administration once weekly for 12 weeks ・sample size: 12 ・5-10age	Safety-related endpoints

https://jrct.niph.go.jp/latest-detail/jRCT2031210252

Exon trapping



Exon trapping:
The presence of a strong splice acceptor site within the inserted retrotransposon, which results from the insertion of the retrotransposon, affects the splicing of the final protein-encoding exon, resulting in abnormal splicing.

Fukuyama congenital muscular dystrophy - Exon trapping inhibition -

- In patients with FCMD, insertional mutations of the "moving gene" SVA retrotransposon into the downstream region of the fukutin gene have been observed.
- Exon trapping (a process in which a copy of a DNA fragment called a retrotransposon is inserted at various sites in the same genome) is not a rare phenomenon, and is estimated to occur at a frequency of about 1 in 20 offspring.
- The splicing changes caused by SVA retrotransposons have also been found in genes responsible for familial hypercholesterolemia and dyslipidemia with SVA insertion mutations, and antisense nucleic acid-mediated exon trapping inhibition may also be effective in the treatment of these diseases.

Development of next-generation antisense nucleic acids

NIPPON SHINYAKU CO., LTD.

Development of next-generation antisense nucleic acids

We are working on the development of next generation antisense nucleic acids using the following three methods.

Membrane-permeable peptide linkage

Membrane-permeable peptide likage enhances PMO internalization.

Stereoselective synthesis

Stereoselective synthesis allows the synthesis of stereochemically pure and optimized modified nucleic acids.

Novel sequence design method

Sequence design in which one sequence has two target sequences improves the activity and specificity of antisense nucleic acids.

Next generation antisense nucleic acids can improve distribution, efficacy (persistence, intensity), safety, and physical properties compared to current antisense nucleic acids. This expands the application of nucleic acid drugs to other diseases.

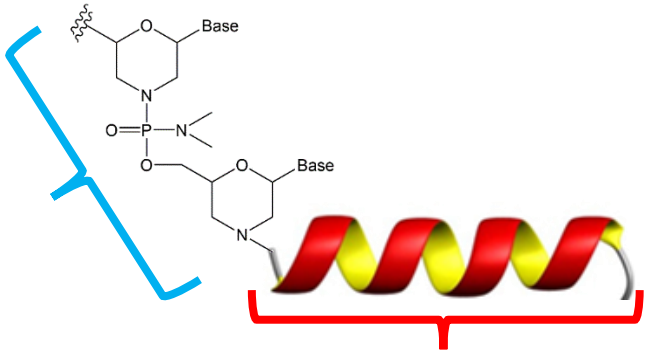
Next-generation antisense nucleic acids - Membrane permeable peptide linkage -

PPMO in which CPP is bound to morpholino nucleic acid as DDS technology to improve the dynamics of nucleic acid drugs by enhanced cell membrane permeability

- improve the drug efficacy
- reduce the frequency of administration

PPMO (Peptide-conjugated phosphorodiamidate morpholino oligomer)

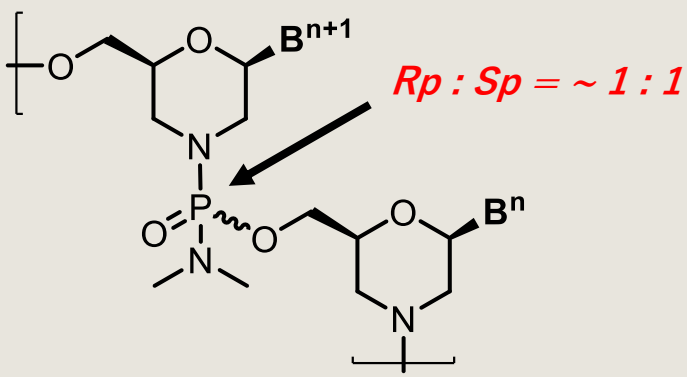
Phosphorodiamidate morpholino oligomer (PMO)



*CPP (cell penetrating peptide): A short peptide of 30 or fewer amino acids with low cell membrane permeability at low concentrations.

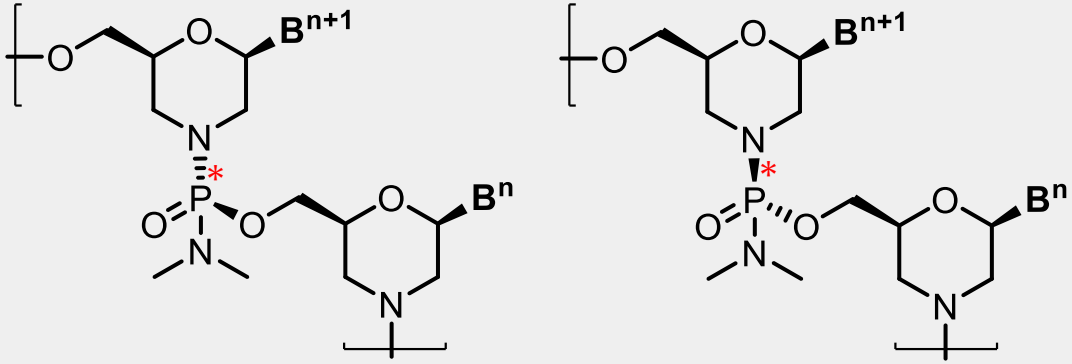
Next-generation antisense nucleic acids - Stereoselective synthesis -

<Conventional>



Steric uncontrolled

<Next Generation>

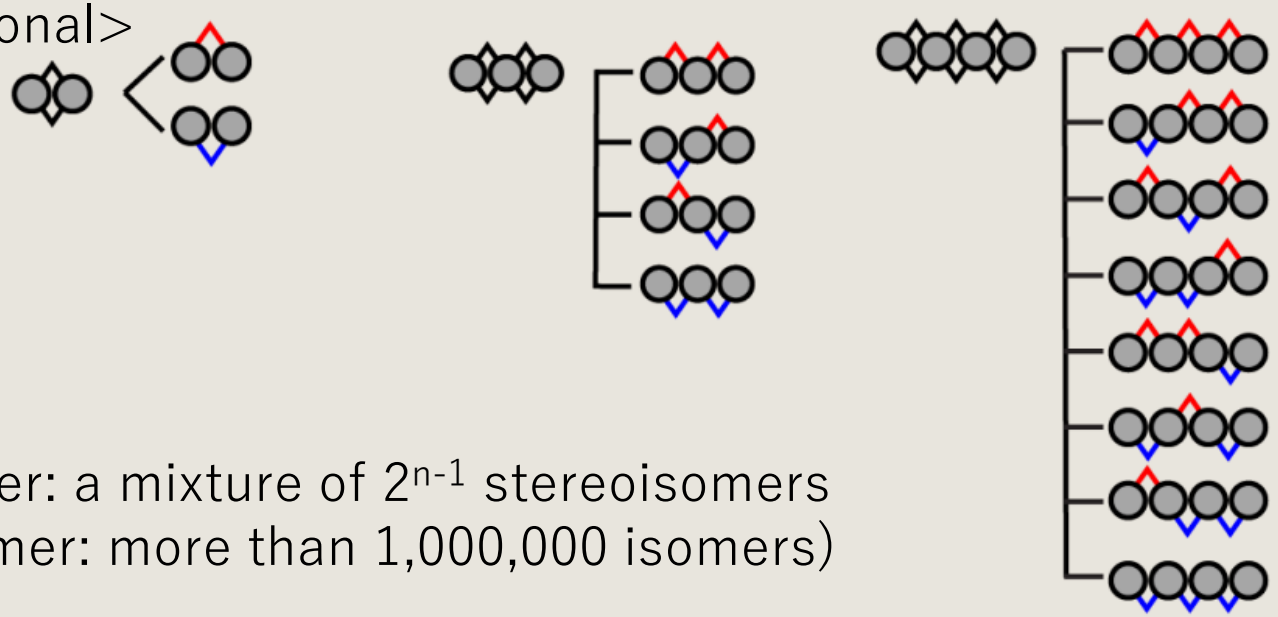


Rp *Sp*

Create new added value by controlling the stereochemistry of morpholinonucleic acid (Phosphorodiamidate morpholino oligomer)

Next-generation antisense nucleic acids - Stereoselective synthesis -

<Conventional>



n-mer: a mixture of 2^{n-1} stereoisomers
(21 mer: more than 1,000,000 isomers)

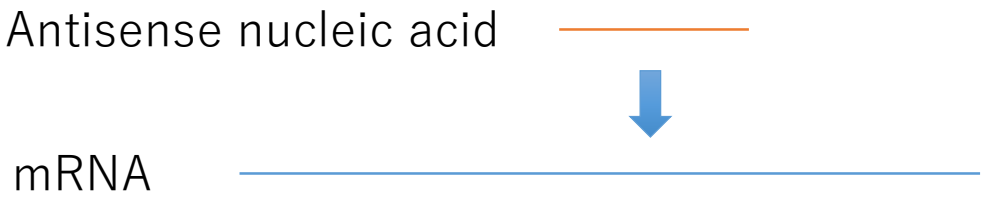
Linkage 1 → Linkage 2 → Linkage 3

<Next Generation>

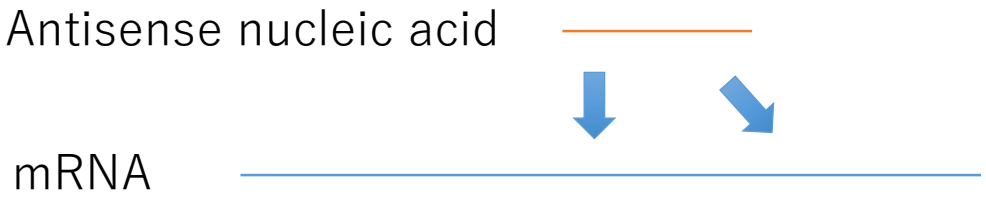
Completely single nucleic acid
(21mer: 1/ 1,000,000)

Next-generation antisense nucleic acids - Novel sequence design method -

Conventional: One sequence acts on one target.



Novel method: One sequence acts on two targets.



Improve the activity and specificity of antisense nucleic acids by applying a novel sequence design method

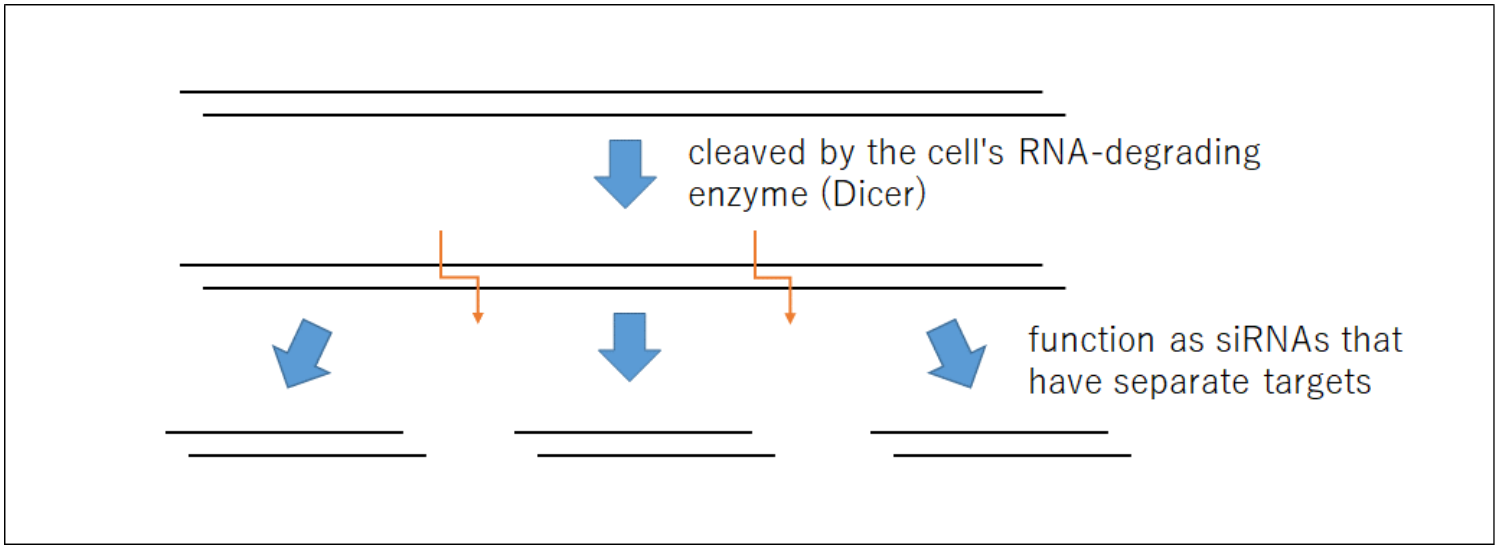
Novel coronavirus infection - Nucleic acid drugs -

NIPPON SHINYAKU CO., LTD.

Novel coronavirus infection
- Nucleic acid drugs -

The types and structures of nucleic acids such as long-chain RNA and antisense nucleic acids (morpholino nucleic acids) will be studied to select the nucleic acids that effectively kill the novel coronavirus.

The figure shows an example of the application of long-chain RNA.



Long-chain RNAs are cleaved within the cell to produce several siRNAs targeting multiple sites on the viral RNA, killing all of the novel coronavirus.

Novel coronavirus infection
- Sequence screening of nucleic acid -

Step 1
- In vitro efficacy evaluation of uninfected experimental systems ✓

Step 2
- In vitro efficacy evaluation of infection experiments ✓

Step 3
- In vivo efficacy evaluation of infection experiments

Step 4
- In vitro and in vivo toxicity assessment

Final candidate decision

Step 3 and Step 4 are being implemented simultaneously, and we will select final candidates.

Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion or failure of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination, obtaining regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This English presentation was translated from the original Japanese version.
  In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.