



TURN INNOVATIVE SCIENCE INTO VALUE FOR PATIENTS

FY2017 PRESS CONFERENCE



July 11th, 2017

Yoshihiko Hatanaka

President and CEO

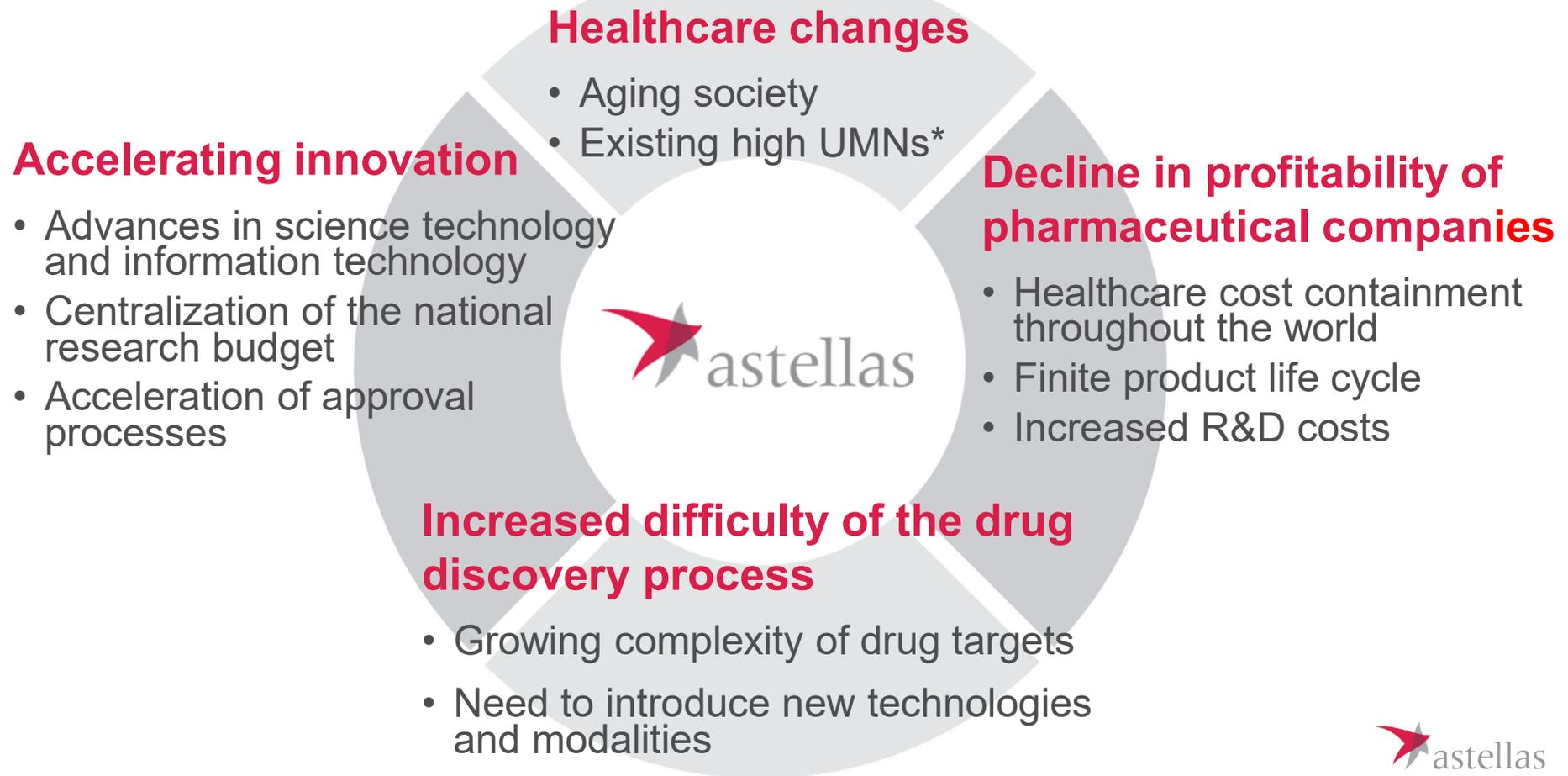
Astellas Pharma Inc.

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. 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.

Balance between improving access to health and innovation are common challenges across the world



FINDING OPPORTUNITY

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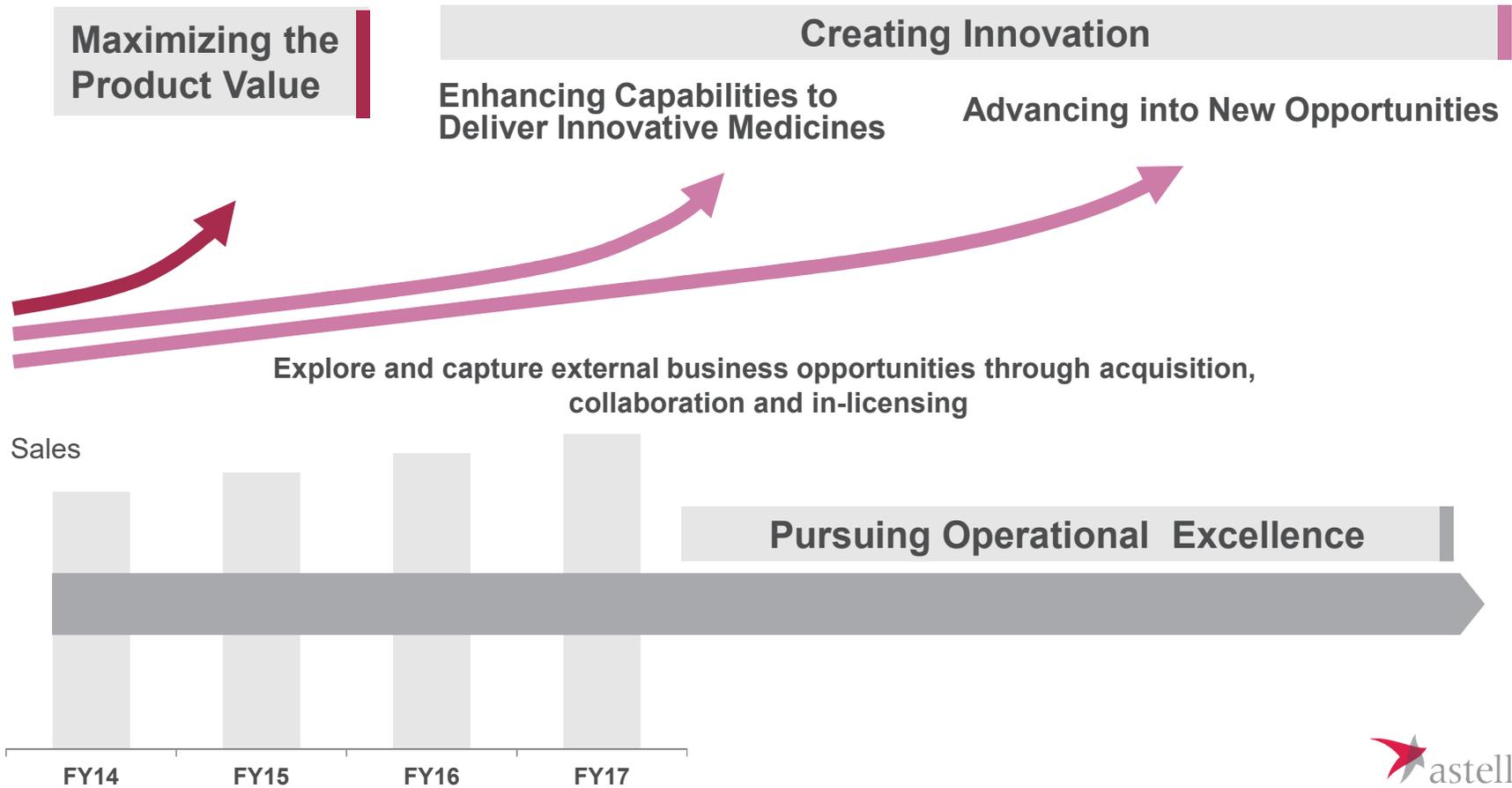
Many opportunities exist where we can provide innovative value to patients

- Novel drug discovery in therapeutic areas with high Unmet Medical Needs
- New modalities such as cell and gene therapy
- Increasing number of technologies with applicability in various fields

ACHIEVING SUSTAINABLE GROWTH

(same as Strategic Plan 2015-2017 slide)

*New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation*





MAXIMIZE THE PRODUCT VALUE

SALES IN THREE KEY AREAS

Each franchise showed solid performance on a CER basis

(billion yen)	FY15	FY16	Change	CER growth
Oncology	320.3	307.7	-4%	+6%
XTANDI	252.1	252.1	+0%	+10%
OAB in Urology	217.4	214.9	-1%	+7%
Vesicare	135.6	116.1	-14%	-7%
Betanis/Myrbetriq/BETMIGA	81.7	98.8	+21%	+31%
Transplantation	203.6	186.2	-9%	-0%



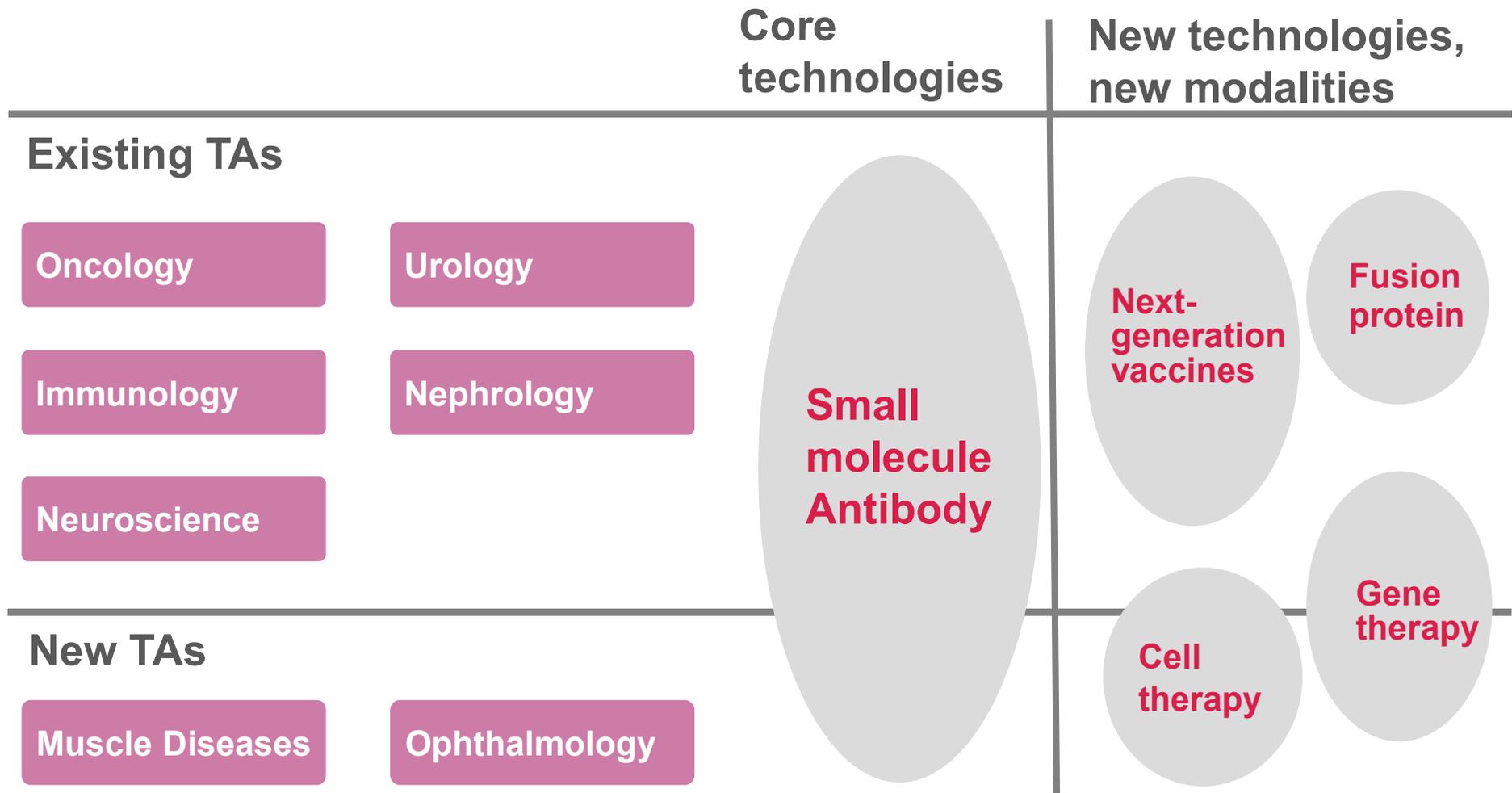
Oncology: XTANDI, Tarceva, Eligard and Gonax
 Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

CER: Constant exchange rate



CREATE INNOVATION

CURRENT FOCUS AREAS





DEVELOP NEW THERAPEUTIC AREAS AND NOVEL TECHNOLOGY PLATFORM

Greater utilization of external R&D resources

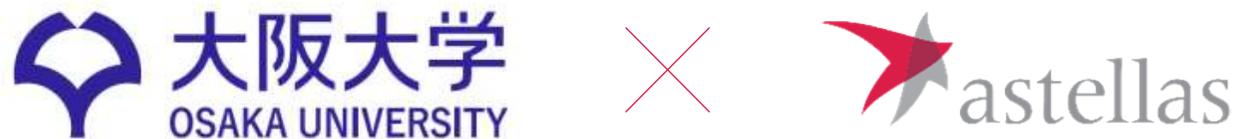
Take on challenges in new therapeutic areas and drug discovery technologies

The number of the collaboration with domestic academia and venture companies is increasing



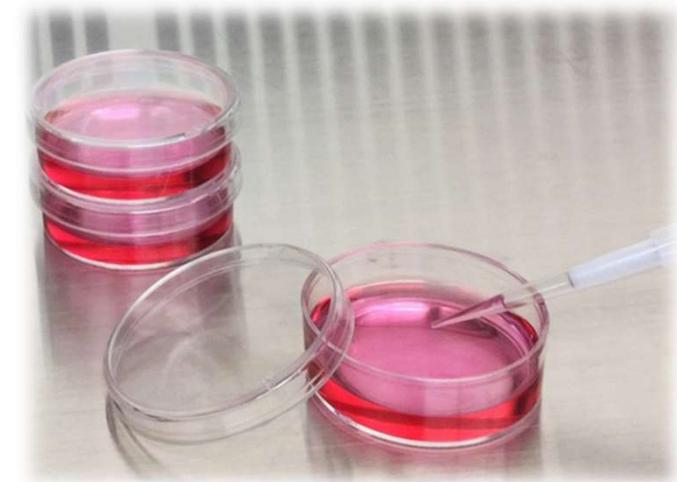
OSAKA UNIVERSITY: JOINT RESEARCH CHAIR

Osaka University and Astellas have established a joint research chair for R&D on next-generation cell therapy



With a view to developing fundamental technologies for next-generation cell therapies and bringing those technologies into practical use

- Develop cell sources
- Develop cell-processing technologies
- Make cells highly functional
- Enhance therapeutic effects



CLINO: GENE THERAPY TO TREAT RETINITIS PIGMENTOSA

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Entering into a license agreement for the worldwide development and commercialization of a gene therapy, Adeno-associated Virus-modified Volvox channelrhodopsin-1

- Modified Volvox channelrhodopsin-1, which was invented by Professor Hiroshi Tomita, Iwate University, and his colleagues, is an engineered photoreceptive ion channel with the ability to respond to broad wavelengths of lights
- Administration of AAV-mVChR1 in a rat model of retinitis pigmentosa resulted in the expression of mVChR1 in retinal ganglion cells and recovery of light sensitivity of these rats



THE INSTITUTE OF MEDICAL SCIENCE, THE UNIVERSITY OF TOKYO (IMSUT):
COLLABORATIVE RESEARCH UTILIZING A RICE-BASED VACCINE, MucoRice

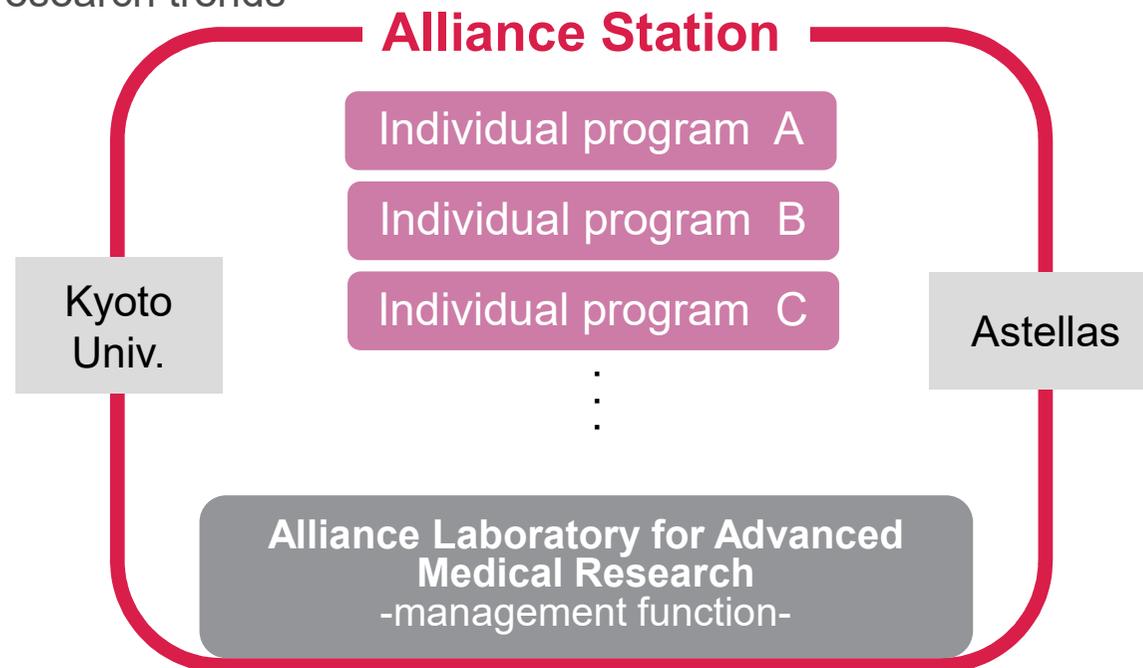
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- ◆ **June 2016: Executed a new collaborative development agreement on MucoRice**
Developing of vaccines against infectious diseases affecting developing countries with the aim of addressing Access to Health issues
 - MucoRice is a rice-based oral vaccine genetically expressing antigens and suppressing the endogenous rice storage protein
 - Expected to meet the UMNs of existing cholera vaccines such as the need for the cold chain and the ineffectiveness against *enterotoxigenic E coli*
 - Through this collaborative research project:
 - IMSUT provides clinical trial materials and trial data, etc. which are necessary for the phase 1 and phase 2 trials of MucoRice for cholera and *enterotoxigenic E coli*
 - Astellas is responsible for conducting and managing the clinical trials.
- ◆ **May 2017 :**
Expanded the scope of the collaborative research to include viral gastroenteritis diarrhea (e.g., norovirus) infection



KYOTO UNIVERSITY: INAUGURATION OF “ALLIANCE STATION” WITH AIM OF REALIZING ADVANCED MEDICAL TREATMENTS

- Inauguration of Alliance Station, a new open innovation scheme at Kyoto University
- Establishment of Alliance Laboratory for Advanced Medical Research as a framework for the implementation of its activities in Graduate School of Medicine Kyoto University
- Acceleration of the search for drug seeds and launch of drugs that could address unmet medical needs as well as inventing new technologies for predicting clinical usefulness by leveraging university resources
- Implementation of collaborative research programs in a prompt and flexible manner according to in-company research trends





PURSUE OPERATIONAL EXCELLENCE

PURSUE OPERATIONAL EXCELLENCE

- **Create organizations and systems that can flexibly respond to rapidly changing environments**
- **Work toward higher quality and efficiency of operations**

- Transferred the global dermatology business to Leo Pharma
- Began operations for Malaysia-based subsidiary, Astellas Pharma Malaysia Sdn. Bhd., and the SESA Umbrella Organization which is responsible for overseeing operations in the South East and South Asia regions
- Transferred a manufacturing subsidiary in US to Avara Norman Pharmaceutical Services
- Decided to outsource facility and equipment management support in Japan, and dissolve its subsidiary, Astellas Business Service Company Limited
- Transferred commercial rights for Qutenza®
- Establishment of a new structure in Sapporo, Hokkaido, to pharmaceuticals support storage and transportation
- Entered into an asset purchase agreement, under which Astellas will transfer its marketing authorization of 16 long-listed products



Resolve social issues and sustainable enhancement of our enterprise value

◆ Initiatives for Access to Health

Participation in Access Accelerated

- To advance access to non-communicable disease prevention, diagnostics and treatment in low- and lower-middle income countries
- A global, multi-stakeholder initiative



Support of Action on Fistula

- In 3 years through 2017, the program had treated 2,471 patients with surgery
- Planning to treat 4,500 women with obstetric fistula in Kenya by 2020

**Action
on Fistula**

◆ Prevention of doping

Agreement with the World Anti-Doping Agency (WADA)

- To partner on the prevention of misuse and abuse of medicines for doping in sports
- Astellas will identify solely developed compounds with the potential for doping abuse and share relevant information to aid WADA to develop detection methods
- Cooperate to minimize the risk of misuse of compounds with doping potential during clinical trials



STRENGTHENING MANAGEMENT STRUCTURE

Further enhanced our global management structure

◆ Executive Committee

- **Added General Counsel as a standing member** (Since Apr. 1, 2017)



From left:
CAO&CECO: Fumiaki Sakurai, CFO: Chikashi Takeda,
CEO: Yoshihiko Hatanaka, General Counsel: Linda Friedman,
CSTO&CCO: Kenji Yasukawa, Ph.D., CMO: Sef Kurstjens, M.D., Ph.D.

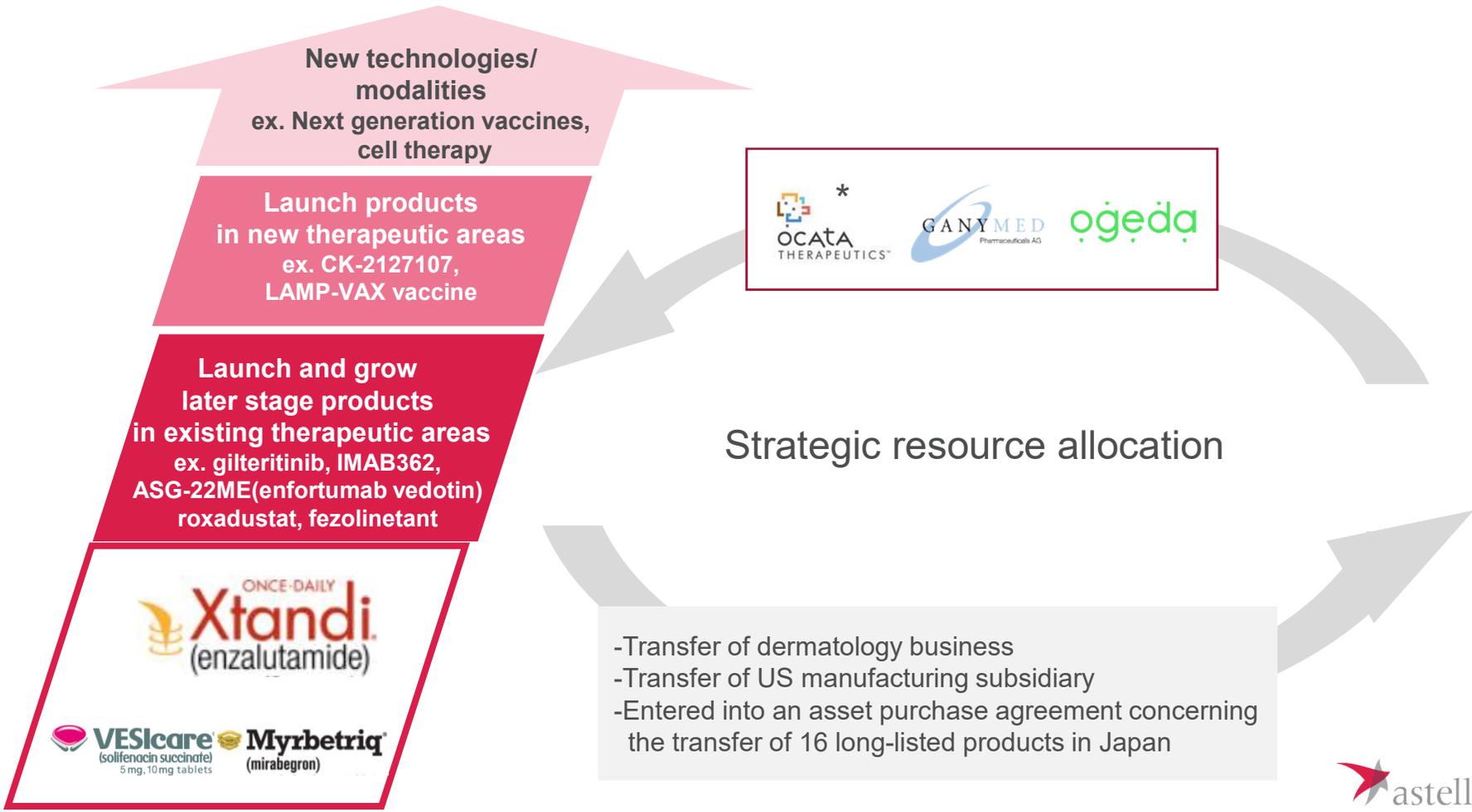
◆ Global Function

- **Enhancement of Compliance** (Since Apr. 1, 2016)
-Divided the Legal and Compliance functions structurally in all regions. Established a new global function to integrate and manage the regional Ethics & Compliance functions in Japan, Americas, EMEA and Asia/Oceania regions
- **Enhancement of Legal** (Since Apr. 1, 2017)
-Established a new global function, Legal, to manage the regional legal functions. Directly reports to CEO
- **Enhancement of Intellectual Property** (Since Apr. 1, 2017)
-Established a new global function, Intellectual Property, to manage the regional intellectual property functions. Directly reports to CEO
- **Restructuring of Pharmaceutical Technology** (Since Apr. 1, 2017)
-Restructured Technology into a new functional structure to strengthen its global operations and management of the contract manufacturing organization, and to enhance the administrative structure, Technology. Renamed as Pharmaceutical Technology



REALIZE SUSTAINABLE GROWTH

Turn innovative science into value for patients on the forefront of healthcare change



*Company name was changed to the Astellas Institute for Regenerative Medicine.

*Turn innovative science into
value for patients*



APPENDIX

Astellas Institute for Regenerative Medicine (AIRM)

Advanced technology that can establish fully-differentiated cells from pluripotent stem cells (PSCs) and strengths in clinical studies and manufacturing for cell therapy

Research

- Technology to establish differentiated target cells from PSCs that could provide functional replacement or trophic support to worn-out or dysfunctional cells and tissues
- Strong IP positions
- Cutting-edge science accepted by top journals

Development

- Expertise in cell-based therapy for high and unmet needs in ophthalmology
- 38 patients treated safely to date
- Active programs currently for macular degeneration (dry AMD and SMD)

Manufacturing

- Capabilities and track records to manufacture clinical grade cell product that was supplied to US and UK
- Strong process and analytical development capabilities (e.g. hyper sensitive impurity cell detection method, novel cell formulation)

ACQUISITION OF GANYMED ~ Dec 2016 ~

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*Acquisition expands Astellas' oncology pipeline with the late-stage antibody IMAB362
Leveraging acquisitions to acquire new platforms and target new tumor types*

◆ Overview of Ganymed

- Privately owned biopharmaceutical discovery company that focuses on the development of antibodies against cancer
- Based in Mainz, Germany
- Founded in 2001
- Number of employees: 85

◆ Most advanced program IMAB362

- The late-stage first-in-class antibody against CLDN18.2
- Received orphan drug designation in the U.S. and EU for gastric and pancreatic cancers
- Phase 2b study in gastroesophageal cancer patients positive for Claudin18.2 showed that IMAB362 extended the median progression-free survival and the median overall survival when added to standard chemotherapy. The most frequent adverse effects observed during the study were vomiting, nausea and neutropenia.

ACQUISITION OF OGEDA SA ~ May 2017 ~

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*Acquisition expands Astellas' late stage clinical pipeline with fezolinetant
Astellas has category leading experience in successful development and commercialization in urology*

◆ Overview of Ogeda

- Privately owned clinical-stage drug discovery company that invents and develops small molecule drug candidates targeting GPCRs*
- Based in Gosselies, Belgium
- Founded in 1994
- Number of employees: 41

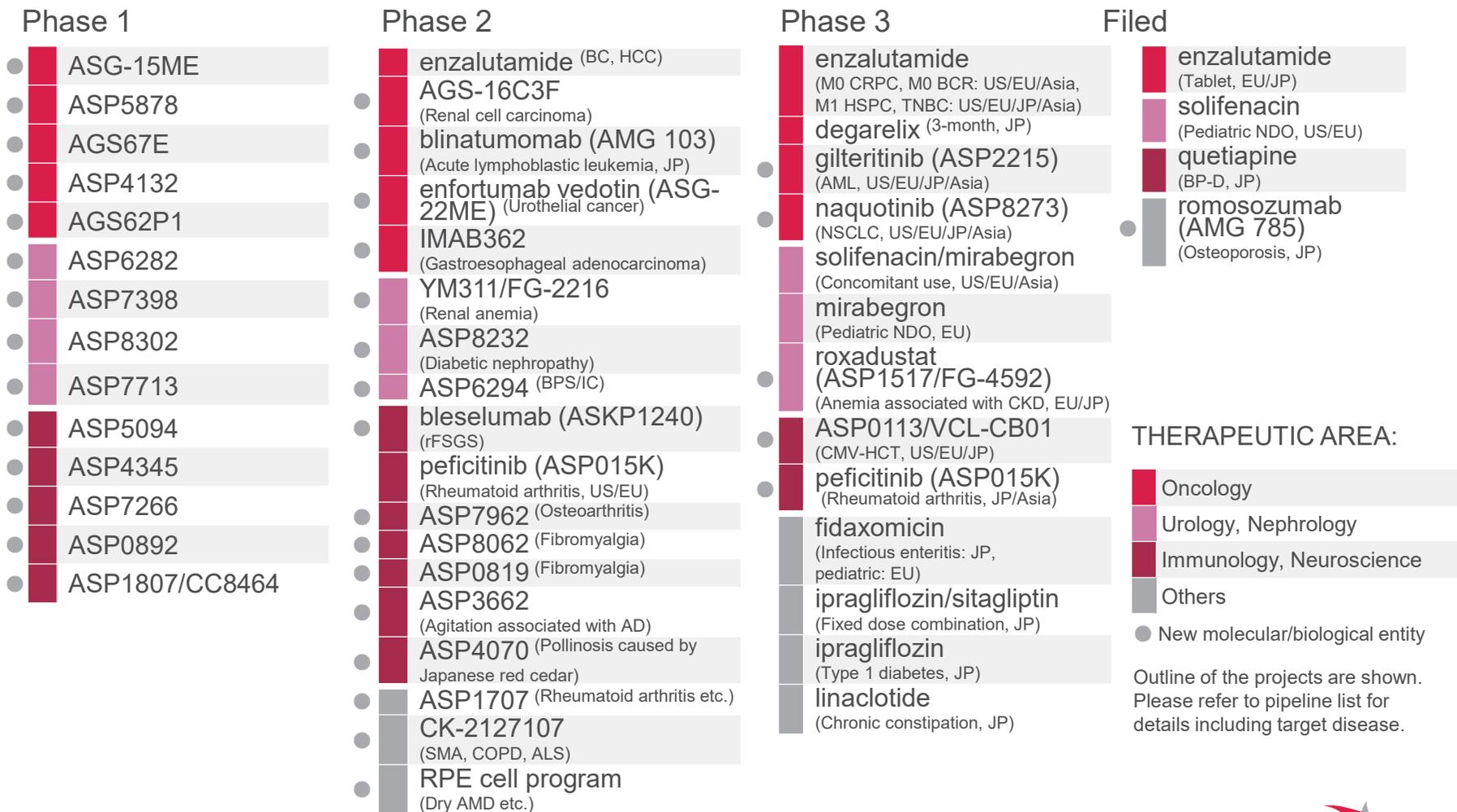
◆ Most advanced program fezolinetant

- Currently being investigated in menopause-related vasomotor symptoms (MR-VMS) or hot flashes
- Tachykinin NK3 receptor antagonist
- Phase 2a study in early postmenopausal women with moderate to severe hot flashes met its primary endpoint and no severe adverse events were reported in either treatment group. The mild-to-moderate adverse events (such as headache and nasopharyngitis) were reported in 67% of the fezolinetant group and 80% in the placebo group.



*GPCRs: G-protein coupled receptors

ROBUST PIPELINE OF ASTELLAS



enzalutamide: (TNBC)Discontinuation of P3 study, (BC, P2)Not be follow-on P3 studies
 naquotinib(ASP8273, P3) Planning to terminate future development programs