STRATEGIC PLAN 2018

DELIVERING AND CREATING VALUE FOR PATIENTS

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President and CEO
Astellas Pharma Inc.
May 22, 2018

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

Vision

On the Forefront of Healthcare Change to Turn Innovative Science into

VALUE for Patients

We will achieve sustainable growth by pursuing innovative science to produce medical solutions that provide VALUE to patients

DEFINITION OF VALUE

Value must meet all stakeholders' needs while being true to Astellas

Common Definition of VALUE*

$$= \frac{\textbf{Outcomes}}{\textbf{Cost}}$$

Outcomes
that matter to patients

Cost
to the healthcare system of delivering those outcomes

Patients

- Payer
- Caregiver
- Healthcare provider

*Source: BCG "Value in Healthcare" seminar

THREE STRATEGIC GOALS FOR SUSTAINABLE GROWTH



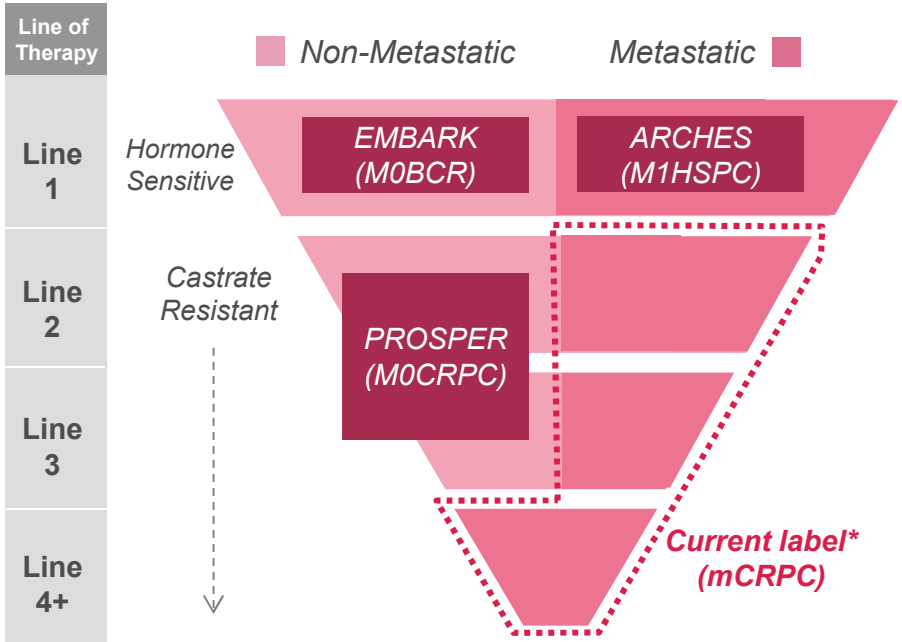
*Key products and late-stage pipeline

Maximizing Product VALUE and Operational Excellence

MAXIMIZING THE VALUE OF XTANDI

XTANDI Global Sales
FY2017-FY2020 CAGR (%): High single-digit

Earlier lines have more patients



For illustrative purposes of patient size

*Indication in Japan: Castration-resistant prostate cancer

Opportunities in the earlier stage

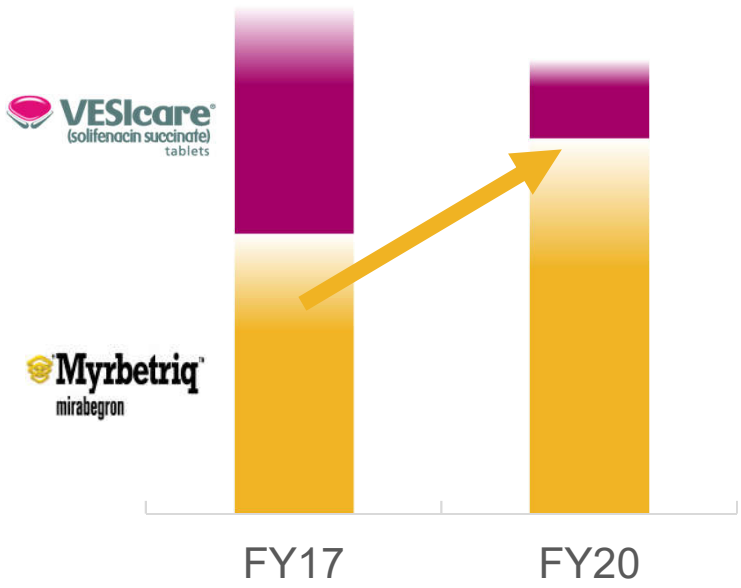
- Expand approved indications to earlier stages of prostate cancer
- Shift commercial resources to increase urologist penetration
- Position “XTANDI-first” in the approved indications using 5 years’ clinical evidence

M0 BCR : Non-metastatic prostate cancer, biochemical recurrence
M1 HSPC : Metastatic hormone-sensitive prostate cancer
M0 CRPC : Non-metastatic CRPC
mCRPC : Metastatic castration-resistant prostate cancer

OAB FRANCHISE
MAXIMIZING THE VALUE OF MIRABEGRON (BETANIS/MYRBETRIQ/BETMIGA)

mirabegron Global Sales
FY2017-FY2020 CAGR (%): Low teens

Educate on mirabegron clinical profile with balance of efficacy and safety



For illustrative purposes only

Expand share in approved markets

- Grow mirabegron sales in newly launched countries such as Germany
- In the US, expand into combination with VESIcare
- Use post-marketing studies to obtain additional data in important sub-populations (e.g., elderly, male)

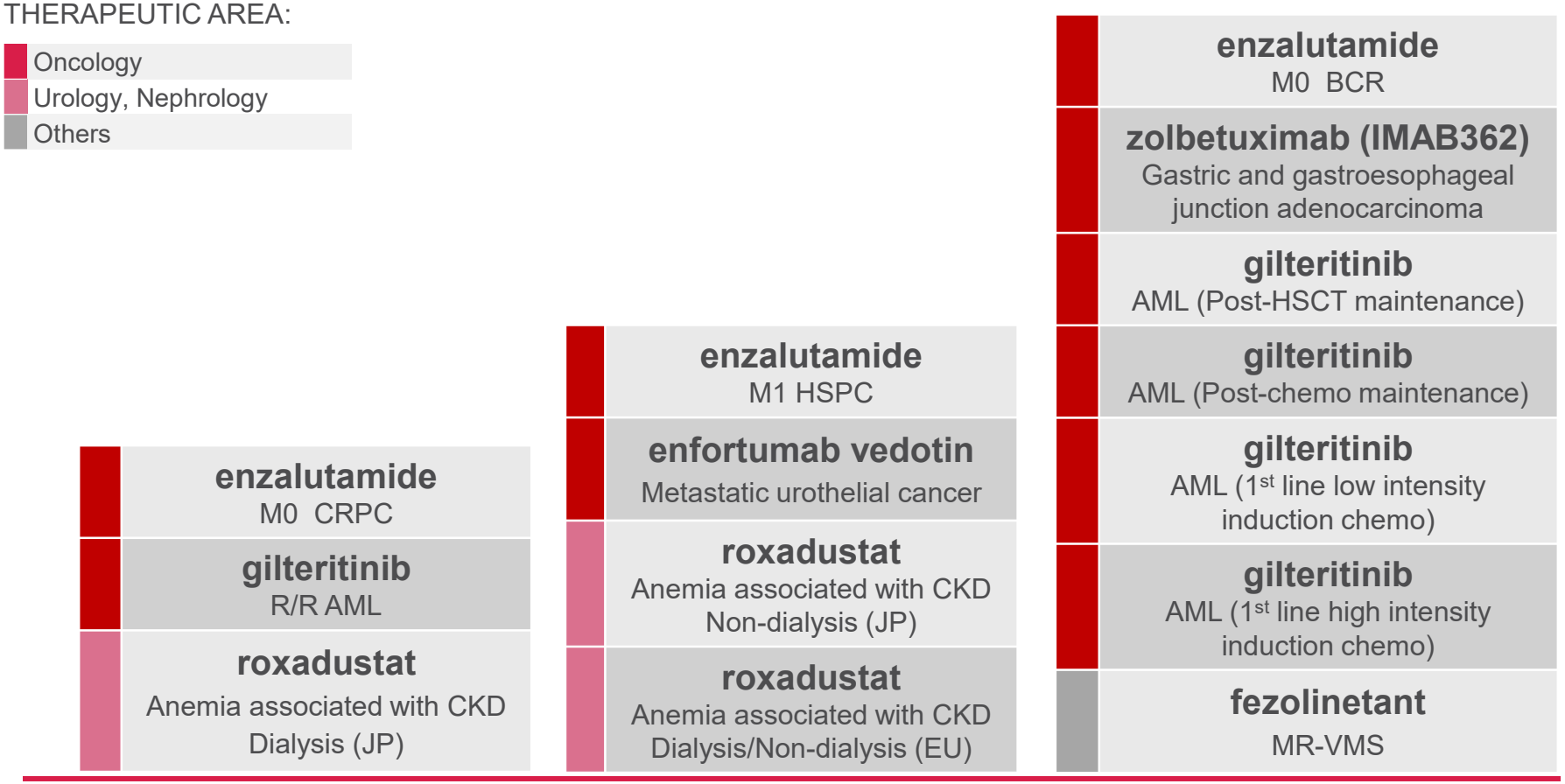
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OAB: Overactive bladder

FILING OPPORTUNITIES: KEY POST-POC PIPELINE

THERAPEUTIC AREA:

- Oncology
- Urology, Nephrology
- Others



*Subject to internal assessment, decision and regulatory consultation, as appropriate.
**Filing timing in the first country/region within US/EU/JP. If the project is regional specific (i.e. development right only in JP/Asia), the region is specified in the column.
R/R: Relapsed or refractory, AML: Acute myeloid leukemia, CKD: Chronic kidney disease, HSCT: hematopoietic stem cell transplantation, MR-VMS: menopause related vasomotor symptoms

POTENTIAL SIZE OF KEY POST-POC PIPELINE

If all succeed, we expect the potential annual sales of following products to reach approximately 1 trillion in next 10 years.

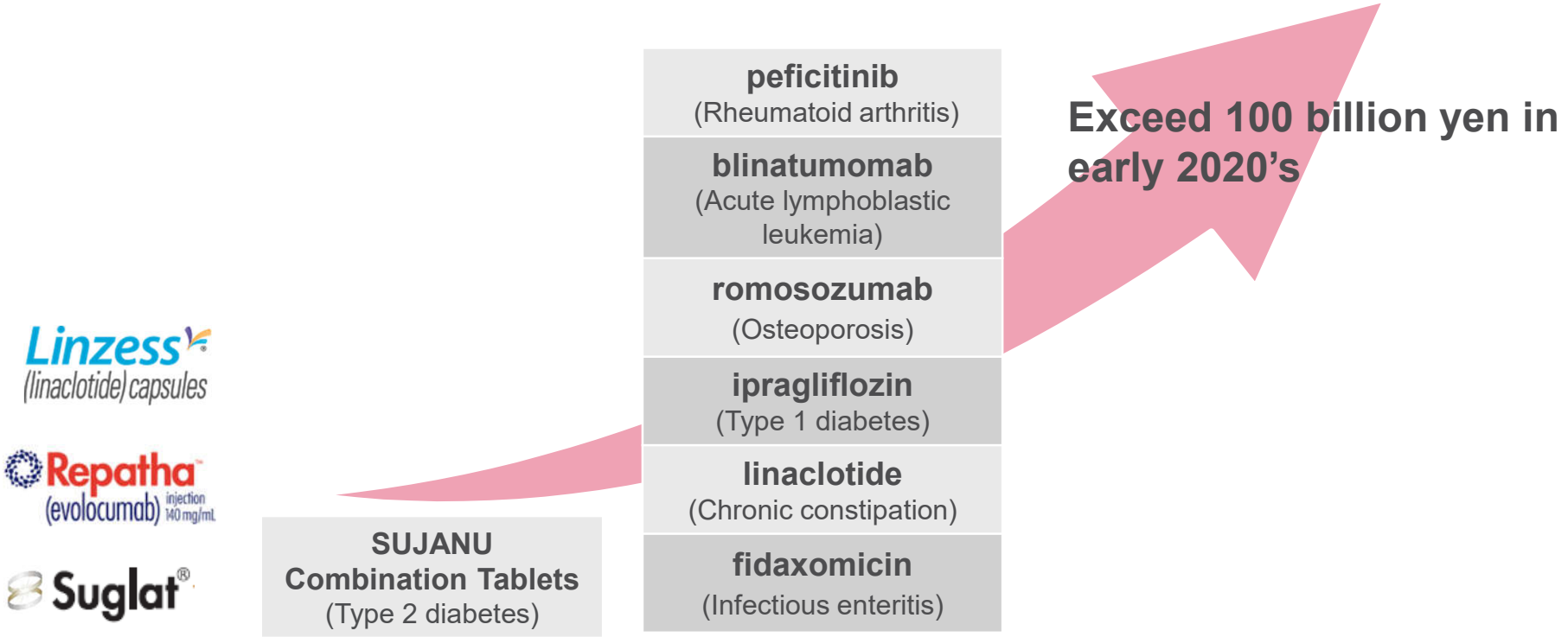
Potential size (at peak, billion yen)	Key Post-POC pipeline*1
400 – 500	● **XTANDI (enzalutamide)** including early-stage of Prostate Cancer (M0 CRPC, M0 BCR, M1 HSPC)
200 – 300	● **fezolinetant**
100 – 200	● **zolbetuximab (IMAB362)**
50 – 100	● **enfortumab vedotin** ● **gilteritinib**

*1: Only indications listed in the current pipeline list (as of Apr 26, 2018) are included for projection.
*For roxadustat, the projection of potential size is under discussion with the partner company.
*Programs listed in alphabetical order within the same range.

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NEW PRODUCTS IN JAPANESE MARKET

Reinforce our presence in Japanese market by steadily launching and maximizing value of new products



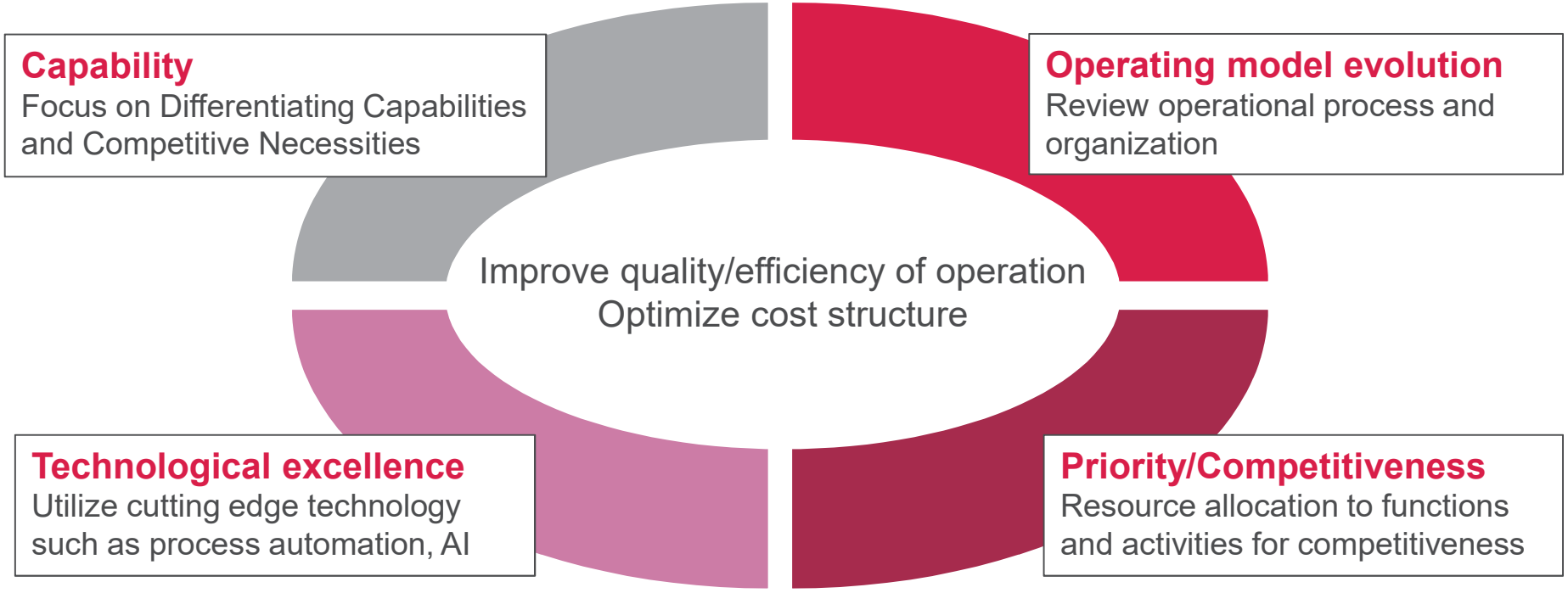
New products*	Approved	Filed or Filing expected in FY2018

*Products launched within 3 years or products scheduled for additional indication and fix dose in FY2018 and beyond

PURSUE OPERATIONAL EXCELLENCE

*Anticipating more than 30 billion yen improvement in core operating profit in FY2020 generated from new initiatives**

Continue to review all activities from zero-basis from various aspects



*Not including initiatives announced as of May 22, 2018

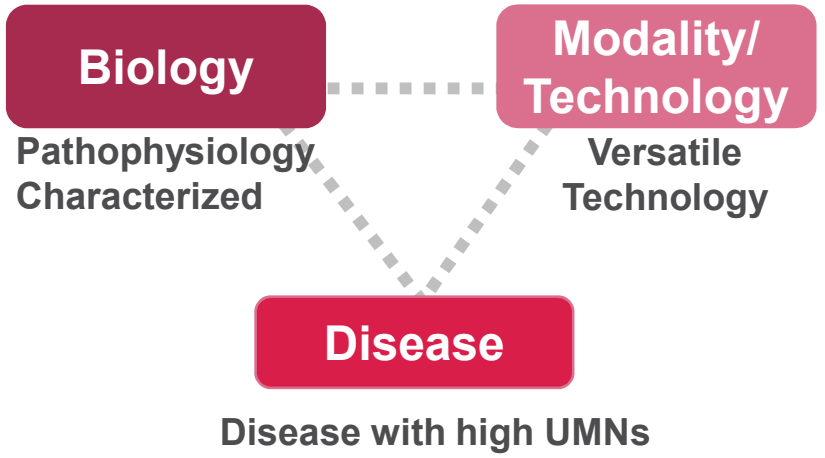
Evolving How We Create VALUE

- With Focus Area Approach -

R&D STRATEGY: FOCUS AREA APPROACH

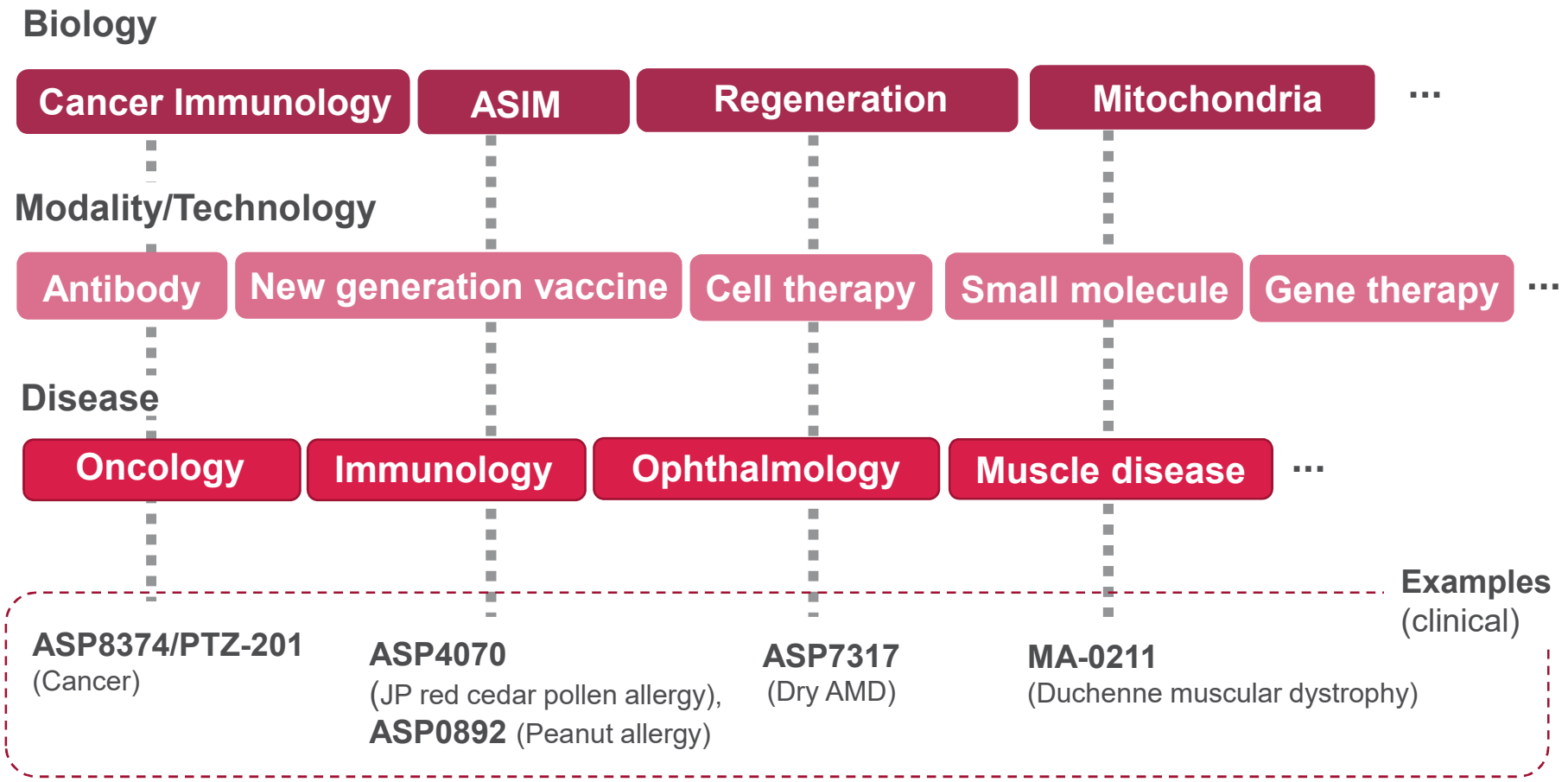
Focus Area approach (Research to pre-POC)

- Approach appropriate targets of disease based on well-characterized pathophysiology **[Elucidation of Biology]**
- Acquire innovative technology and establish a versatile platform to provide optimal treatment approach that can control target biology **[Utilization of Modality/Technology]**
- A unique combination of Biology and Modality/Technology based on emerging science can be translated into an innovative solution for patients with high unmet needs through continuous efforts to ensure development progress and market access **[Fulfilling patient needs]**



UMN: unmet medical needs

R&D STRATEGY: FOCUS AREA APPROACH



ASIM: antigen-specific immuno-modulation, AMD: age-related muscular degeneration

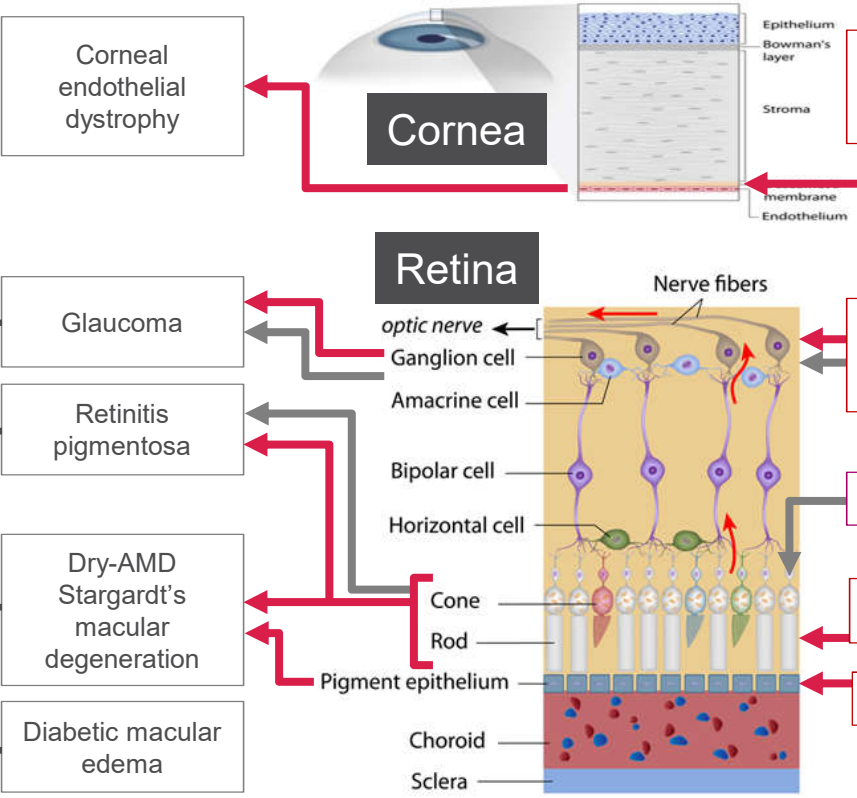
FOCUS AREA APPROACH

Cell therapy
Ophthalmology Regeneration

To ophthalmologic disorders which become blind, we are aiming to develop treatments which can maintain or recover visual function by regenerating and maintaining the cause cells

Cell therapy
Gene Therapy

Visual symptom	Disease	Region	Target cell type	Approach
Normal vision	Corneal endothelial dystrophy	Cornea	Corneal endothelial cell	Corneal endothelial cell therapy (PC) **AIRM**
	Glaucoma	Retina	Retinal ganglion cells	Retinal ganglion progenitor cell therapy (PC) **AIRM**
	Retinitis pigmentosa			Gene therapy (PC) **Clino**
	Dry-AMD Stargardt's macular degeneration		Cone	Gene therapy (PC) **Harvard Medical School**
			Cone Rod	Photoreceptor progenitor cell therapy (PC) **AIRM**
	Diabetic macular edema		RPE cell	RPE cell therapy (PII) **AIRM**



PC : Preclinical
PII : Phase 2

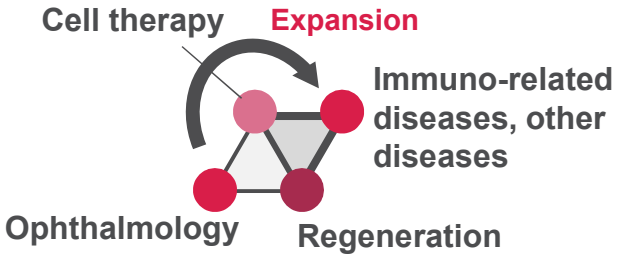
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AIRM: Astellas Institute for Regenerative Medicine

FOCUS AREA APPROACH

Applying Universal Donor Cell technology which overcomes immune rejection to the AIRM's technology for cell differentiation expands the opportunity to various indications

Focus Area approach

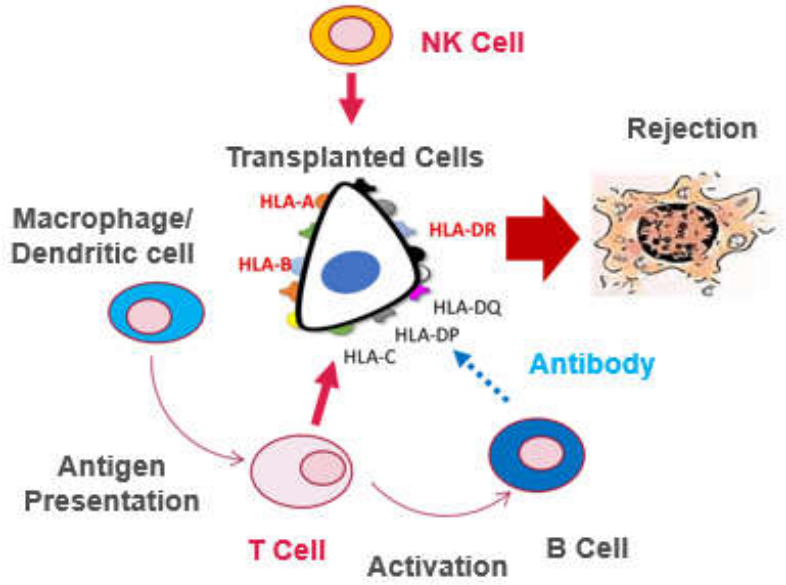


Universal Donor Cell technology

- Technology to create cell therapies that overcome immune rejection
- Universal Donor Cell technology can be administered to any recipient without the need for Human Leukocyte Antigen (HLA) matching
- Expands research potential to wide range of differentiated cells

Mechanism of immune rejection

- Allogeneic cells are rejected by the recipient's immune system
- HLA molecules play a major role

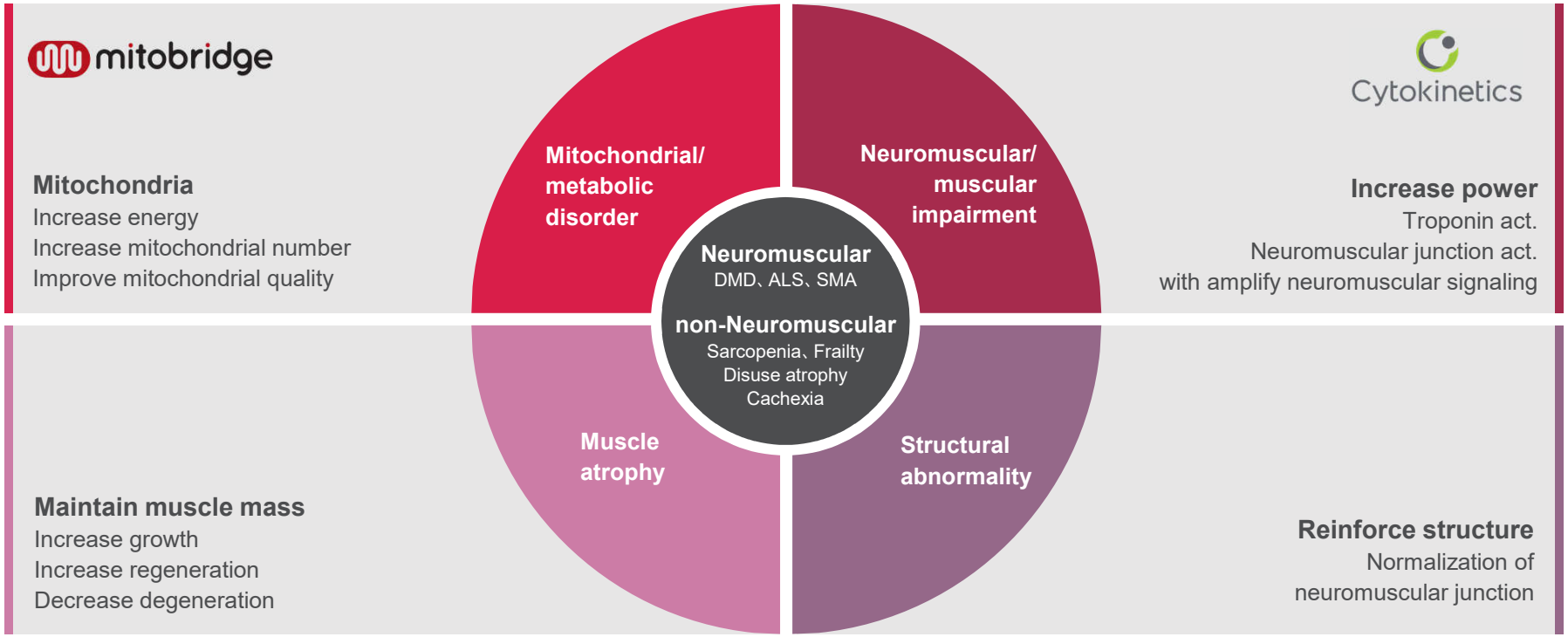


Universal Cells

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FOCUS AREA APPROACH IN MUSCLE DISEASES

Create novel NMEs which brings benefit to the patients with various muscle diseases by the multiple approaches possibly improve the muscle functions



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DMD: Duchenne Muscular Dystrophy, ALS: Amyotrophic Lateral Sclerosis, SMA: Spinal Muscular Atrophy

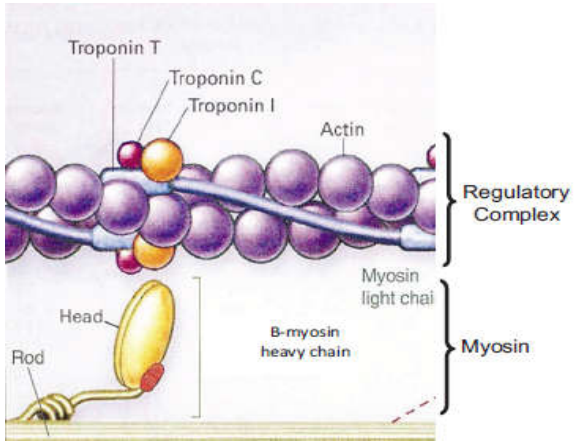
FOCUS AREA APPROACH

reldesemtiv potentially improves muscle function in various diseases with muscle impairment/weakness by a novel approach to skeletal muscles

Skeletal muscle biology-driven approach

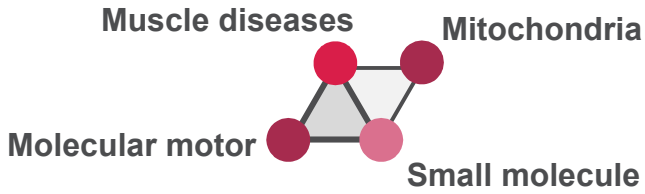
reldesemtiv (CK-2127107)

- First-in-class, next-generation, fast skeletal muscle troponin activator which regulates molecular motors
- Based on MoA, reldesemtiv could potentially improve muscle function and physical performance



Cytokinetics

Focus Area approach



Programs in clinical stage:

Neuromuscular diseases *Cytokinetics-sponsored studies

- **SMA**: Phase 2 study on-going
- **ALS**: Phase 2 study on-going

Non-neuromuscular diseases *Astellas-sponsored studies

- **COPD**: Phase 2 study on-going
- P1b (proof of mechanism) study in elderly subjects with limited mobility is also on-going

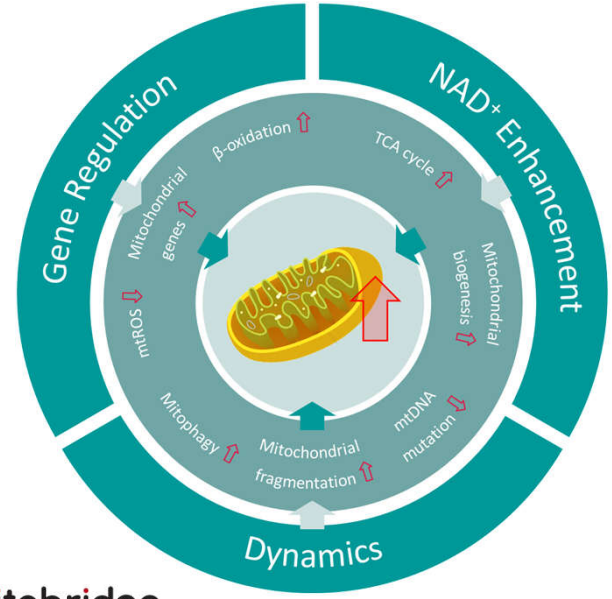
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FOCUS AREA APPROACH

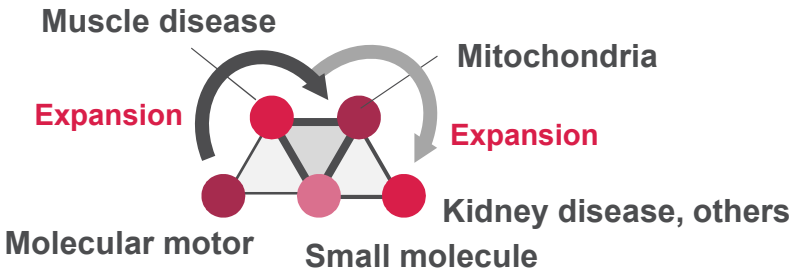
Characterize mitochondria biology involved in muscle function and approach to the various diseases relating to mitochondria biology

Mitochondria biology

Distinct aspects of mitochondrial function (i.e. bioenergetics, dynamics, and cellular signaling) are well described and impairments in these activities likely contribute to disease pathogenesis.



Focus Area approach



Programs in clinical stage

- **MA-0211 (P1):** Duchenne muscular dystrophy
- **MA-0217 (P1):** Acute kidney injury

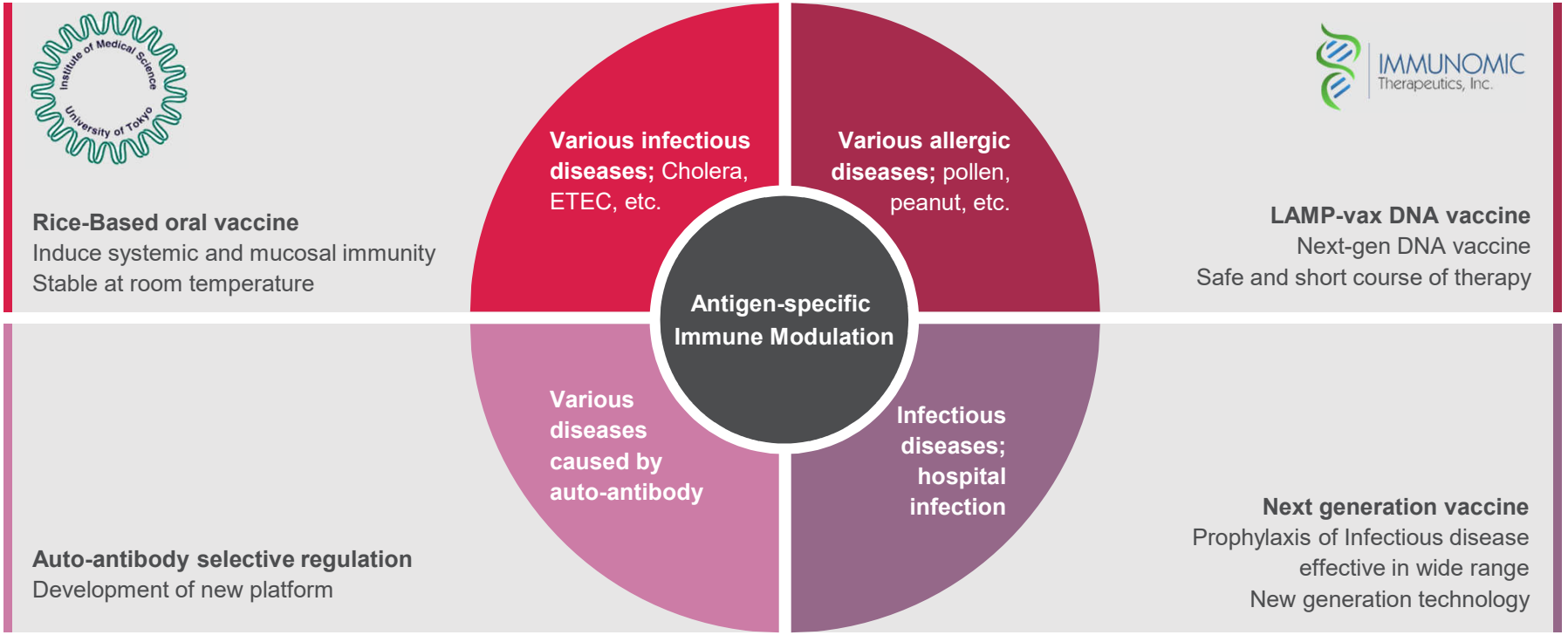
*Multiple programs are in non-clinical stage

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FOCUS AREA APPROACH IN IMMUNOLOGY

Develop an innovative platform which can achieve antigen-specific immune modulation, and create curative therapeutics against allergy, autoimmune diseases and infectious diseases



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ETEC: EnteroToxigenic *E coli*, LAMP: Lysosomal Associated Membrane Protein

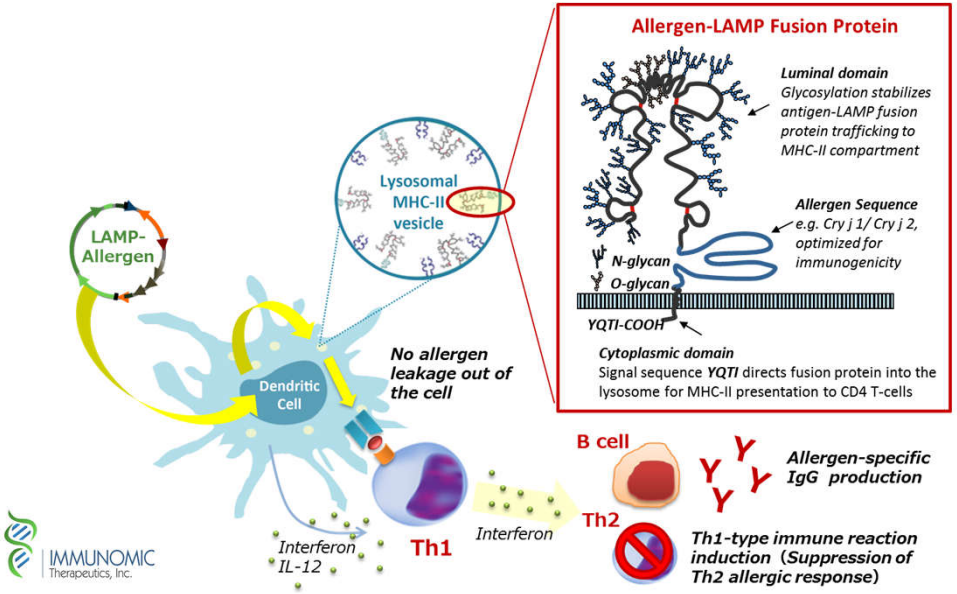
FOCUS AREA APPROACH

We focus on LAMP-vax technology as modality/technology of antigen-specific immuno-therapy which regulates immune reactions. With this emerging technology, we are aiming to develop drug to cure allergic diseases

LAMP-vax DNA vaccine platform

Revolutionary Technology

- LAMP-vax induce a Th1 immune response, which suppress the Th2 allergic response
- Decrease the risk of anaphylaxis
- Applicable to a wide variety of allergic diseases



Focus Area approach



Various allergic diseases

Seasonal allergy

- ASP4070 (Phase 2)：Japanese red cedar pollen allergy
- Other： ragweed, birch, etc.

Food allergy

- ASP0892 (Phase 1)： Peanuts allergy
- Other：shellfish, etc.

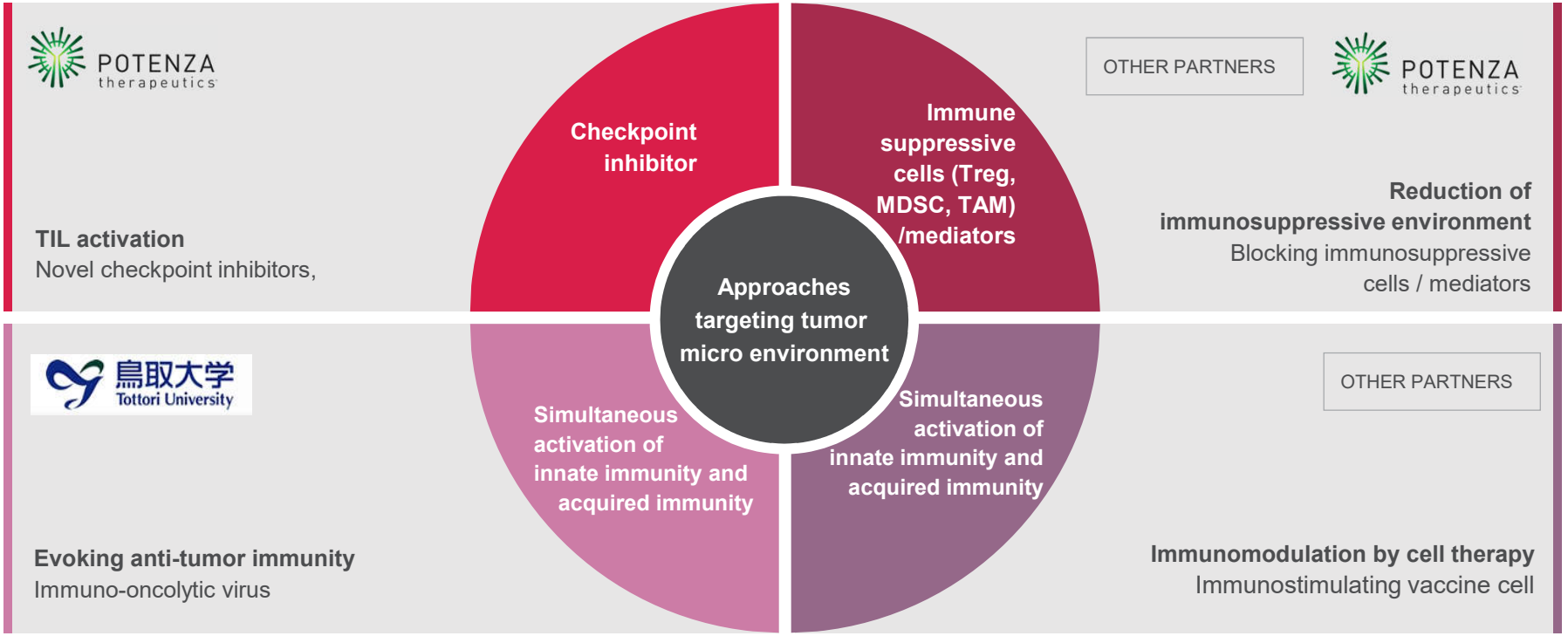
Perennial allergy

- House dust mite, pet, etc.

*ASIM: antigen-specific immuno-modulation

FOCUS AREA APPROACH IN IMMUNO-ONCOLOGY

Develop pipeline of novel immuno-oncology therapeutics to address tumor types which are inadequate response to PD-1/PD-L1 blockers



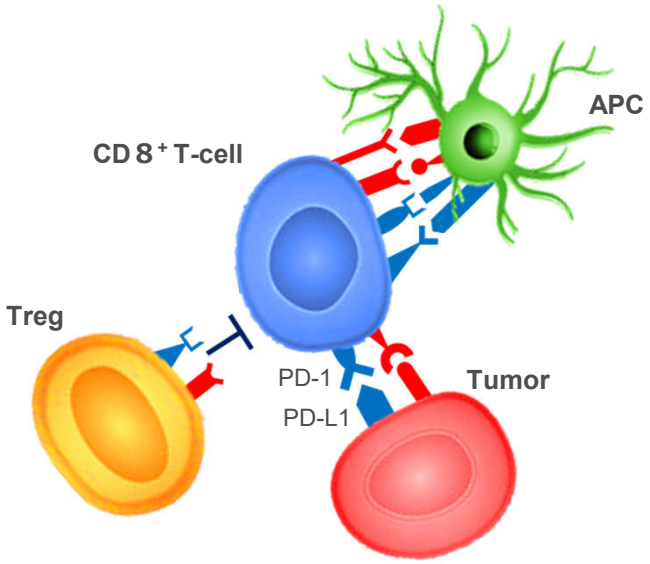
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PD-1: Programmed cell Death-1, PD-L1: Programmed cell-Death Ligand 1, TIL: Tumor Infiltrating Lymphocyte,
Treg: regulatory T cell, MDSC: Myeloid-Derived Suppressor Cell, TAM: Tumor-Associated Macrophage

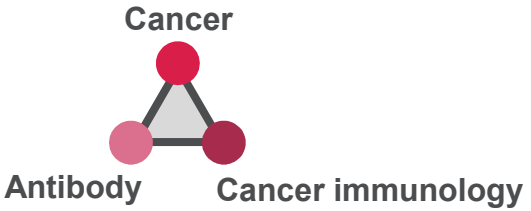
FOCUS AREA APPROACH

Develop pipeline of novel checkpoint inhibitor, co-stimulatory agonist and modulator of immunosuppressive cells etc. for tumor cell types inadequate response to PD-1/L1 blockers

Mechanism of Immunomodulation



Focus Area approach



ASP8374/PTZ-201

- anti-TIGIT antibody
- Phase 1 study in various solid tumors is on-going

T_{reg} modulator

- Stage up to Phase 1 soon

Co-stimulatory agonist

- Non-clinical stage

POTENZA therapeutics

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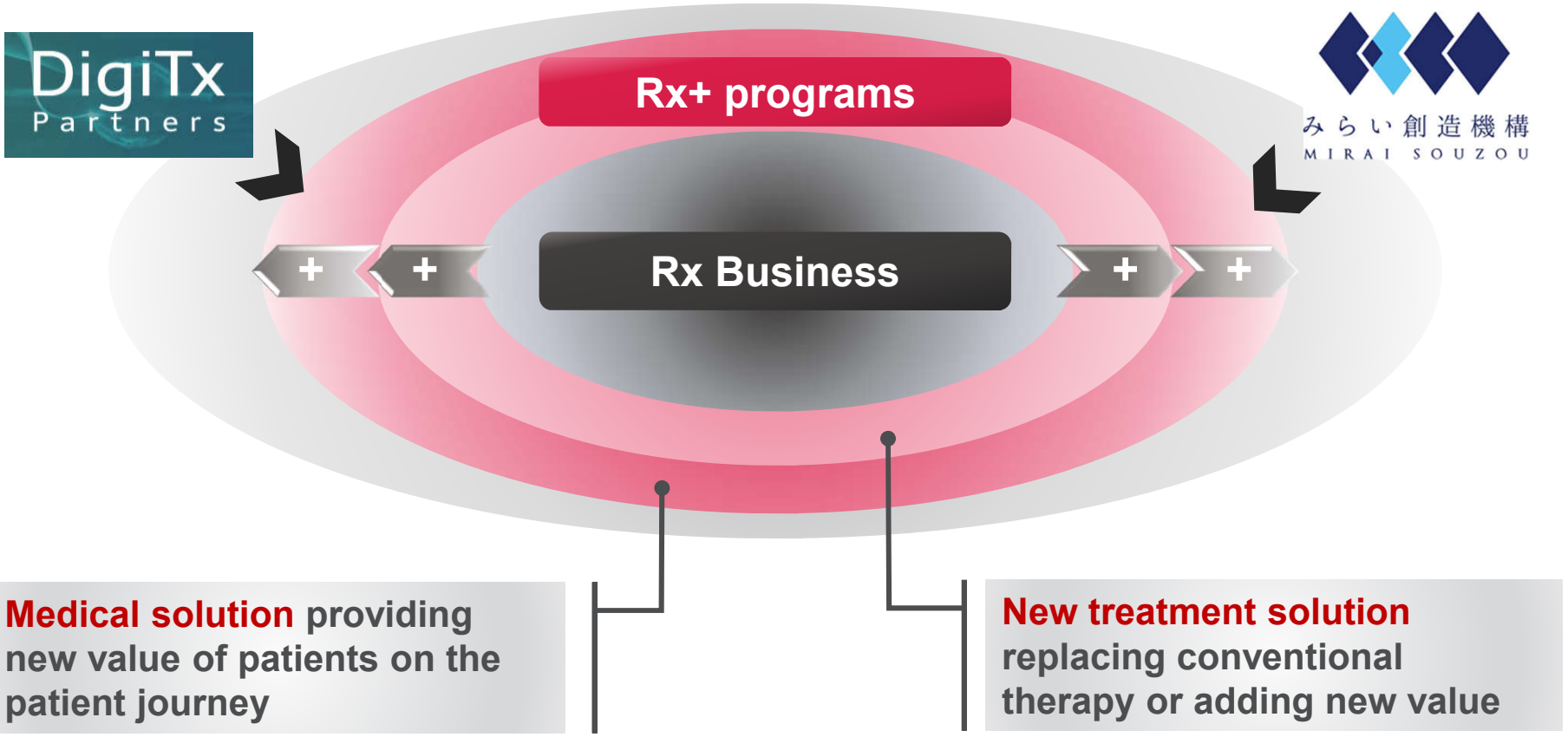


Developing Rx+ programs

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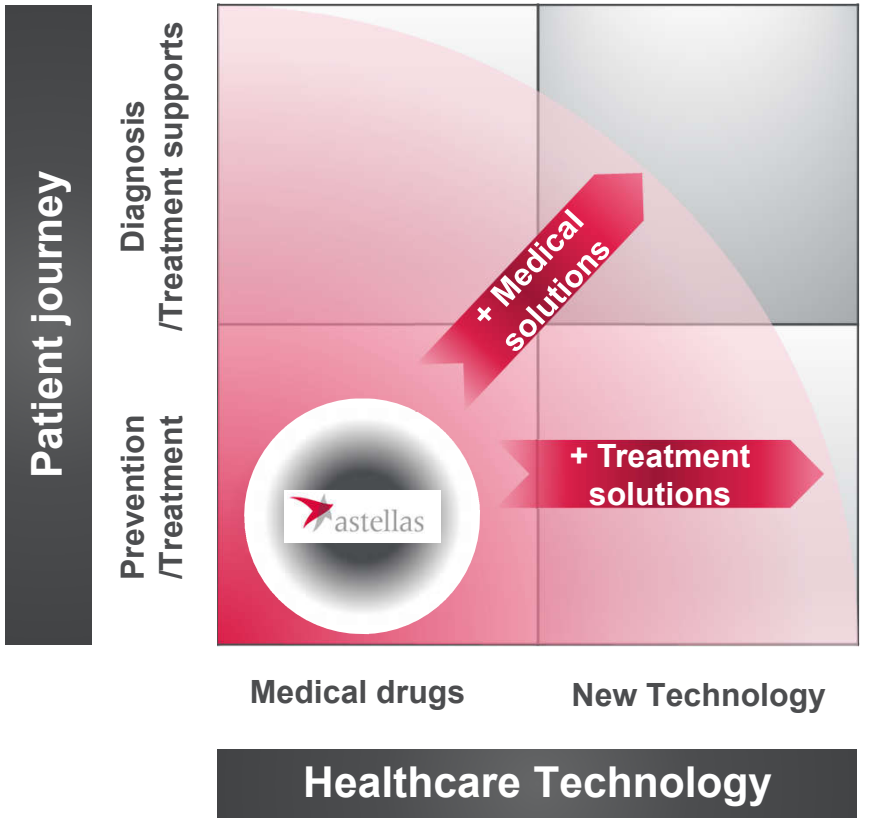
Rx+: HEALTHCARE SOLUTIONS BEYOND Rx BUSINESS

Combine our expertise and experiences with technology and knowledge from different fields to create new revenue streams separate from our core Rx products



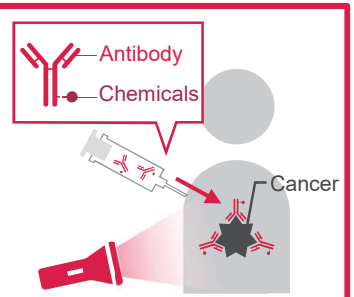
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Rx+: IDEAS TO REALITY



Examples

New diagnostic solution for cancer patients
by combining Astellas technology (e.g. antibody) with medical technologies (e.g. optical, radioisotope or nanomaterial)



Digital device including electrical stimulation technology and medical software



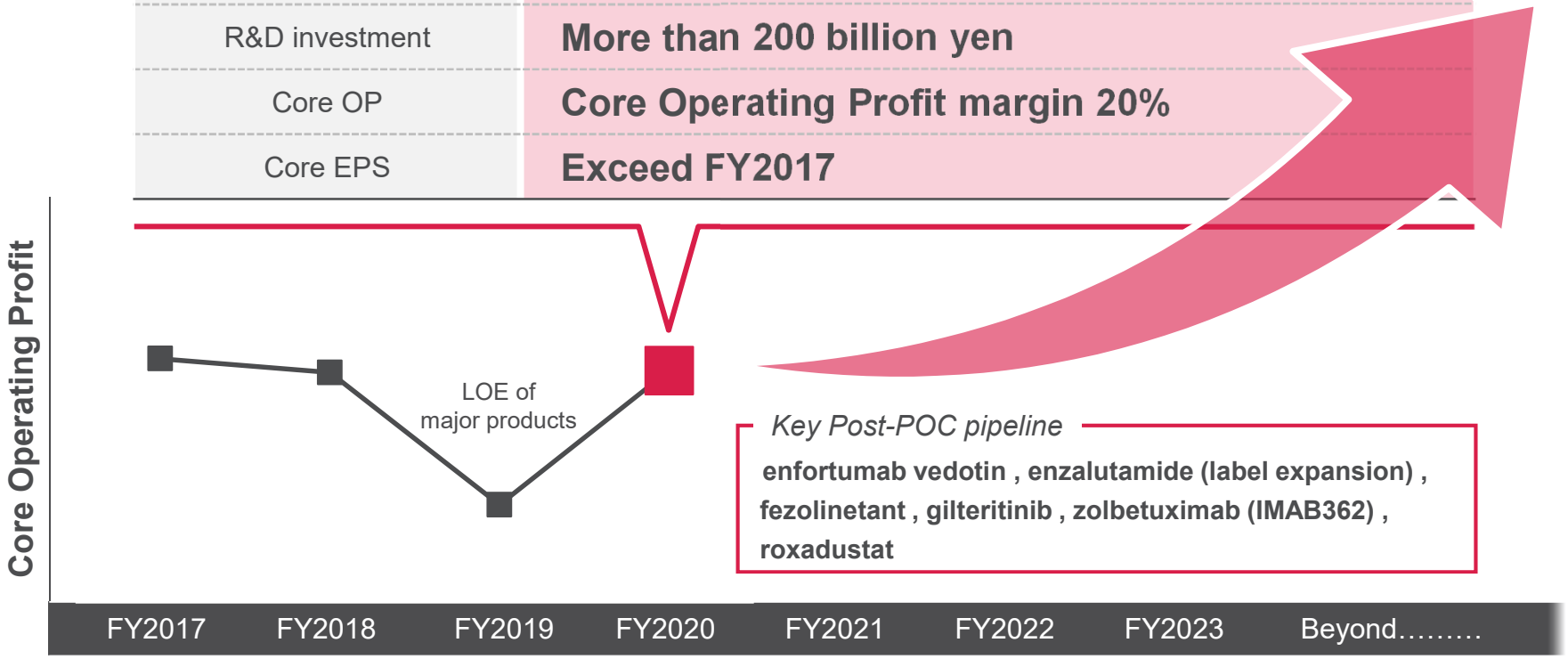
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Financial guidance and Capital allocation

FINANCIAL GUIDANCE IN FY2020

Aiming for mid- to long-term Core OP growth trend after the bottom in FY2019

Indicators	FY2020 Guidance
Net sales	**FY2017 level**
R&D investment	**More than 200 billion yen**
Core OP	**Core Operating Profit margin 20%**
Core EPS	**Exceed FY2017**

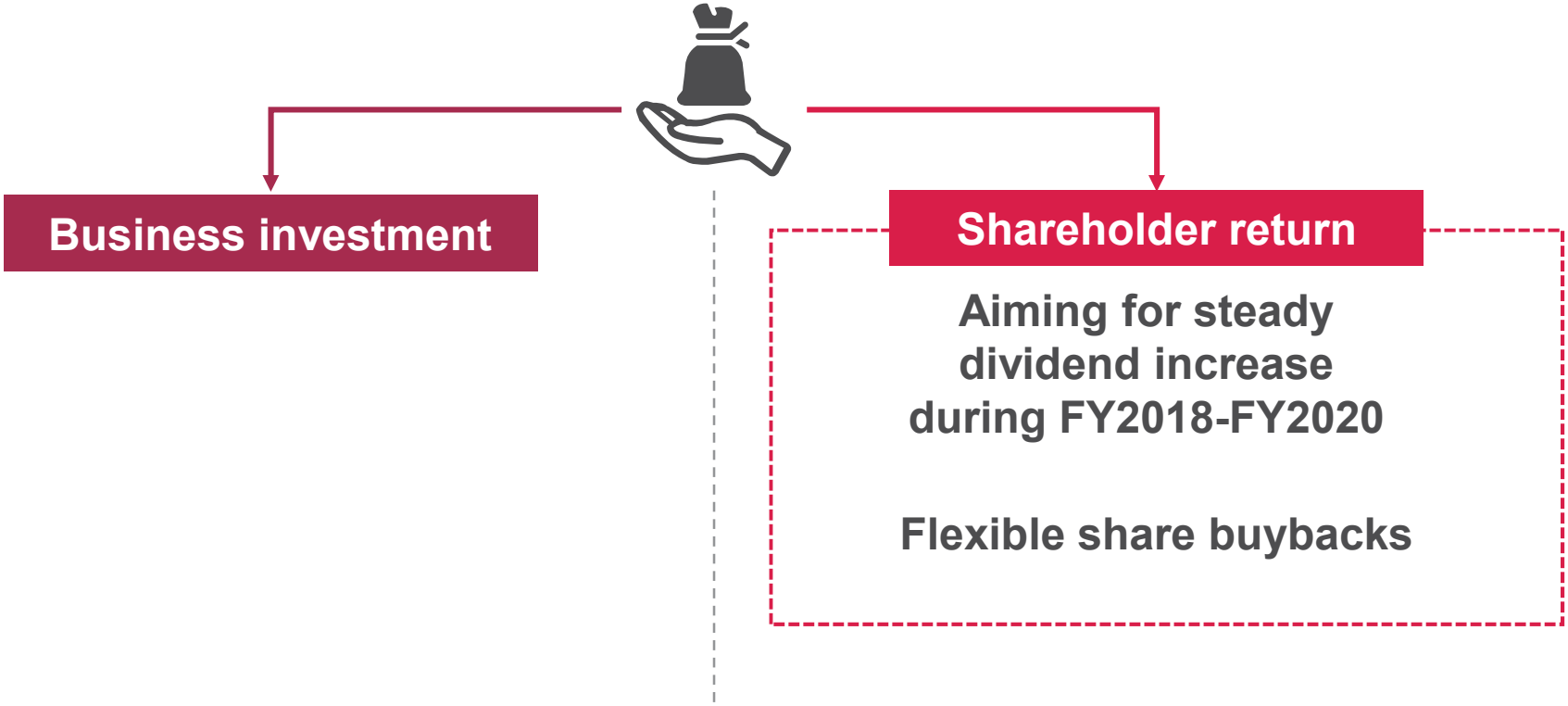


Transform cost structure

For illustrative purposes only

CAPITAL ALLOCATION

Top priority is investment for business growth
Dividends to be increased continuously based on mid-and long-term growth
Share buybacks to be implemented in a flexible manner



SUMMARY: THREE STRATEGIC GOALS

Realize sustainable growth by executing our new strategic plan



*Key products and late-stage pipeline