



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows

# Sumitovant Meeting

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March 23, 2021

Sumitomo Dainippon Pharma Co., Ltd.

## Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

# Today's Agenda

1	Introduction	Representative Director, President and CEO	Hiroshi Nomura 5 minutes	P3~P5
2	Sumitovant Biopharma, Inc. Portfolio Overview	CEO of Sumitovant	Myrtle Potter 25 minutes	P6~P30
3	Digital Transformation Update	CIO of Sumitovant and CDO of Sumitomo Dainippon Pharma group	Dan Rothman 15 minutes	P31~P60
4	The DrugOME	Chief Algorithmic Analytics Officer of Sumitovant	Bill McMahon 10 minutes	P61~P69
5	Expectations for Sumitovant and Synergies in R&D	Member, Board of Directors, Senior Executive Officer and CSO	Toru Kimura, Ph.D. 10 minutes	P70~P79
6	Q&As		50 minutes	

# Introduction

**Hiroshi Nomura**  
**Representative Director, President and CEO**

# Business Model and Strategic Alliance with Roivant

✓ To add the “Best in class focused on value” to our R&D areas → **Achieving sustained growth**  
 ✓ To accelerate the digital transformation (DX)

- Through the Strategic Alliance with Roivant, acquired late-stage development assets such as relugolix and vibegron, that are potential near-term blockbuster products
- Allows us to mitigate our risks as a pharmaceutical company and continually invest in first in class drug discovery

## Opportunities and risks of first in class drug discovery

- ✓ While the three focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy involve high unmet medical needs and allow us to tap into our strengths, there is a high degree of uncertainty and difficulty in research and development
- ✓ It is challenging to develop/launch a seamless flow of new drugs only in those three areas in which we seek to develop first in class new medications

## Position we aspire to establish in 2033



Best in class: There are existing drugs, but new drugs that have a clear advantage over the existing drugs

## Business Model and Strategic Alliance with Roivant

- ✓ To add the “Best in class focused on value” to our R&D areas
- ✓ To accelerate the digital transformation (DX)



**Achieving sustained growth**

### DX strategies

DX is considered to be one of the “growth engines” and “foundations of a flexible and efficient organization” in the Mid-term Business Plan 2022

- ✓ Through the Strategic Alliance with Roivant, acquired technology platforms, DrugOME and Digital Innovation, and the involved talents, we will accelerate DX by focusing on the creation/enhancement of business value
- ✓ Focus technology initiatives on business value delivery and develop digital talents

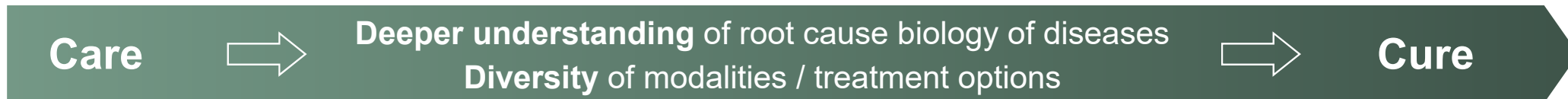
- Each business unit promotes utilization of digital technology (some have begun accelerating efforts due to COVID-19)
  - ✓ Promoting DX such as AI drug discovery, DrugOME and Digital Innovation in R&D (Japan, U.S.)
  - ✓ Accelerating operational reform such as building a telework system and digitizing in-house procedure work corresponding to COVID-19 (Japan)
  - ✓ Utilizing digital tools for information provision activities such as online interviews by MRs (Japan, U.S., China)

# Sumitovant Biopharma, Inc. Portfolio Overview

**Myrtle Potter**  
**Chief Executive Officer**

# Sumitovant's Focus

## Modality / Technology



## Sumitovant Vision / Mission / Values

- Change lives for the better
- Address unmet medical needs
- Put patients first
- Commit to quality
- Leverage technology to make us smarter, faster and our products better
- Diversity, inclusion and equity

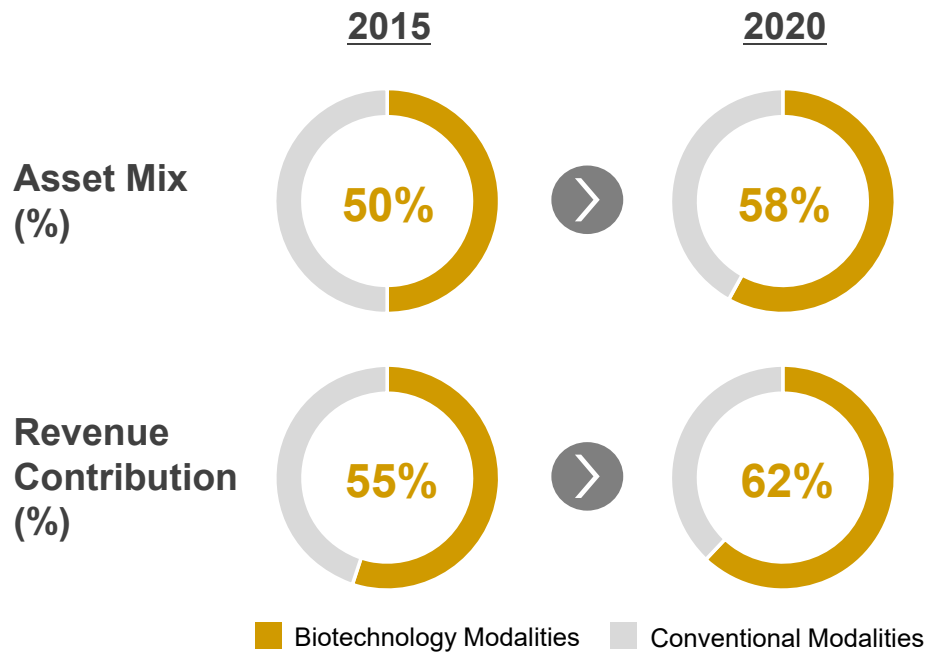


# Biotechnology Modalities Represent a Significant Proportion of Pharmaceutical Industry Commercial Revenues and Growth

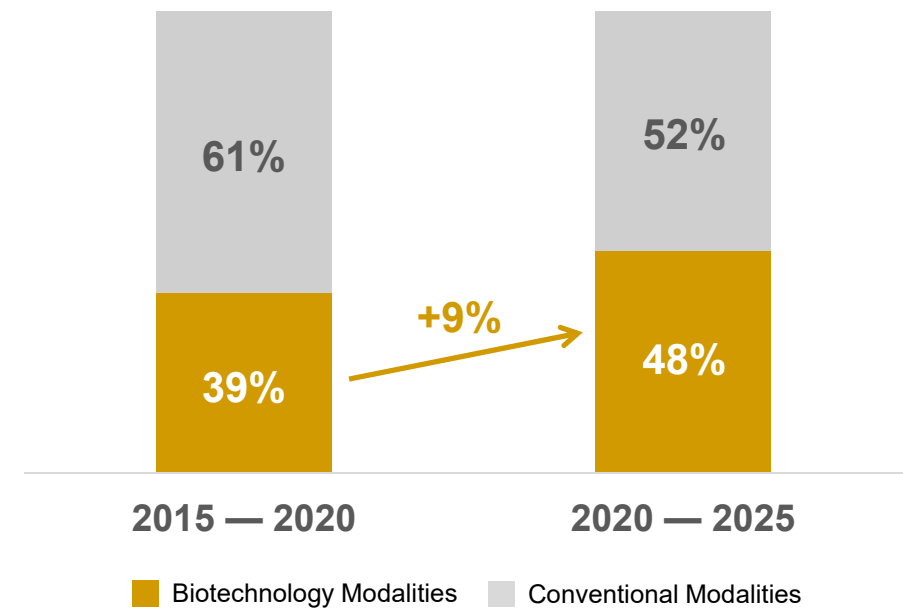
Biotechnology modalities have increasingly become a more significant contributor to top-selling global therapies and on average generate more revenue per asset<sup>1</sup>

Biotechnology modalities' contribution to revenue growth across all global therapies is also expected to increase over the next four years

## Top 50 Therapies by Worldwide Revenue



## Biotechnology Modalities Percent Contribution to Global Pharmaceutical Revenue Growth<sup>2</sup>



(1) Top 50 therapies by worldwide revenue in 2015 and 2020

(2) Inclusive of worldwide revenue for therapies that grew from 2015-2020 and are anticipated to grow from 2020-2025






Biotechnology Modalities: Monoclonal antibody, recombinant protein, bioengineered vaccine, cell therapy, DNA & RNA therapeutics, gene therapy, oncolytic virus

Conventional Modalities: All other (~90% are small molecule)

Source: EvaluatePharma, February 4, 2021

# Sumitovant Biopharma Pipeline Summary

Sumitovant has a diverse development pipeline spanning numerous modalities & indications that address significant unmet patient need. 67% of our pipeline molecules are biotechnology modalities

	Compound	Modality	Indication	Therapeutic Area	Phase	Milestone (Date <sup>1</sup> )
	relugolix	Small Molecule	Advanced Prostate Cancer	Oncology	FDA Approved	FDA approval (December 18, 2020) MAA filing (Q1 2021)
		Small Molecule (Combo)	Symptoms of Uterine Fibroids	Women's Health	NDA Accepted; MAA Filed	FDA PDUFA (June 1, 2021) MAA decision (Mid-2021)
			Symptoms of Endometriosis	Women's Health	Phase 3	NDA filing (1H 2021) MAA filing (2021)
	MVT-602	Oligopeptide	Female Infertility	Women's Health	Phase 2	Phase 2a data results (June 2019)
	vibegron	Small Molecule	Overactive Bladder	Urology	FDA Approved	FDA approval (December 23, 2020)
			Overactive Bladder in Men w/ BPH	Urology	Phase 3	Topline results (June 2022)
	URO-902	Gene Therapy	Overactive Bladder	Urology	Phase 2a	Positive DSMB recommendation <sup>2</sup> (Feb 2021)
	RVT-802	Regenerative Therapy	Pediatric Congenital Athymia	Rare Disease	Received CRL to BLA	BLA resubmission (2021)
	rodatristat ethyl	Small Molecule	Pulmonary Arterial Hypertension	Respiratory	Phase 2b	Study start (March 2021)
	ALTA-2530	Recombinant Protein	Bronchiolitis Obliterans Syndrome	Respiratory	Preclinical	IND submission (2023)
			Chemical Lung Injury (in partnership w/ BARDA & NIAID)	Respiratory	Preclinical	IND submission (2022)
	SP-101	Gene Therapy (AAV)	Cystic Fibrosis	Respiratory	Preclinical	IND submission (2022)
	SP-102	Gene Therapy (LVV)	Cystic Fibrosis	Respiratory	Preclinical	IND submission (2025)

(1) Calendar year

(2) FDA Data and Safety Monitoring Board (DSMB) recommended the continuation of the Phase 2a study of URO-902 in patients with overactive bladder (OAB) and urge urinary incontinence (UUI)

BPH: Benign Prostatic Hyperplasia; CRL: Complete Response Letter; BARDA: Biomedical Advanced Research and Development Authority; NIAID: National Institute of Allergy and Infectious Diseases

# **ORGOVYX™ (relugolix) and Relugolix Combination Therapy**

# ORGOVYX™: Product Profile Overview

ORGOVYX™ (relugolix) received FDA approval on December 18, 2020

First and only oral GnRH receptor antagonist for the treatment of adult patients with advanced prostate cancer



picture of drug formulation

PRODUCT PROFILE



**Mechanism of Action:** GnRH receptor antagonist



**Dosing / Administration:** Oral; Initial loading dose of 360 mg on Day 1 followed by once daily 120 mg

## Current Standard of Care



Injectable



Initial hormonal surge



Weeks to reduce PSA; Months for testosterone recovery



## ORGOVYX™ Clinical Profile



Oral



No hormonal surge



Sustained and rapid reduction in PSA<sup>1</sup>; Quick testosterone recovery<sup>2</sup>

(1) In the clinical trial, PSA levels were monitored and were lowered on average by 65% 2-weeks after administration of ORGOVYX™, 83% after 4-weeks, 92% after 3-months and remained suppressed throughout the 48-weeks of treatment

(2) 55% of patients achieved testosterone levels above the lower limit of the normal range (> 280 ng/dL) or baseline at 90 days after discontinuation of ORGOVYX™

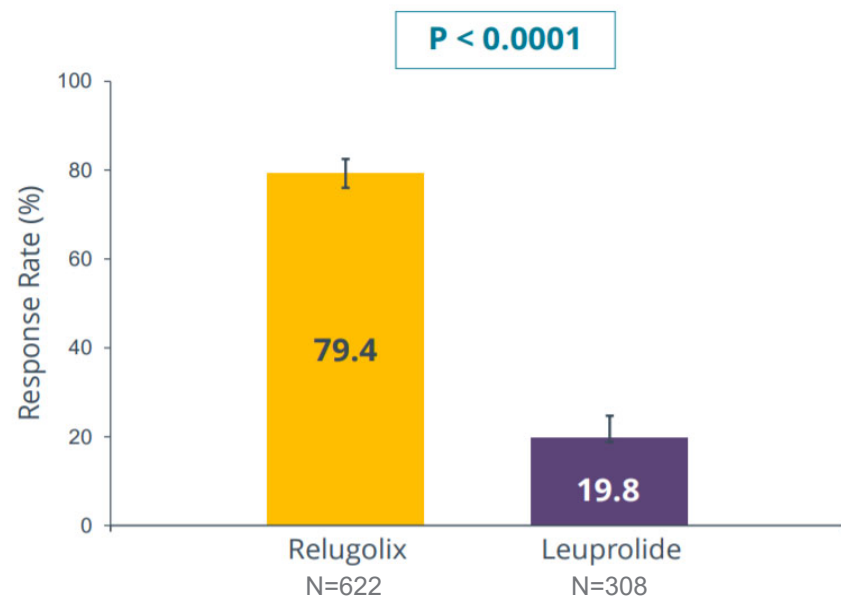
Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325

NOT FOR PROMOTIONAL USE; not direct comparative claims; full prescribing information for ORGOVYX™ is available at [www.myovant.com/orgovyx-prescribing-information.pdf](http://www.myovant.com/orgovyx-prescribing-information.pdf)

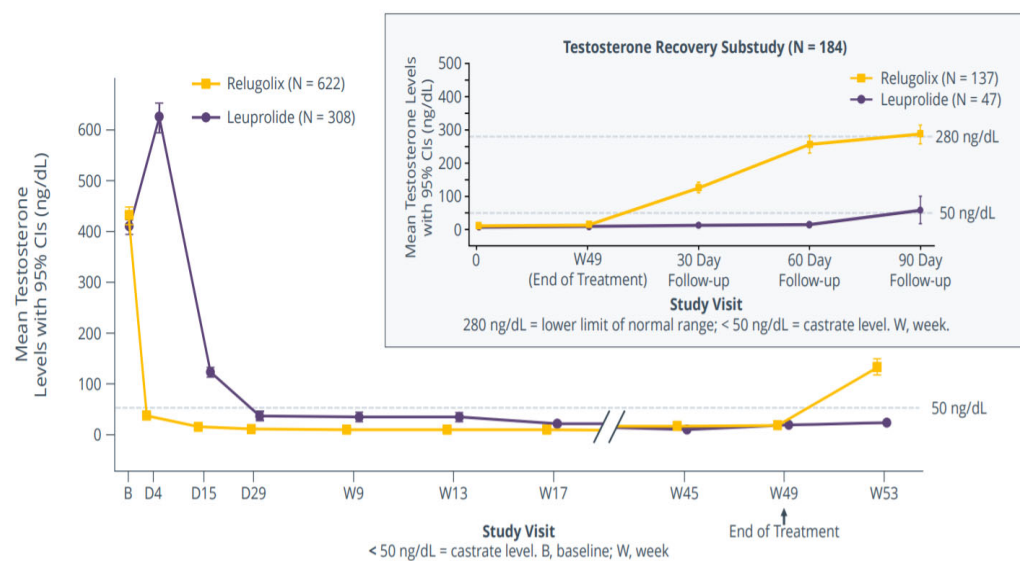
# ORGOVYX™: Product Clinical Highlights

The Phase 3 HERO study results demonstrated ORGOVYX™'s favorable efficacy profile in terms of PSA response rate and overall time course of testosterone suppression

ORGOVYX™ achieved a high PSA response rate<sup>1</sup> in the majority of men at Day 15



ORGOVYX™ demonstrated rapid testosterone suppression with no initial hormonal flare and recovery within 90 days



(1) Defined as  $\geq 50\%$  reduction in PSA from baseline at Day 15 and confirmed at Day 29

PSA: Prostate-specific Antigen

Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325

Full prescribing information for ORGOVYX™ is available at [www.myovant.com/orgovyx-prescribing-information.pdf](http://www.myovant.com/orgovyx-prescribing-information.pdf)

## ORGOVYX™: Product Clinical Highlights (Continued)

The Phase 3 HERO study results also demonstrated ORGOVYX™’s favorable safety profile

ORGOVYX™ was generally well-tolerated with an adverse event profile similar to Leuprolide

	Relugolix (N = 622)	Leuprolide (N = 308)
Hot Flush	54.3%	51.6%
Fatigue	21.5%	18.5%
Constipation	12.2%	9.7%
Diarrhea <sup>1</sup>	12.2%	6.8%
Arthralgia	12.1%	9.1%
Hypertension	7.9%	11.7%

(1) Adverse events of diarrhea were grade 1 or 2 and did not result in study discontinuation

Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325

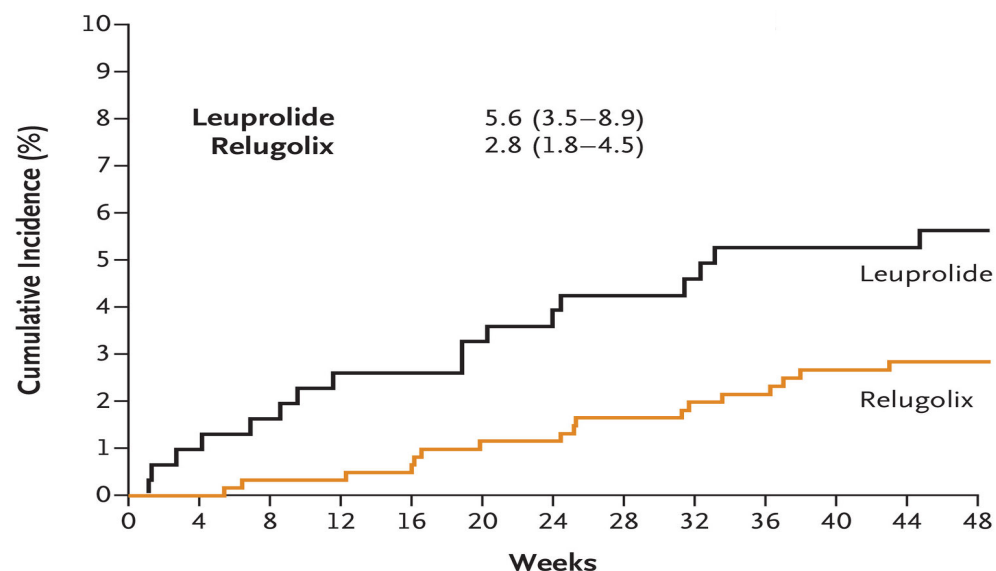
Full prescribing information for ORGOVYX™ is available at [www.myovant.com/orgovyx-prescribing-information.pdf](http://www.myovant.com/orgovyx-prescribing-information.pdf)

Additional Warnings & Precautions: ORGOVYX™ may prolong QT/QTc interval prolongation and may cause fetal harm and loss of pregnancy when administered to a pregnant female. The therapeutic effect of ORGOVYX™ should be monitored by measuring serum concentrations of prostate specific antigen (PSA) periodically

# ORGOVYX™: Product Clinical Highlights (Continued)

The Phase 3 HERO study results also demonstrated ORGOVYX™’s favorable safety profile, including the incidence of Major Adverse Cardiovascular Events (MACE)

## Cumulative Incidence of Major Adverse Cardiovascular Events (MACE) Through Week 48



No. at Risk		0	4	8	12	16	20	24	28	32	36	40	44	48
Leuprolide		308	305	303	298	298	293	292	288	281	279	278	269	259
Relugolix		622	621	616	610	605	596	595	588	582	575	563	559	538

(1) Adverse events of diarrhea were grade 1 or 2 and did not result in study discontinuation  
 Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325  
 NOT FOR PROMOTIONAL USE; THESE ARE NOT SUPERIORITY CLAIMS. The incidence of major adverse cardiovascular events was a prespecified safety analysis and was not a prospective efficacy endpoint in the study. For these reasons, the FDA did not include the incidence of major adverse cardiovascular events for leuprolide in the label. Full prescribing information for ORGOVYX™ is available at [www.myovant.com/orgovyx-prescribing-information.pdf](http://www.myovant.com/orgovyx-prescribing-information.pdf)  
 Additional Warnings & Precautions: ORGOVYX™ may prolong QT/QTc interval prolongation and may cause fetal harm and loss of pregnancy when administered to a pregnant female. The therapeutic effect of ORGOVYX™ should be monitored by measuring serum concentrations of prostate specific antigen (PSA) periodically

## ORGOVYX™: Launch Highlights

Myovant launched ORGOVYX™ in the U.S. on January 4, 2021 and is actively executing on launch priorities, including **100 Myovant sales representatives** actively promoting ORGOVYX™ to prescribers

**ORGOVYX™**  
(relugolix) 120 mg tablets



Educate  
Prescribers



Establish  
Broad Access



Engage  
Patients

The Myovant-Pfizer collaboration, announced in December 2020, can potentially accelerate uptake and maximize the commercial potential of ORGOVYX™ by leveraging Pfizer's **100-person uro-oncology sales team**, commercial infrastructure and expertise



- Pfizer has demonstrated success in the prostate cancer market through its promotion of **XTANDI®**, a leading prostate cancer therapeutic that is co-administered with androgen deprivation therapy
- Pfizer recorded U.S. sales for XTANDI® of **\$1.0B** in 2020<sup>1</sup>
- 2020 U.S. growth for XTANDI® was **22%**<sup>1</sup>, despite COVID-19 pandemic
- This transformative collaboration will significantly strengthen the launch of ORGOVYX™

(1) 2020 Pfizer Q4 Earnings Press Release  
XTANDI® is a registered trademark of Astellas Pharma Inc. Xtandi® in the U.S. and is being developed and commercialized through a collaboration between Astellas Pharma Inc. and Pfizer



# ORGOVYX™: Educate Prescribers

Early progress leading to ORGOVYX™ orders from priority accounts

## Educate Prescribers

## Establish Broad Access

## Engage Patients

### Clinical

Educate HCPs on ORGOVYX™ clinical profile to build confidence to prescribe

- Over 10,000 total HCP interactions<sup>1</sup> since launch
- Since launch, Myovant's sales team has had meaningful interactions<sup>2</sup> with physicians and opinion leaders



### Economic

Offer approved contract terms for practices with in-office dispensing capabilities

- Vast majority of in-office dispensing practices have access to contract pricing
- 10 of our top 20 highest priority accounts have placed orders<sup>3</sup>
- 30% of accounts that have placed ORGOVYX™ orders have already re-ordered<sup>3</sup>



### Operational

Enable seamless ORGOVYX™ prescribing

- Enable ORGOVYX™ to be captured in the EMR system for e-prescribing, a leading indicator for potential adoption
- Seeing good progress along this front

(1) Interactions defined as sales calls, downloads from orgovyxhcp.com, and unsolicited medical inquiries from HCPs

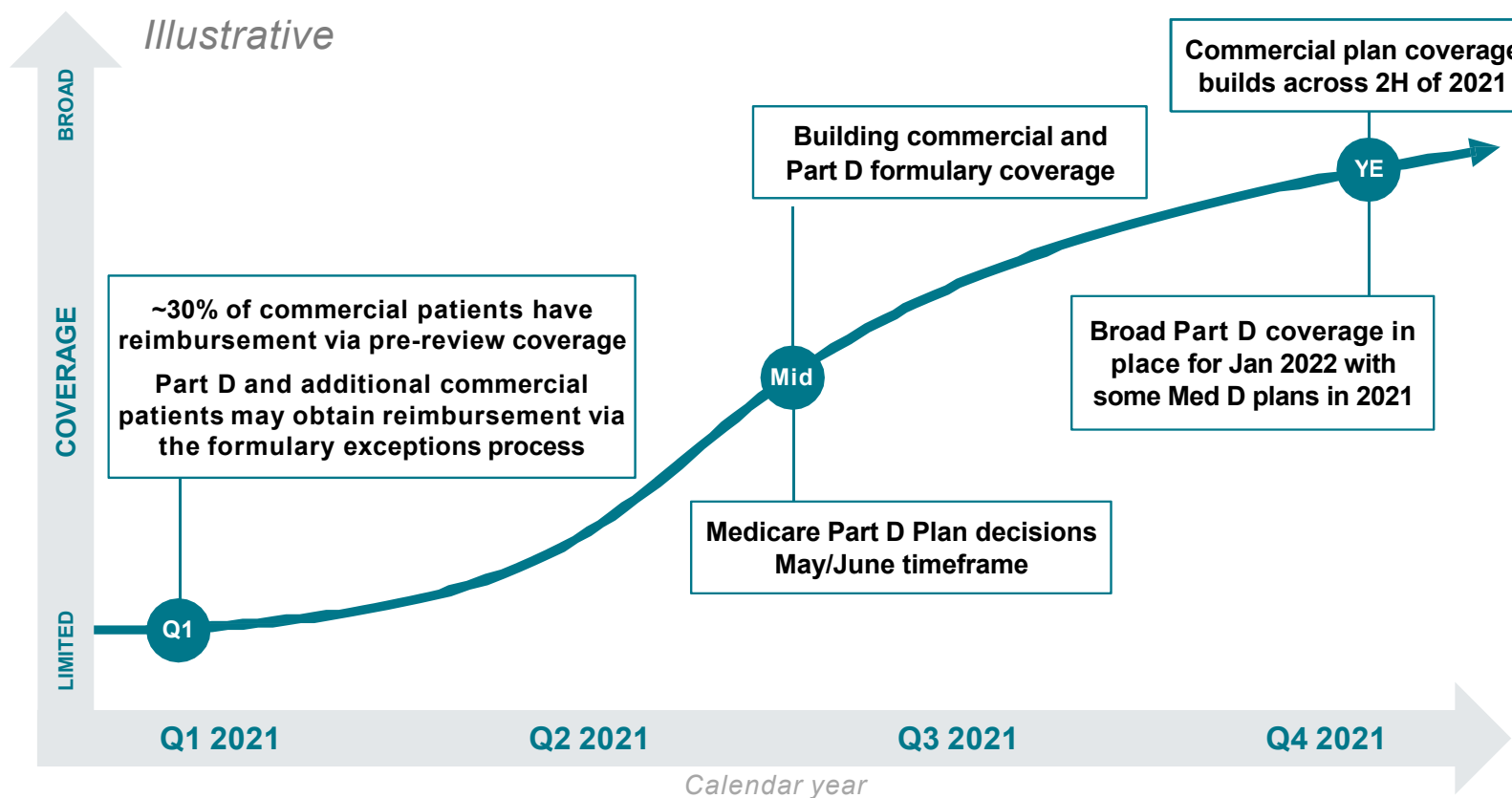
(2) Meaningful interaction defined as an in-person or virtual discussion regarding the ORGOVYX™ safety and efficacy profile for the treatment of advanced prostate cancer with a health care professional who is directly involved in patient care

(3) Within the first 6 weeks post-launch

EMR = Electronic Medical Record

# ORGOVYX™: Establish Broad Access

Myovant is seeking broad commercial and Medicare Part D coverage by year-end 2021



- Positive interactions with key commercial & Medicare plans to support broad coverage by end of 2021
- Anticipate initial commercial formulary decisions in 1H 2021
- Bids for 2022 Medicare Part D bid cycle submitted by Q1 2021

# ORGOVYX™: Engage Patients

## High initial patient interest in ORGOVYX™ since launch

Educate Prescribers

Establish Broad Access

Engage Patients

# 37K

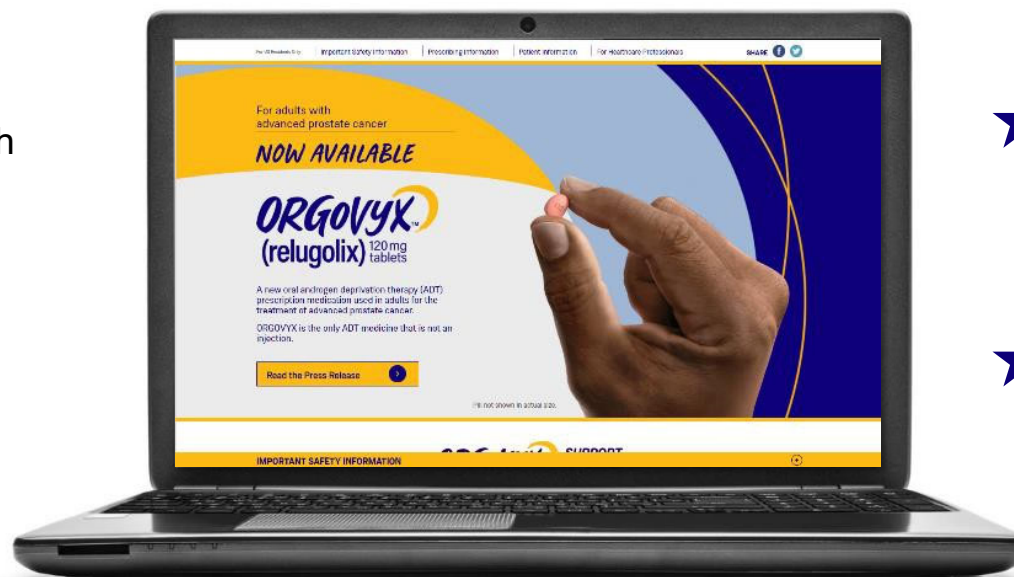
Total visits to  
**ORGOVYX.com** since launch

# 83%

of total visits are unique

# 1:20

Average time spent on site  
*DTC benchmark = 0:50*



★ Total visits are **~4x higher** than typical oncology product launches<sup>1</sup>

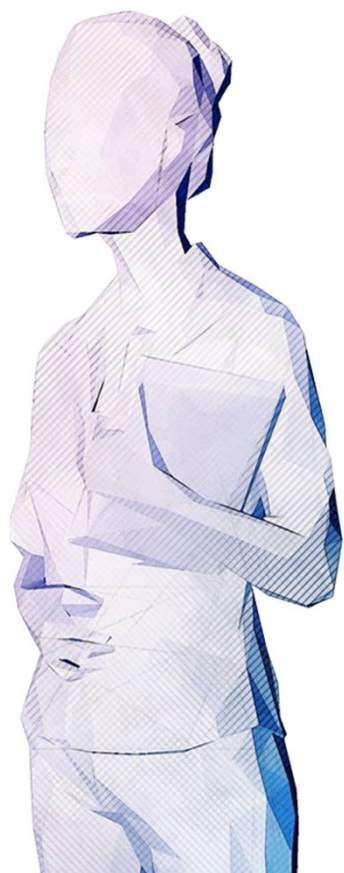
★ **17% of visits** downloaded or clicked on key site actions<sup>2</sup>

(1) Direct-to-consumer oncology benchmark = 175 website visits per day

(2) Includes patient brochure, doctor discussion guide, treatment tracker, copay enrollment form, press release, and patient information

## Relugolix Combination Tablet in Women's Health

If approved by the FDA, relugolix combination tablet (CT) has potential to become the best-in-class therapy for uterine fibroids and endometriosis



PRODUCT  
PROFILE



**Mechanism of Action:** GnRH receptor antagonist with added estrogen and progestin



**Dosing / Administration:** Oral; once-daily tablet (relugolix 40 mg + estradiol 1.0 mg + norethindrone acetate 0.5 mg)

- Relugolix CT has the potential to transform multiple hormone-driven diseases in women's health
- **Uterine fibroids:**
  - FDA has designated PDUFA action date of **June 1, 2021** for relugolix combination tablet in uterine fibroids
  - Recently announced the publication in the New England Journal of Medicine of the Phase 3 LIBERTY 1 & 2 studies
- **Endometriosis:**
  - Submission of FDA New Drug Application (NDA) anticipated for **1H 2021**
- Myovant's women's health sales force and Pfizer's sales force will co-promote relugolix combination tablet in both indications
- The Pfizer collaboration will also support promotional efforts by leveraging its expertise in direct-to-consumer promotion



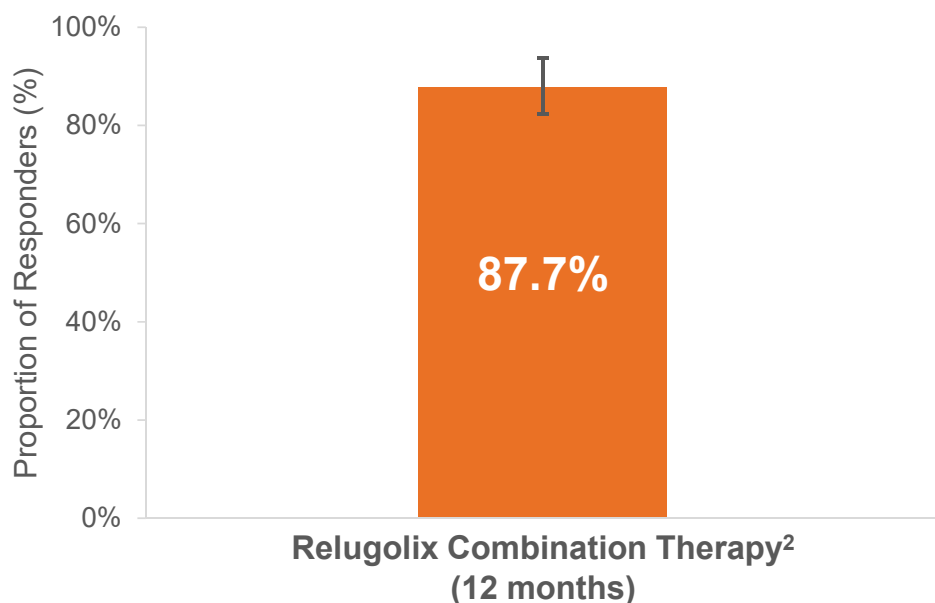
*picture of drug formulation*

# Relugolix Combination Therapy: Clinical Profile (Uterine Fibroids)

At 52 weeks, both the efficacy and safety data for relugolix combination therapy were consistent with prior data demonstrating a clinically meaningful reduction in menstrual blood loss while maintaining bone health

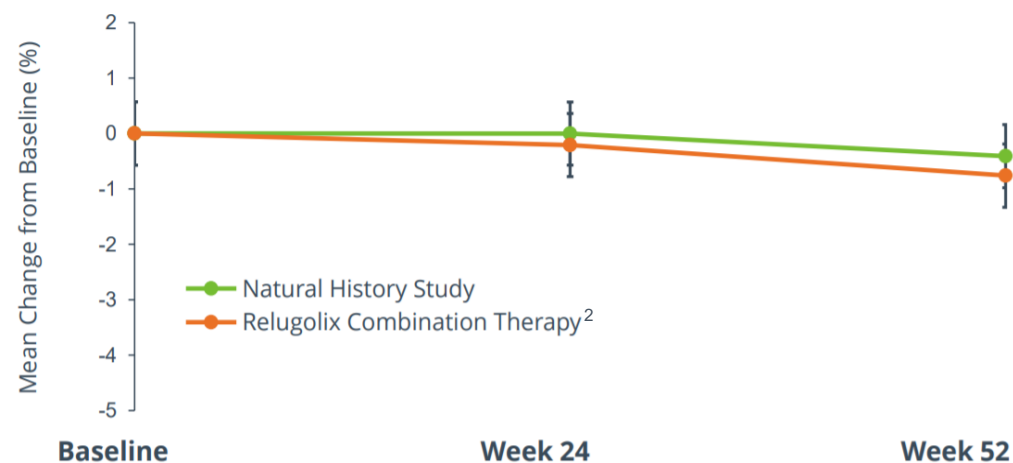
Primary efficacy endpoint was met at one year, demonstrating durability of the response observed in LIBERTY 1 & 2<sup>1</sup>

Proportion of responders with <80 mL menstrual blood loss/cycle and at least a 50% reduction in menstrual blood loss by alkaline hematin method



Changes in lumbar spine bone mineral density maintained through one year and were consistent with those in LIBERTY 1 & 2<sup>1</sup>

Lumbar spine bone mineral density was also consistent with that of untreated women with uterine fibroids in a concurrent natural history study



(1) Al-Hendy A, et al. LIBERTY: Long-Term Extension Study Demonstrating One-Year Efficacy and Safety of Relugolix Combination Therapy in Women with Symptomatic Uterine Fibroids. Fertility and Sterility. 2020 September. DOI: <https://doi.org/10.1016/j.fertnstert.2020.08.027>  
 (2) Relugolix 40 mg + estradiol 1.0 mg + norethindrone acetate 0.5 mg  
 Relugolix combination tablet is an investigational drug that has not been approved for any use

# Relugolix Combination Therapy: Clinical Profile (Endometriosis)

Results at 52 Weeks	SPIRIT Extension <sup>1</sup>		Other GnRH Antagonist Extension Study 1 <sup>3</sup>		Other GnRH Antagonist Extension Study 2 <sup>3</sup>	
	Once Daily Relugolix CT <sup>2</sup> (40 mg)		Once Daily Other GnRH Antagonist (150 mg)	Twice Daily Other GnRH Antagonist (200 mg)	Once Daily Other GnRH Antagonist (150 mg)	Twice Daily Other GnRH Antagonist (200 mg)
<b>Dosing</b>						
<b>Responder Rate<sup>4</sup></b>						
<b>Dysmenorrhea</b>	<b>84.8%</b>		<b>52.1%</b>	<b>78.2%</b>	<b>50.8%</b>	<b>75.9%</b>
<b>Non-Menstrual Pelvic Pain</b>	<b>73.3%</b>		<b>67.1%</b>	<b>69.1%</b>	<b>66.4%</b>	<b>67.2%</b>
<b>LS Mean Change from Baseline in Overall Pelvic Pain<sup>5</sup></b>	<b>-3.80</b>		<b>-2.58</b>	<b>-3.09</b>	<b>-2.81</b>	<b>-3.14</b>
<b>Bone Mineral Density Loss (Lumbar Spine)</b>	<b>-0.81%</b>		<b>-0.63%</b>	<b>-3.60%</b>	<b>-1.10%</b>	<b>-3.91%</b>
<b>Hot Flashes</b>	<b>14.4%</b>		<b>29.5%</b>	<b>52.2%</b>	<b>25.4%</b>	<b>55.0%</b>

**NOTE: No direct head-to-head data available – caution advised when comparing clinical studies with different assessment measures**

(1) SPIRIT Phase 3 long-term extension clinical trial

(2) Relugolix 40 mg + estradiol 1.0 mg + norethindrone acetate 0.5 mg

(3) Other GnRH antagonist Phase 3 long-term extension clinical trials

(4) Proportion of responders with clinically meaningful reduction in the respective pain type and no increase in analgesic use. Different responder thresholds were used for the SPIRIT and other GnRH antagonist programs

(5) LS mean change from baseline in overall pelvic pain based on an 11-point Numerical Rating Scale, with 10 being "worst pain possible" and 0 being "no pain"

Relugolix combination tablet is an investigational drug that has not been approved for any use

# **GEMTESA<sup>®</sup> (vibegron)**

## GEMTESA<sup>®</sup>: Product Profile Overview

GEMTESA<sup>®</sup> (vibegron) received FDA approval on December 23, 2020 for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency in adults



picture of drug formulation

PRODUCT PROFILE



**Mechanism of Action:** Selective human beta-3 adrenergic receptor agonist



**Dosing / Administration:** One 75 mg tablet once daily

GEMTESA<sup>®</sup> is a compelling alternative for patients with OAB



**GEMTESA<sup>®</sup>**

is the only FDA approved  $\beta$ 3 agonist with...

- ✓ A single, **crushable** dose
- ✓ **No** dose titration<sup>1</sup>
- ✓ **Urgency data** included in the label
- ✓ **No** blood pressure warning
- ✓ **No** CYP2D6 interaction warning

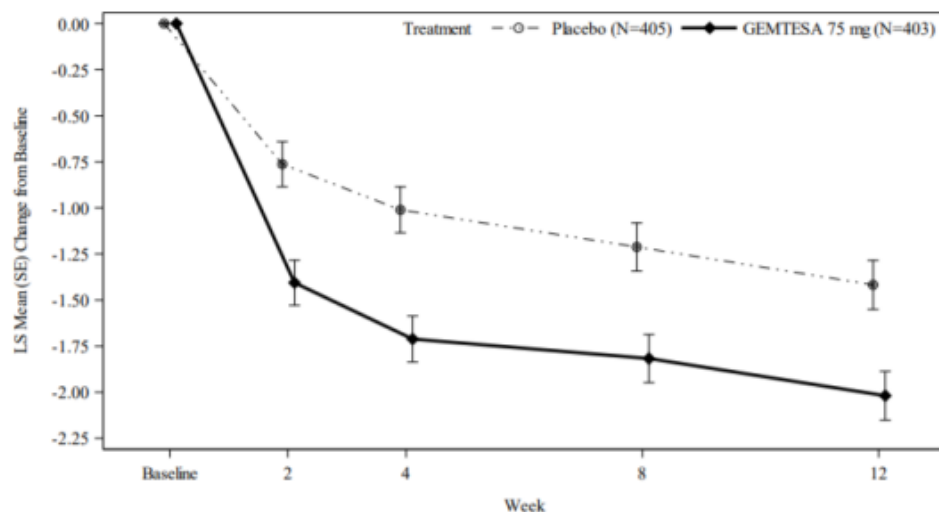
(1) Patients receive fully effective starting dose of 75mg  
Source: GEMTESA<sup>®</sup> U.S. FDA label for the treatment of overactive bladder  
Full prescribing information for GEMTESA<sup>®</sup> is available at [www.gemtesa.com](http://www.gemtesa.com)



# GEMTESA®: Product Clinical Highlights

The Phase 3 EMPOWUR study demonstrated GEMTESA®'s favorable clinical profile, highlighting its ability to sustain improved incontinence efficacy while maintaining a favorable safety profile

Mean change from baseline over time in average daily number of urge urinary incontinence episodes<sup>1</sup>



	Baseline Mean	Change from Baseline <sup>2</sup>
<b>GEMTESA® (75 mg)</b>	<b>3.4 (403)</b>	<b>-2.0 (383)</b>
<b>Placebo</b>	<b>3.5 (405)</b>	<b>-1.4 (372)</b>

GEMTESA® was generally well-tolerated with adverse event rates comparable to placebo, including hypertension<sup>3</sup>

Adverse events of special interest <sup>2,3,4</sup>	Placebo (n=540)	GEMTESA® (n=545)	Tolterodine (n=430)
<b>Hypertension</b>	<b>9 (1.7)</b>	<b>9 (1.7)</b>	<b>11 (2.6)</b>
<b>Blood pressure increased</b>	<b>5 (0.9)</b>	<b>4 (0.7)</b>	<b>8 (1.9)</b>
<b>Tachycardia</b>	<b>0</b>	<b>0</b>	<b>1 (0.2)</b>
<b>Hypotension</b>	<b>1 (0.2)</b>	<b>1 (0.2)</b>	<b>1 (0.2)</b>
<b>Dizziness</b>	<b>6 (1.1)</b>	<b>5 (0.9)</b>	<b>4 (0.9)</b>
<b>Urinary tract infection</b>	<b>33 (6.1)</b>	<b>27 (5.0)</b>	<b>25 (5.8)</b>
<b>Urinary retention</b>	<b>2 (0.4)</b>	<b>3 (0.6)</b>	<b>3 (0.7)</b>
<b>Dry mouth</b>	<b>5 (0.9)</b>	<b>9 (1.7)</b>	<b>28 (6.5)</b>
<b>Constipation</b>	<b>7 (1.3)</b>	<b>9 (1.7)</b>	<b>6 (1.4)</b>
<b>Fatigue</b>	<b>5 (0.9)</b>	<b>2 (0.4)</b>	<b>6 (1.4)</b>

(1) GEMTESA® U.S. FDA label for the treatment of overactive bladder

(2) At Week 12

(3) Staskin D, Frankel J, Varano S, et al. Phase 3 EMPOWUR results. The Journal of Urology. Volume 204. Issue 2. August 2020. Page: 316-324

(4) List of adverse events is not exhaustive and is focused on potential cardiovascular and anti-cholinergic effects  
Full prescribing information for GEMTESA® is available at [www.gemtesa.com](http://www.gemtesa.com)


# GEMTESA<sup>®</sup>: Launch Objectives

Urovant to launch GEMTESA<sup>®</sup> in the U.S. market in April 2021



## Brand Vision

Establish GEMTESA<sup>®</sup> as the best in category treatment option for patients suffering from symptoms of OAB

- 
- 1 Anchor Launch Performance Through a Focus in Urology
  - 2 Establish Leadership for OAB in Long-Term Care
  - 3 Broaden uptake in Primary Care for OAB Patients
  - 4 Secure and Maintain Access & Affordability for Patients & HCPs
  - 5 Drive Awareness, Education & Advocacy for OAB Patients

# GEMTESA<sup>®</sup>: Launch Highlights

## Urovant is actively preparing for the upcoming GEMTESA<sup>®</sup> launch

Key elements of GEMTESA<sup>®</sup> commercial strategy include:



Fully-scaled sales force in urology, long-term care (LTC), and high-prescribing primary care physician segments

- **160 Urovant sales representatives** will detail prescribers in these segments



Co-promotion agreement with Sunovion to promote GEMTESA<sup>®</sup> in the broader primary care segment

- **90 Sunovion sales representatives** will promote GEMTESA<sup>®</sup> in this segment

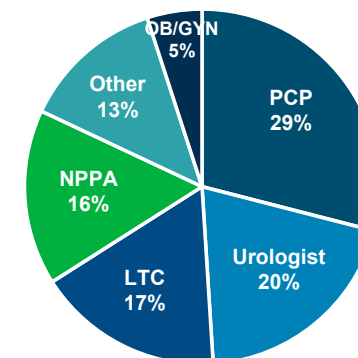


Market access team engaging with payers to ensure rapid and broad access



Activating patients through multi-channel marketing campaign, including the use of digital and social media

OAB Rx 2018 Volume by Specialty<sup>1</sup>



- Urologists, LTC, and high-prescribing PCPs account for **>50%** of all OAB prescriptions
- Urologists prescribe **30%** of all β3 agonists
- Urologists, other specialties, and high prescribing PCPs can be managed with **~100-120** Urovant FTEs, while LTC segment can be managed with **~30-50** FTEs

(1) IQVIA (IMS) NPA data ending December 2018  
Full prescribing information for GEMTESA<sup>®</sup> is available at [www.gemtesa.com](http://www.gemtesa.com)

# Rodatrivat Ethyl

# Rodatrstat Ethyl: Oral Disease Modifier for the Treatment of Pulmonary Arterial Hypertension (PAH)

PAH is a rare disease with a high mortality rate (~50% 5-year mortality rate<sup>1</sup>) and is currently treated with vasodilators, which offer some benefit but fail to address the underlying cause of disease (i.e., vessel remodeling)

**Development Phase:** Phase 2b (ELEVATE 2)

**Modality:** Small molecule (Oral)

- Oral prodrug designed to selectively reduce peripheral serotonin production (with negligible BBB penetration) by inhibiting tryptophan hydroxylase 1 (TPH1), which is responsible for the conversion of tryptophan to serotonin (5-HT)
- In animal models, rodatrstat alone and in combination with ambrisentan showed robust reduction in vessel wall thickness<sup>2</sup>
- Dose-dependent urinary 5-HIAA (serotonin metabolite) suppression supports 300-600 mg BID Phase 2b study dosing, which provides 50% or greater reduction in 5-HIAA (target reduction level)<sup>3</sup>

Rodatrstat Alone and in Combination with Ambrisentan Decreases Pulmonary Vessel Wall Thickness in the SUGEN-Hypoxia Model<sup>2</sup>



Treatment Group	Untreated	SUGEN Hypoxia			
	Vehicle	Vehicle	Rodatrstat Alone	Combo: Rodatrstat + Ambrisentan	Combo: Ambrisentan + Tadalafil
Relative Vessel Wall Thickness	31%*	100%	71%*	59%*	78%*

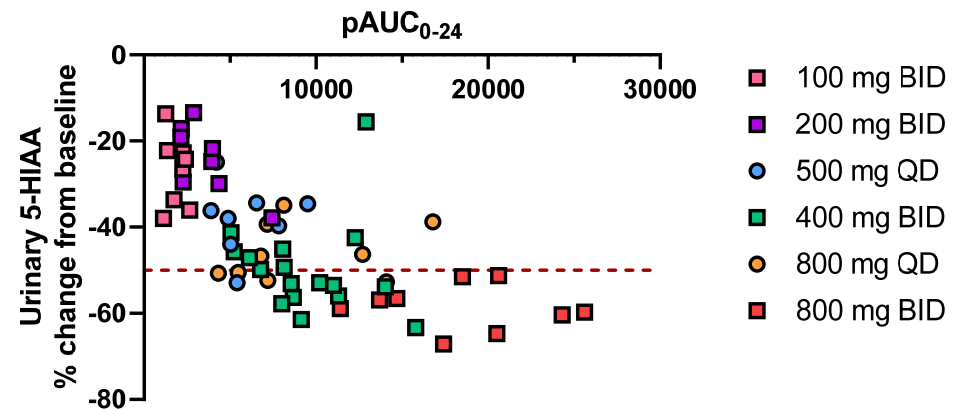
\*  $P < 0.0001$  versus SUGEN Hypoxia, Vehicle Group,  $n = 4-12$  rats per group

(1) Thenappan T., The BMJ; March 2018

(2) Aiello, R.J, Journal of Pharmacology and Experimental Therapeutics 360, 267-279

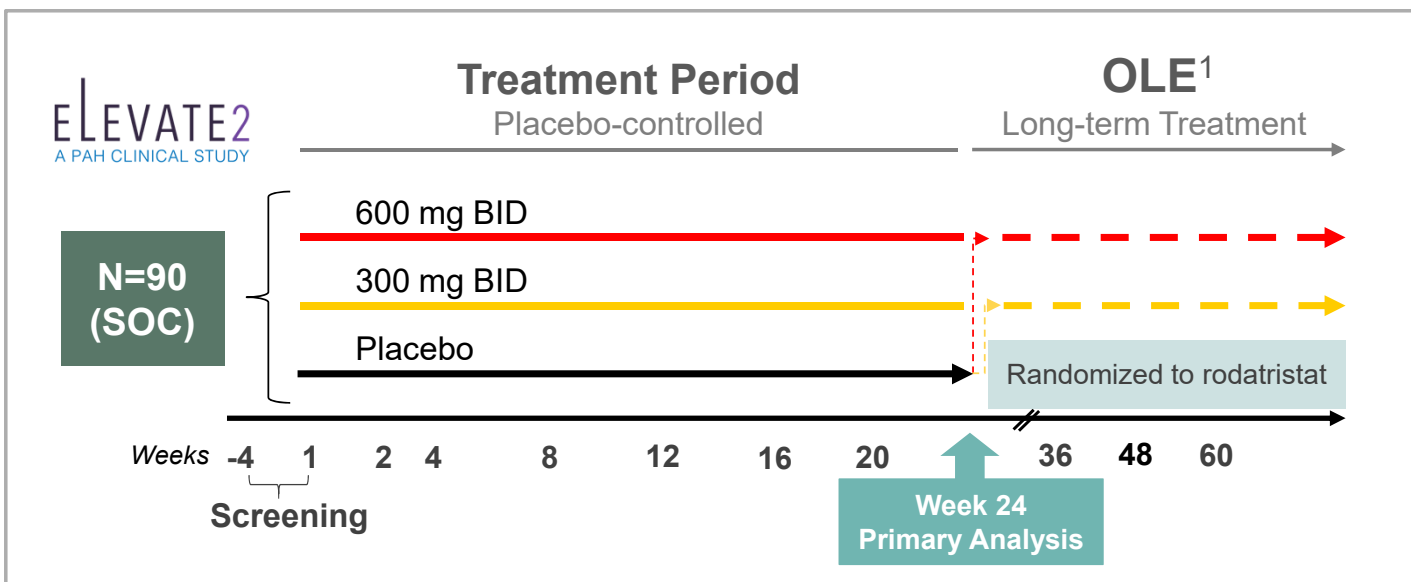
(3) Wring S et al, European Respiratory Society International Congress; Madrid, Spain  
PAH: Pulmonary Arterial Hypertension; BBB: Blood-brain barrier

Rodatrstat Exposure vs. Percentage Change from Baseline of Urine 5-HIAA: Creatinine Ratio on Day 14<sup>3</sup>



# Rodatrstat Ethyl: International Phase 2b Dose-Finding Trial Design

<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• 90 patients with Group 1 PAH, WHO Functional Class II or III on stable treatment (≥ 12 weeks)</li> <li>• Randomization 600 mg BID: 300 mg BID: Placebo = 1:1:1</li> </ul>
<b>Concomitant medication</b>	<ul style="list-style-type: none"> <li>• Standard of care with 1-3 drugs are allowed (prostanoid infusion permitted)</li> </ul>
<b>Treatment duration</b>	<ul style="list-style-type: none"> <li>• 24 weeks</li> </ul>



### Primary Endpoint (at Week 24):

- Pulmonary vascular resistance

### Secondary Endpoints:

- Hemodynamic parameters
- TTCW (Time to Clinical Worsening)
- 6MWD (6-Minute Walking Distance)
- Biomarker levels (NT-proBNP)
- WHO Functional Class
- Right ventricular function (cardiac echo)
- PAH-SYMPACT (PRO) score
- REVEAL 2.0 Lite score
- Plasma & urine 5-HIAA levels

(1) Patients will continue to be blinded to the treatment they received in the Main Study until completion of all analyses of the 24-week treatment period for all patients  
 Source: Clinicaltrials.gov  
 NT-proBNP: N-terminal pro-Brain Natriuretic Peptide; PRO: Patient Reported Outcomes

# Sumitovant Biopharma Pipeline Summary

Sumitovant is poised for significant growth over the coming years, driven by an innovative portfolio of diverse molecules targeting indications with significant unmet patient need



**Vants**



**Launched Products**



**Pipeline Programs**

**11**

Additional pipeline programs across a wide array of modalities



Small Molecules



Regenerative Medicine



Biologics



Gene therapy

# Digital Transformation Update

**Dan Rothman**  
**Chief Information Officer, Sumitovant**  
**Chief Digital Officer, Sumitomo Dainippon Pharma Group**



# Digital Transformation

Apply technology to drive a culture of innovation across the Sumitomo Dainippon Pharma Group



**Drive Behavioral  
Change**



**Develop Internal  
Technology**



**Leverage External  
Technology Providers**



**Transform Approach  
To Technology**

# Coordination, Collaboration, and Digital Transformation

Leveraging new teams to drive collaboration and align on strategic objectives

## Introduce New Teams

DrugOME™



## Digital Innovation



# Coordination, Collaboration, and Digital Transformation

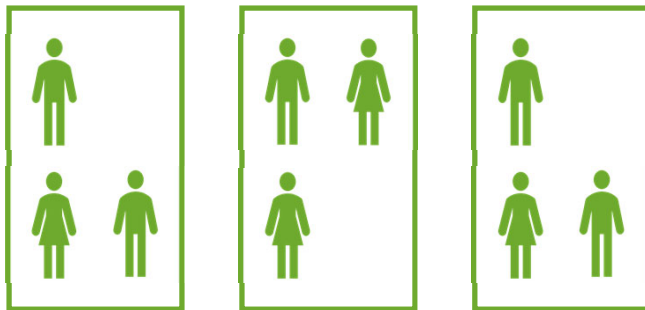
Leveraging new teams to drive collaboration and align on strategic objectives

## Introduce New Teams

DrugOME™



## Digital Innovation



# Coordination, Collaboration, and Digital Transformation

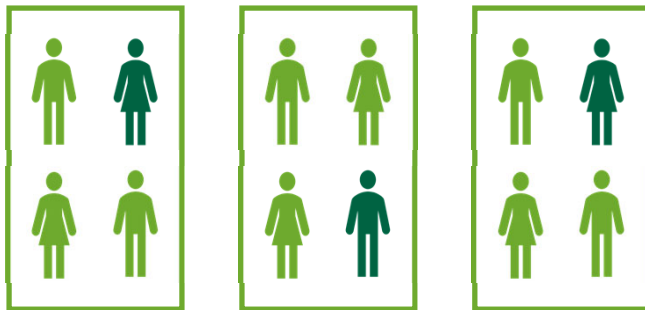
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## Introduce New Teams

DrugOME™



Digital Innovation



# Coordination, Collaboration, and Digital Transformation

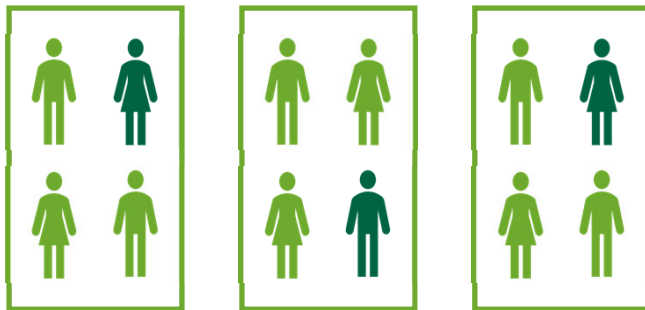
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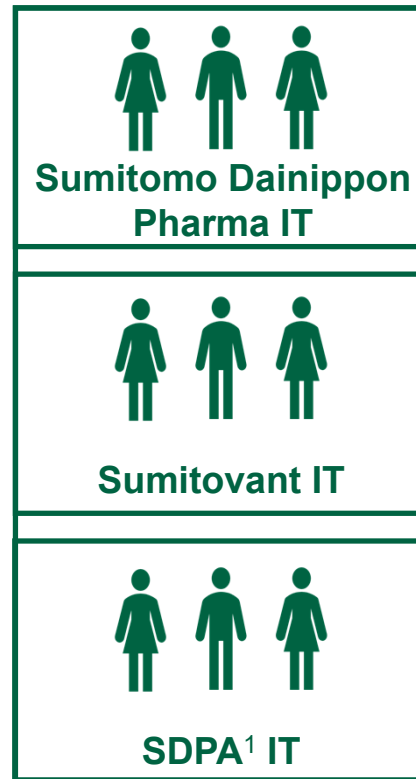
DrugOME™



Digital Innovation



## Drive Connectivity



## Align Objectives



(1)Sumitomo Dainippon Pharma America, Inc.

## Our Group FY2021 Digital Transformation Objectives



**Enhance Core Businesses**



**Increase Value Delivery in Execution**



**Increase revenues across the commercial portfolio**



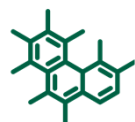
**Improve business operations and processes**



**Bring more drugs to market more rapidly**



**Increase transparency and collaboration across the organization**



**Increase the success of drug discovery programs**



**Technology teams partner with the business to create value**

Data referenced in this presentation is fictitious and randomly generated provided for demonstration purposes

## Our Group FY2021 Digital Transformation Objectives



**Enhance Core Businesses**



**Increase Value Delivery in Execution**



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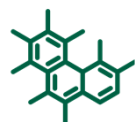
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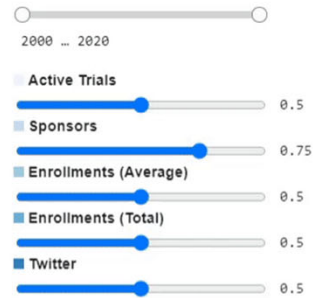
# Increase revenues across the commercial portfolio



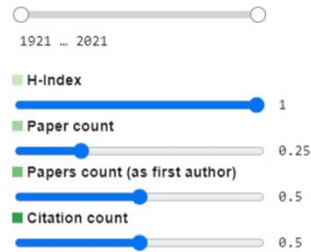
## Optimizing KOL outreach with analytics

### KOL Identification

#### Investigators



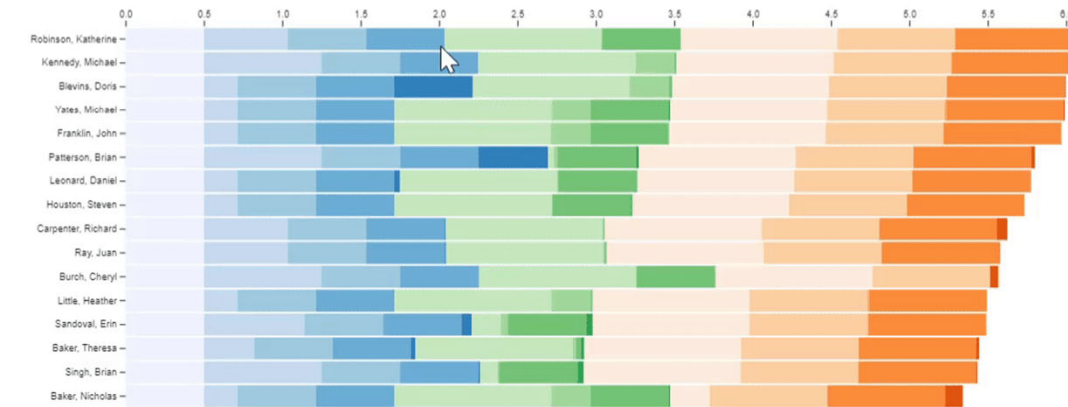
#### Authors



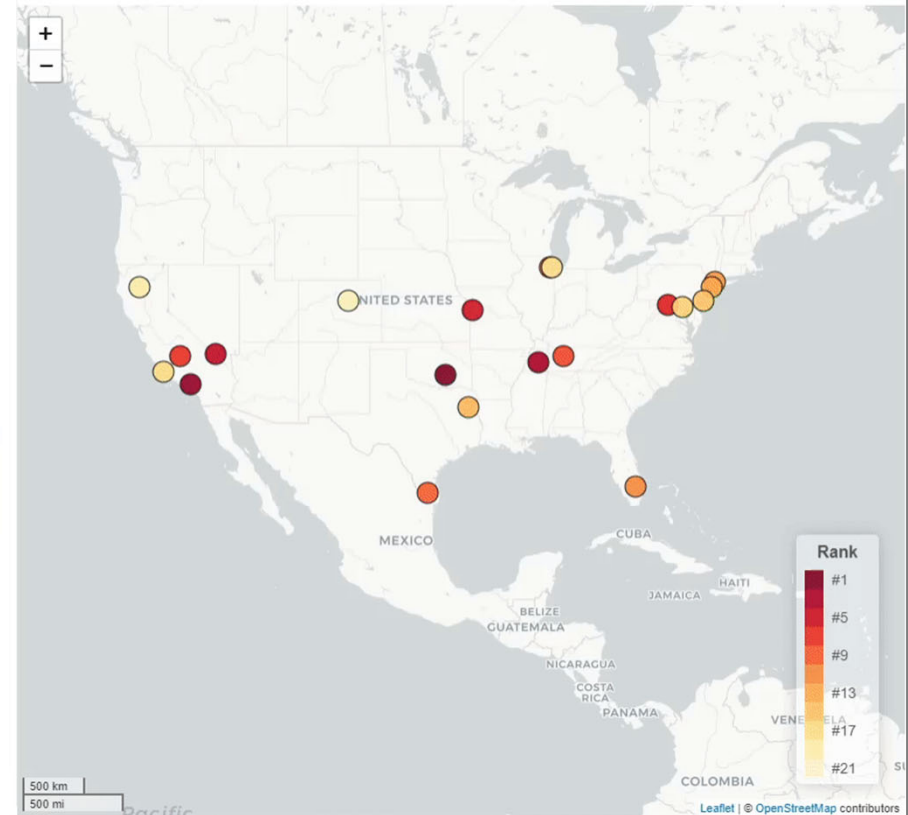
#### Speakers



### Top KOLs by Metric



### Top Ranking KOLs by Location



All data referenced herein is fictitious and randomly generated provided for demonstration purposes. All metrics, including KOL names, have been randomly generated





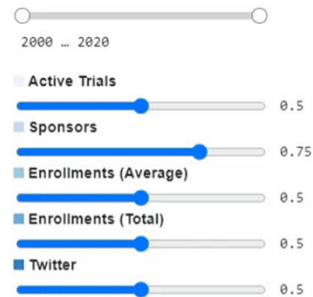
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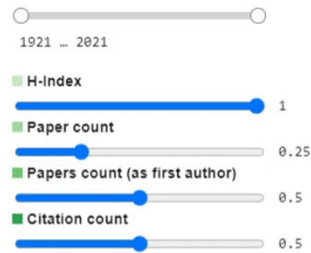
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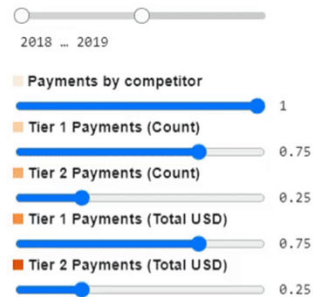
#### Investigators



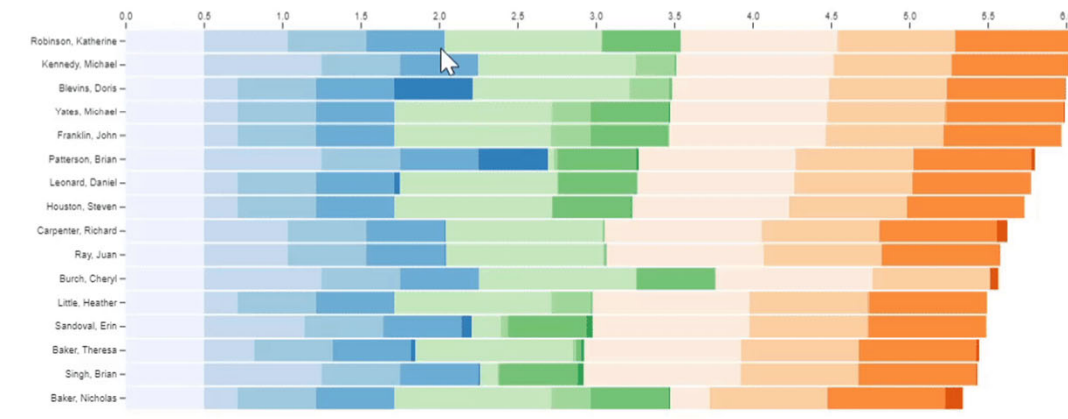
#### Authors



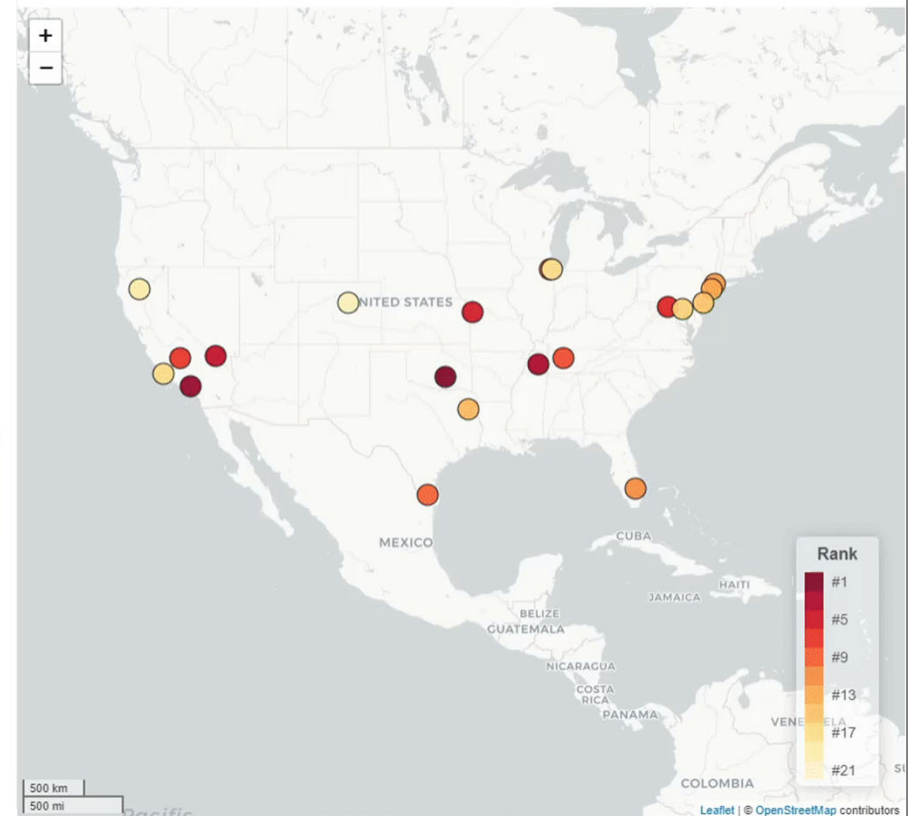
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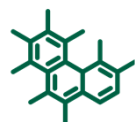
### Enhance Core Businesses



Increase revenues across the commercial portfolio



Bring more drugs to market more rapidly



Increase the success of drug discovery programs



### Increase Value Delivery in Execution



Improve business operations and processes



Increase transparency and collaboration across the organization



Technology teams partner with the business to create value

## Our Group FY2021 Digital Transformation Objectives



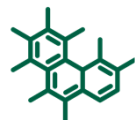
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## Cataloguing abnormal animal behavior using machine learning

**Agile Summary Viewer**

JSONファイルの選択: T:\DSPrecognition\output\sample.mp4\_result 参照... 読み開始 (ファイル形式は「json」に対応しています)

■異常行動の有無:

■異常行動の種類

forelimb_tremor	<input checked="" type="checkbox"/>
head_shaking	<input checked="" type="checkbox"/>

■異常行動の種類を確認された時間

00:00:01.301	forelimb_tremor	表示
00:00:01.335	head_shaking	表示
00:00:02.069	forelimb_tremor	表示
00:00:02.102	forelimb_tremor	表示

Video only



Bring more drugs to market  
more rapidly



## Cataloguing abnormal animal behavior using machine learning

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00:00:02.069	forelimb_tremor	表示
00:00:02.102	forelimb_tremor	表示

Video only

## Our Group FY2021 Digital Transformation Objectives



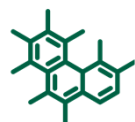
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**Bring more drugs to market more rapidly**



**Increase the success of drug discovery programs**



### Increase Value Delivery in Execution



**Improve business operations and processes**



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## Our Group FY2021 Digital Transformation Objectives



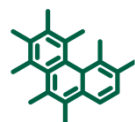
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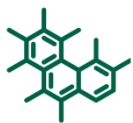
**Improve business operations and processes**



**Increase transparency and collaboration across the organization**



**Technology teams partner with the business to create value**



## Accelerating drug target identification using an integrated platform to distill and aggregate relevant data

Change Role Current Role: Discovery Author History

### Target Articles

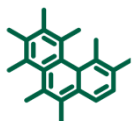
#### Articles

Gene Name	UniprotID	Article Title	Published Date	Source	Open
AKT1	P31749	<a href="#">Capiwasertib, an AKT Kinase Inhibitor, as Monotherapy or in Combination with Fulvestrant in Patients with AKT1 (E17K)-Mutant, ER-Positive Metastatic Breast Cancer.</a>	7/28/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">CircRNA_09505 aggravates inflammation and joint damage in collagen-induced arthritis mice via miR-6089/AKT1/NF-kappaB axis.</a>	6/21/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">A mutation analysis of the EGFR pathway genes, RAS, EGFR, PIK3CA, AKT1 and BRAF, and TP53 gene in thymic carcinoma and thymoma type A/B3.</a>	6/19/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">No Association Between AKT1 Polymorphisms and Methamphetamine Addiction in Iranian Population.</a>	5/31/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">Analysis of variants of AKT1 in schizophrenia multiplex families.</a>	5/26/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">High-intensity muscle contraction-mediated increases in Akt1 and Akt2 phosphorylation do not contribute to mTORC1 activation and muscle protein synthesis.</a>	4/30/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">A Biodegradable Mg-Based Alloy Inhibited the Inflammatory Response of THP-1 Cell-Derived Macrophages Through the TRPM7-PI3K-AKT1 Signaling Axis.</a>	4/22/2020	Trend_Analysis	Explore
AKT1	P31749	<a href="#">Juvenile papillomatosis of the breast (Swiss cheese disease) has frequent associations with PIK3CA and/or AKT1 mutations.</a>	3/27/2020	Trend_Analysis	Explore

Rows per page: 10 1-10 of 10

Reference to AKT1 and articles are included for demonstration purposes only





Increase the success of drug discovery programs



## Accelerating drug target identification using an integrated platform to distill and aggregate relevant data

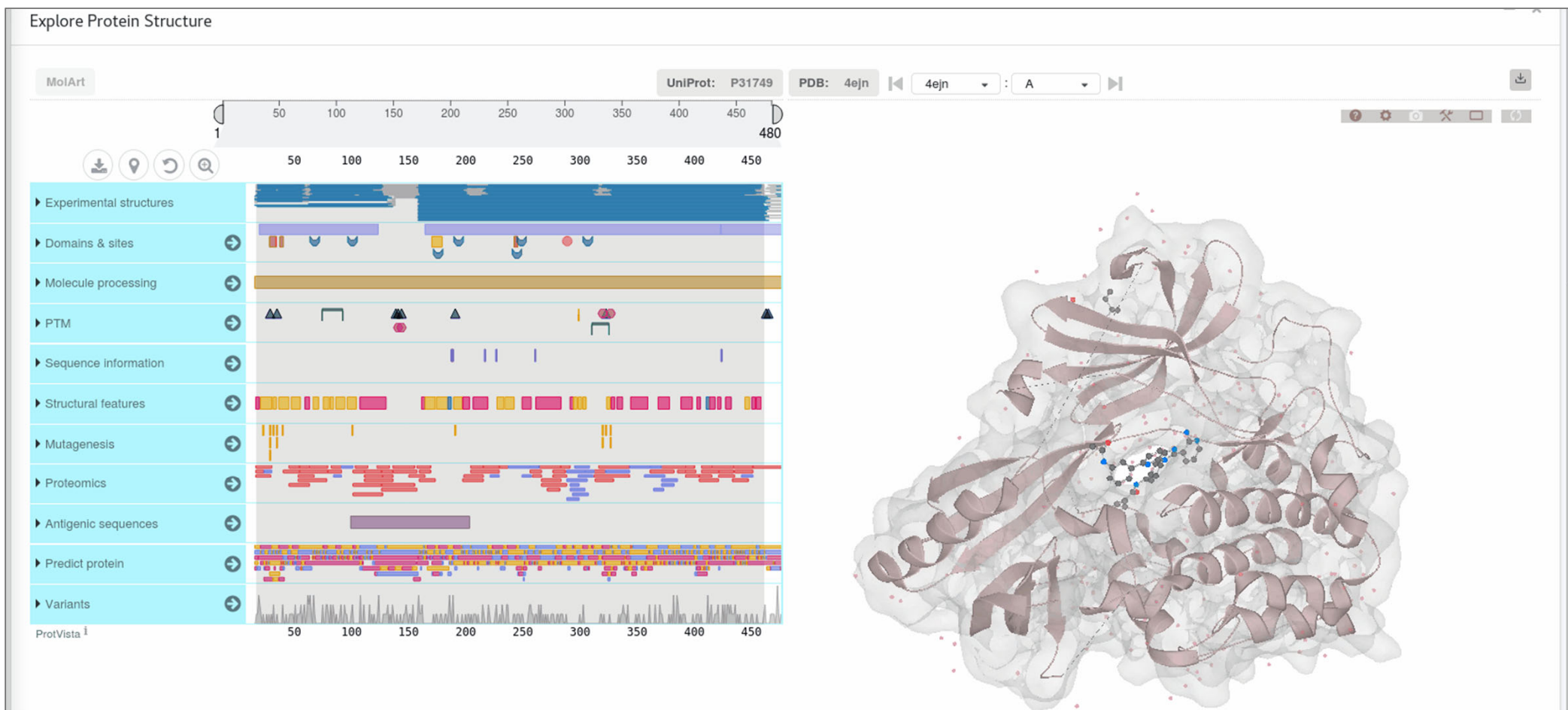
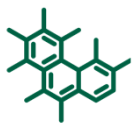


Image of AKT1 is provided for demonstration purposes only



# Increase the success of drug discovery programs



## Accelerating drug target identification by integrated platform to distill and aggregate relevant data


Rich text editor toolbar with options: Bold (B), Underline (U), Cantarell font, Background color, Bulleted list, Numbered list, Table, Link, Image, Video, Unlink, Source code, Help.

Post Comment

No comments yet


Show Comments

### Cancer Score




Change Score:

### DE Score



Change Score:

### Developmental Stage Score



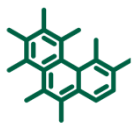
Change Score:

Submit

SDPO, Target explorer © 2021

Version D1.0.2.11

All scores shown herein are randomly generated for demonstration purposes only



## Accelerating drug target identification by integrated platform to distill and aggregate relevant data


Rich text editor toolbar with options: Bold (B), Underline (U), Cantarell font, Background color, Bulleted list, Numbered list, Table, Link, Image, Video, Unlink, Source code, Help.

Post Comment

No comments yet


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Change Score:

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Change Score:

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SDPO, Target explorer © 2021

Version D1.0.2.11

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## Our Group FY2021 Digital Transformation Objectives



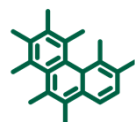
### Enhance Core Businesses



Increase revenues across the commercial portfolio



Bring more drugs to market more rapidly



Increase the success of drug discovery programs



### Increase Value Delivery in Execution



Improve business operations and processes



Increase transparency and collaboration across the organization



Technology teams partner with the business to create value

## Our Group FY2021 Digital Transformation Objectives



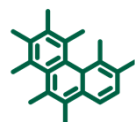
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# Improve business operations and processes

## Improving collaboration through agile practices

The screenshot shows a Kanban board interface with the following structure:

- Header:** "Planner および To Do に" with navigation icons on the right.
- Navigation:** "バックでグループ化", "フィルター", "リスト", "ボード" (selected), "グラフ", "スケジュール".
- Columns:**
  - Backlog:** Contains a "+ タスクを追加" button and five task cards: "A-5: リクルート", "A-6: 研修実施", "Story C: データドリブン講座", "Story D: ストーリーテリング講座", "Story E: OKRブラッシュアップ".
  - 直近タスク:** Contains a "+ タスクを追加" button and six task cards: "A-1: 情報収集", "A-2: 大日程作成", "A-3: コンテンツ作成", "A-4: コンテンツレビュー", "Story A: デザイン思考研修" (with sub-tasks: 情報収集, 大日程作成, コンテンツ作成, コンテンツレビュー, リクルート, 研修実施), "Story B: アジャイル展開". A "0/6" indicator is at the bottom.
  - 実施中:** Contains a "+ タスクを追加" button.
  - 停滞中:** Contains a "+ タスクを追加" button.
  - 完了:** Contains a "+ タスクを追加" button.



# Improve business operations and processes

## Improving collaboration through agile practices

The screenshot shows a Kanban board interface with the following elements:

- Header:** "Planner および To Do に" with search, refresh, and other icons.
- Navigation:** "バックでグループ化", "フィルター", "リスト", "ボード" (selected), "グラフ", "スケジュール".
- Columns:**
  - Backlog:** Contains 5 tasks: "A-5: リクルート", "A-6: 研修実施", "Story C: データドリブン講座", "Story D: ストーリーテリング講座", "Story E: OKRブラッシュアップ".
  - 直近タスク:** Contains 5 tasks: "A-1: 情報収集", "A-2: 大日程作成", "A-3: コンテンツ作成", "A-4: コンテンツレビュー", "Story A: デザイン思考研修". Below these is a sub-list: "情報収集", "大日程作成", "コンテンツ作成", "コンテンツレビュー", "リクルート", "研修実施", "0/6", and "Story B: アジャイル展開".
  - 実施中:** Empty.
  - 停滞中:** Empty.
  - 完了:** Empty.

# Our Group FY2021 Digital Transformation Objectives



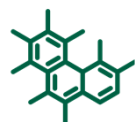
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Increase the success of drug discovery programs



## Increase Value Delivery in Execution



Improve business operations and processes



Increase transparency and collaboration across the organization



Technology teams partner with the business to create value



# Our Group FY2021 Digital Transformation Objectives



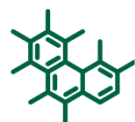
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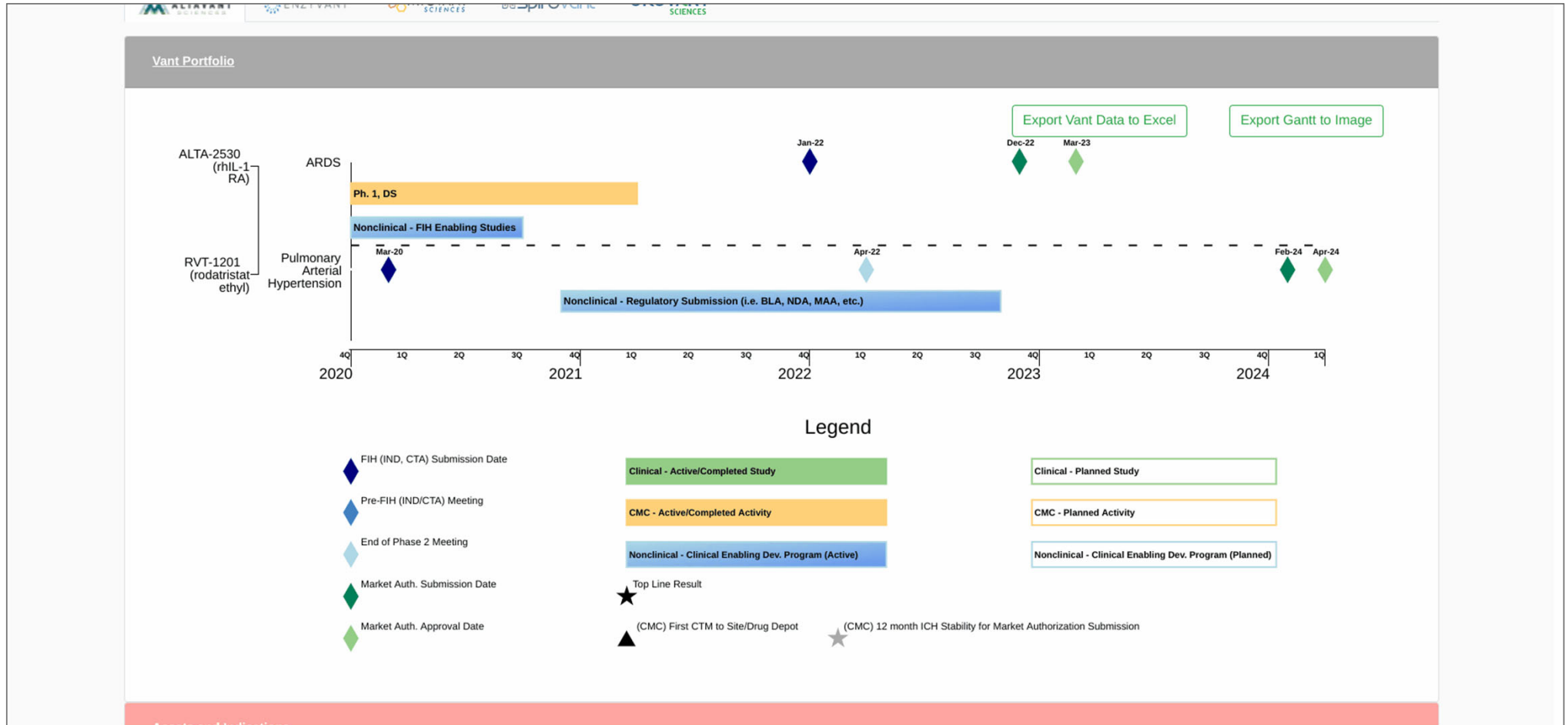
Technology teams partner with the business to create value



# Increase transparency and collaboration across the organization



## Leveraging automation to create transparency



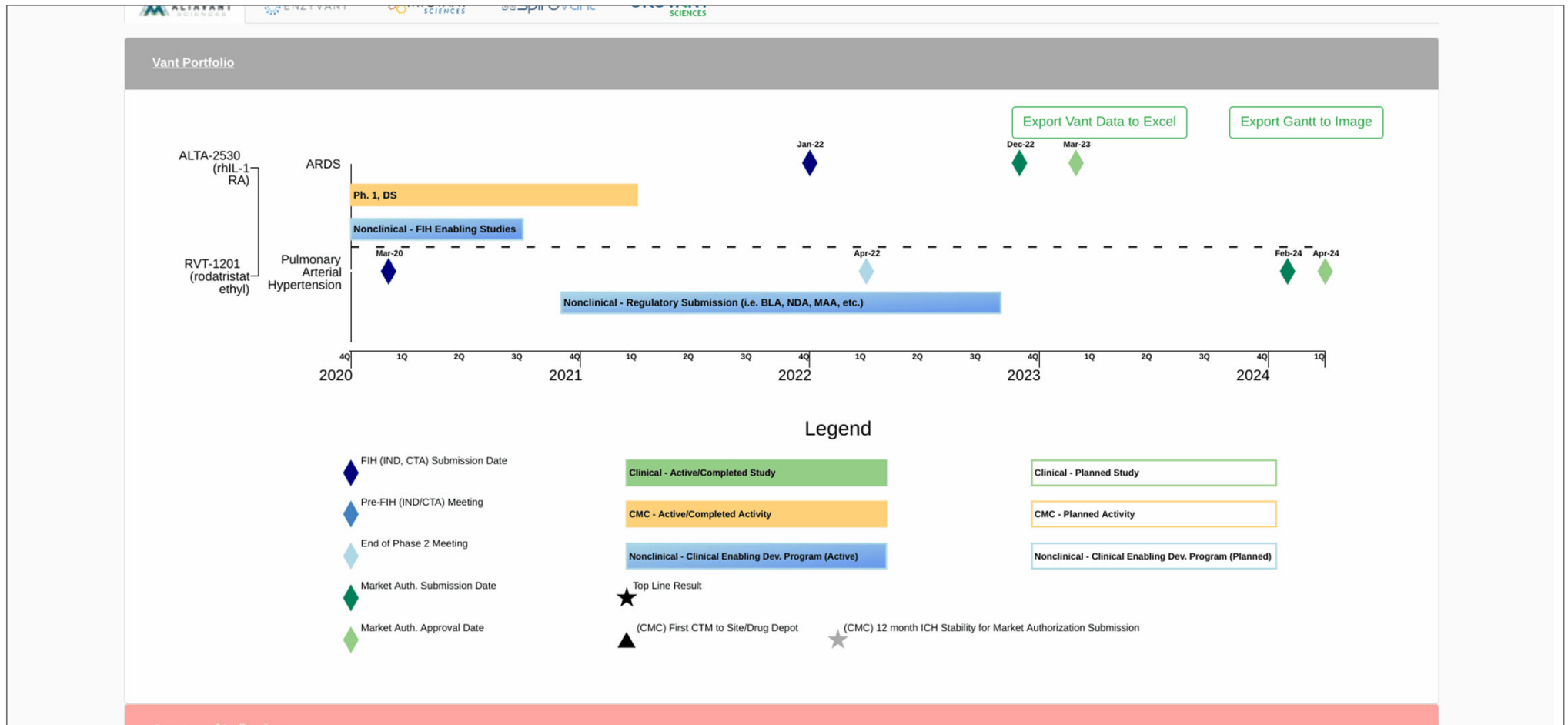
Dates, timeline and all other data is randomly generated for demonstration purposes only



# Increase transparency and collaboration across the organization



## Leveraging automation to create transparency



Dates, timeline and all other data is randomly generated for demonstration purposes only

## Our Group FY2021 Digital Transformation Objectives



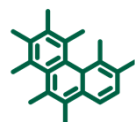
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**Increase revenues across the commercial portfolio**



**Bring more drugs to market more rapidly**



**Increase the success of drug discovery programs**



### Increase Value Delivery in Execution



**Improve business operations and processes**



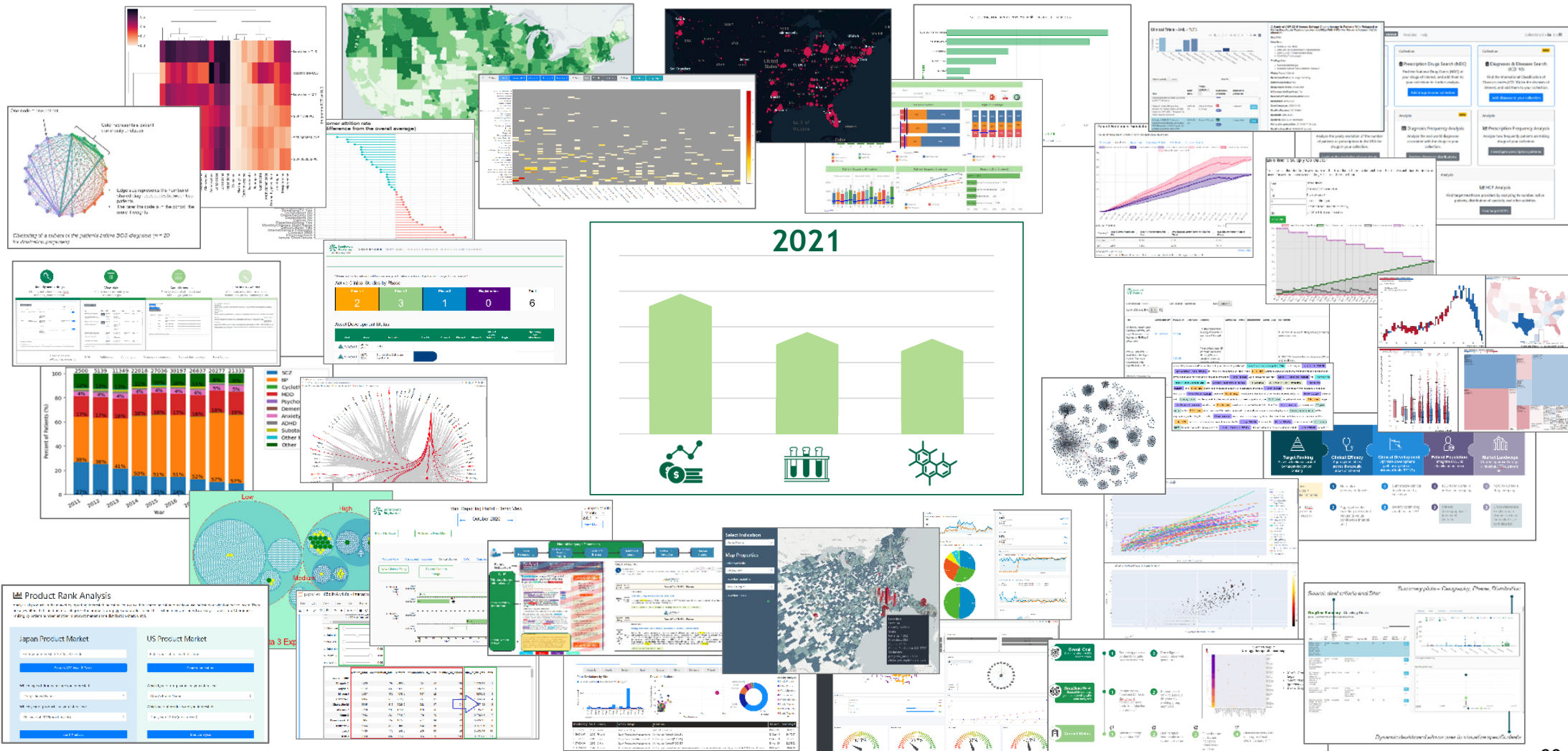
**Increase transparency and collaboration across the organization**



**Technology teams partner with the business to create value**

# Digital Transformation Update

## Our Digital Transformation is Just Beginning



Screenshots provided for demonstration purposes only

# The DrugOME

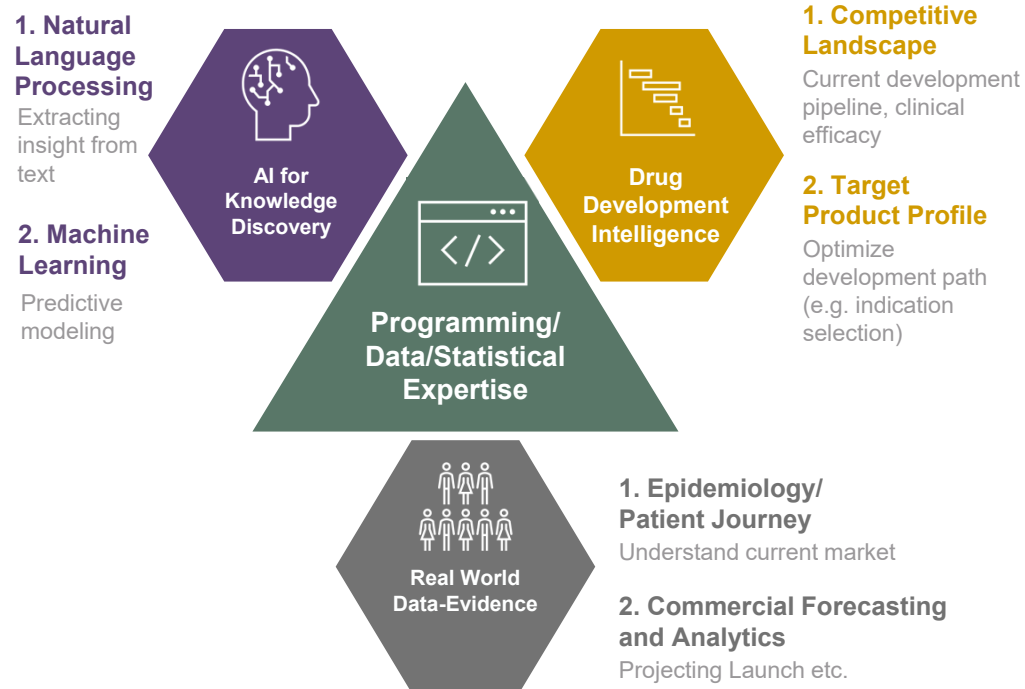
**Bill McMahon**  
**Chief Algorithmic Analytics Officer, Sumitovant**

# The DrugOME is...

A computational ecosystem  
to enable fast, high quality answers  
to strategic pharma questions

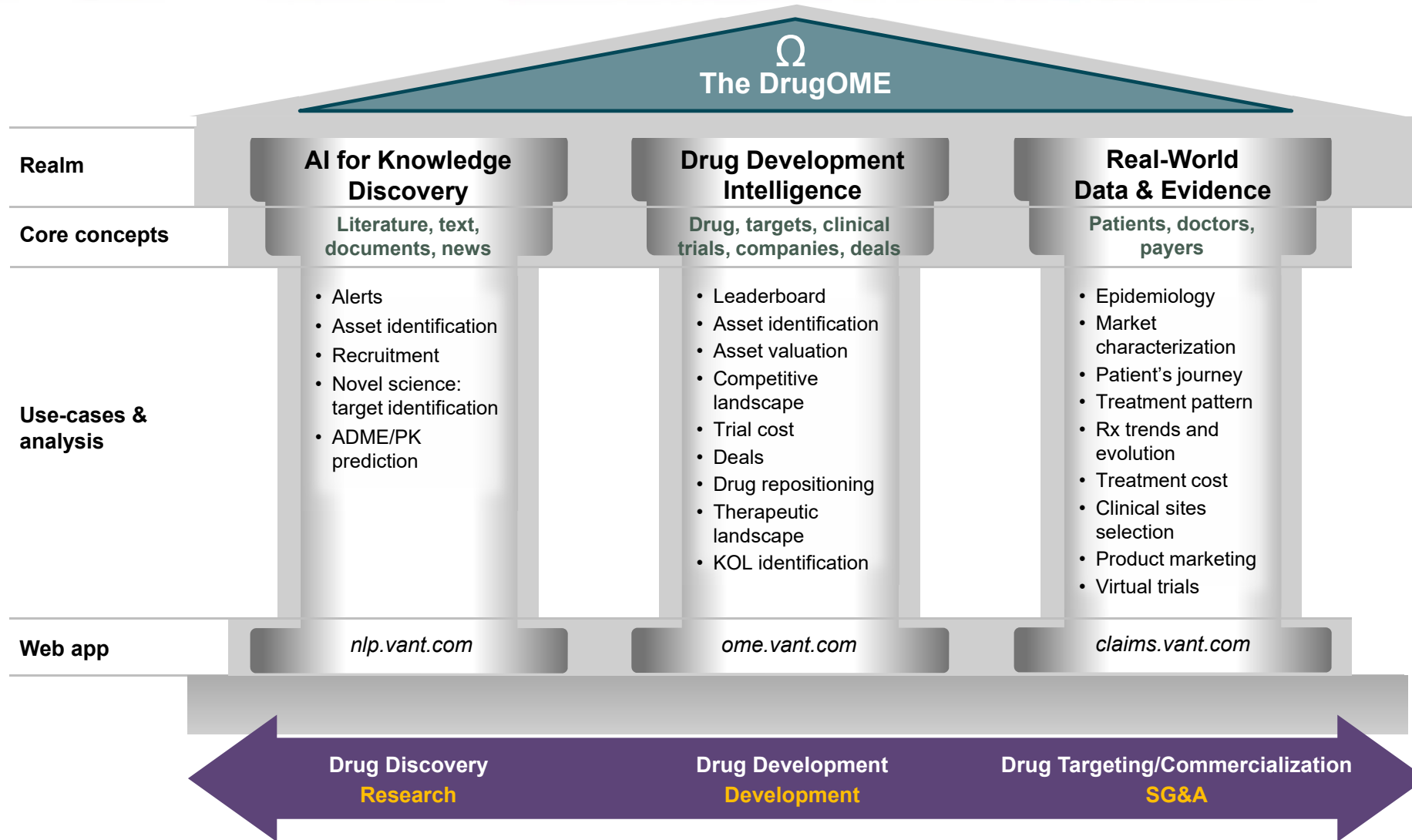
# The DrugOME Ecosystem

## Personnel



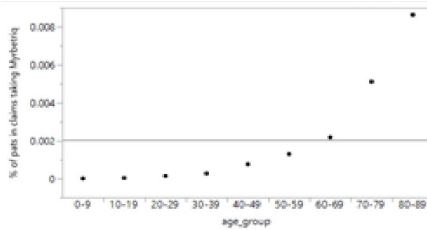


# Overview of DrugOME Capabilities



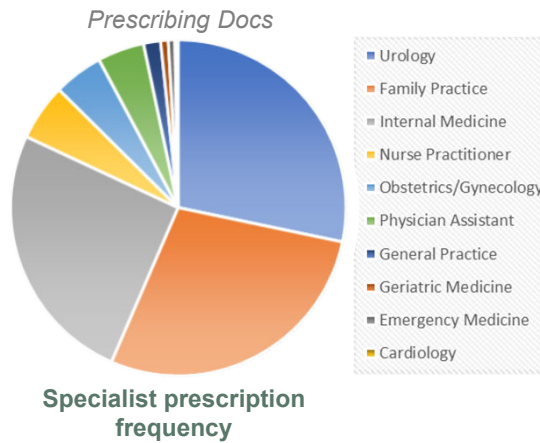
## Using Claims to test potential value of drugs given different clinical development pathways

### Geriatricity of competitor drug



### Persistence of patients vs dose

Drugs Taken	Unique Patients
Total Patients	29664
High Dose	16529
Low Dose	15106
Both Doses	1971
Only Low Dose	13135
Only High Dose	14558



## Generating metrics for clinical competitive intensity



## Using NLP on top of the scientific literature to explore Drug-Target relationships



Press Releases, Abstracts,...

### Natural Language Processing

Text extraction & entity tagging

Drug-target relationship extraction

List of drugs that hit Target

# DrugOME RWD Analyses within Sumitomo Dainippon Pharma Group

In FY2020, the DrugOME RWD team has performed hundreds of RWD analyses for...

- Clinical strategy
- Commercial forecasting
- Commercial strategy
- Business Development

Our HEOR partnerships have already resulted in...

- 1 accepted Publication, 2 submitted, multiple in progress

## Differences in change of exacerbations occurrences and frequencies before and after treatment initiation comparing nebulized Glycopyrrolate to other LAMA

J. Wang et al. "Exacerbations in Patients with Chronic Obstructive Pulmonary Disease Treated with Nebulized Glycopyrrolate versus Other Long-acting Muscarinic Antagonists: A U.S. Healthcare Administrative Database Analysis" submitted to ATS 2021

## Sensitivity analysis: Number of Health Care Resource Utilization visits in the baseline and treatment periods

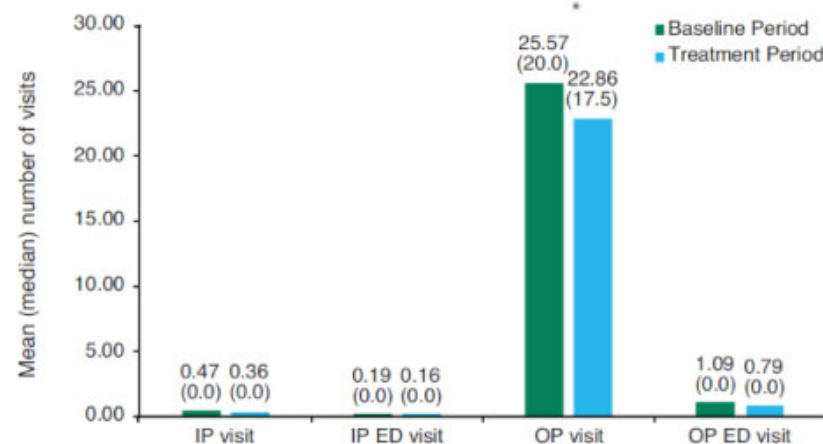
G. R. Williams et al. "Healthcare Resource Utilization Among Patients with Focal Seizure Initiating Eslicarbazepine Acetate after Historical Use of Widely Used First- or Second-Generation Antiseizure Drugs" AES 2020

Primary analysis: Nebulized GLY vs. other LAMA 1:1 PS matched								
Measure		Nebulized GLY (N=61)			Other LAMA (N=61)			DID <sup>a</sup> (95% CI)
		Pre-index	Post-index	Change <sup>b</sup>	Pre-index	Post-index	Change	
Proportion of patients (Count, %)	Moderate Exacerbation <sup>c</sup>	33 (54.1%)	24 (39.3%)	-9 (-14.8%)	27 (44.3%)	21 (34.4%)	-6 (-9.8%)	-4.9% (-28.1%, 18.2%)
	Severe Exacerbation <sup>c</sup>	10 (16.4%)	4 (6.6%)	-6 (-9.8%)	5 (8.2%)	4 (6.6%)	-1 (-1.6%)	-8.2% (-21.3%, 4.9%)
Number of exacerbation (Mean, SD)	Moderate Exacerbation	0.85 (0.96)	0.62 (0.97)	-0.23 (1.02)	0.61 (0.78)	0.57 (0.96)	-0.03 (1.06)	-0.20 (-0.57, 0.17)
	Severe Exacerbation	0.16 (0.37)	0.07 (0.25)	-0.10 (0.40)	0.10 (0.35)	0.08 (0.33)	-0.02 (0.34)	-0.08 (-0.21, 0.05)

Sub-group analysis: Nebulized GLY vs. Tiotropium Respiat <sup>®</sup> 1:1 PS matched								
Measure		Nebulized GLY (N=60)			Tiotropium Respiat <sup>®</sup> (N=60)			DID (95% CI)
		Pre-index	Post-index	Change	Pre-index	Post-index	Change	
Proportion of patients (Count, %)	Moderate Exacerbations	32 (53.3%)	23 (38.3%)	-9 (-15.0%)	24 (40.0%)	27 (36.7%)	-2 (-3.3%)	-11.7% (-33.4%, 10.1%)
	Severe Exacerbations	9 (15.0%)	4 (6.7%)	-5 (-8.3%)	9 (15.0%)	5 (8.3%)	-4 (-6.7%)	-1.7% (-15.7%, 12.4%)
Number of exacerbation (Mean, SD)	Moderate Exacerbations	0.85 (0.97)	0.62 (0.98)	-0.23 (1.03)	0.68 (0.98)	0.58 (0.91)	-0.10 (0.84)	-0.13 (-0.47, 0.2)
	Severe Exacerbations	0.15 (0.36)	0.07 (0.25)	-0.08 (0.38)	0.17 (0.42)	0.08 (0.28)	-0.08 (0.46)	0 (-0.15, 0.15)

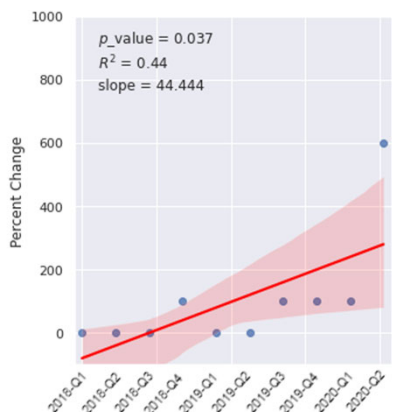
<sup>a</sup>Severe exacerbations were defined as an IP admission with a COPD dx code in the primary position.  
<sup>b</sup>Moderate exacerbations were defined as either an ER visit with a COPD dx in the primary position or an office visit with a COPD dx code in any position plus a pharmacy claim for OCS or antibiotic within 7 days of the office visit. Exacerbations occurring within 14 days of each other was considered a single exacerbation episode and classified according to the highest severity contributing event.  
<sup>c</sup>Change = Post-index measure - Pre-index measure  
<sup>d</sup>DID = Change in GLY cohort - Change in LAMA cohort  
 Abbreviations: GLY, glycopyrrolate; LAMA, long-acting muscarinic antagonist; PS, propensity score; DID, difference in difference; CI, confidence interval; SD, standard deviation.



<sup>a</sup>P < 0.05  
 ED, emergency department; IP, inpatient; OP, outpatient.

# DrugOME-SDPO Collaboration: Oncology Target Search

The DrugOME is bringing an expanded set of data to target viability assessment in the oncology setting to SDPO<sup>1</sup> researchers



Article metadata highlights contextual importance of an article

Journal h-index: 199    Citation velocity: NA    Target #: 10  
 Affiliation type: University    Publication type: Journal Article    Cancer #: 7

**CircZNF609** promotes breast cancer cell growth, migration, and invasion by elevating p70S6K1 via sponging miR-145-5p.

Background: Accumulating evidence suggests that circular RNAs (circRNAs) play critical roles in carcinomas. However, the contributions of circRNAs to breast cancer remain unclear. Herein, we determined the role of circZNF609 in breast cancer. Methods: A total of 143 breast cancer and 38 normal tissues were collected to assess the expression of circZNF609 and its relationship with breast cancer prognosis. A series of in vitro and in vivo functional experiments were carried out to elucidate the role of circZNF609 in breast cancer progression and its underlying molecular mechanisms. Results: CircZNF609 was markedly over-expressed in breast cancer tissues and cell lines, and high circZNF609 expression was closely associated with poor outcome. Silencing of circZNF609 inhibited the malignant phenotype of breast cancer in vitro and in vivo. Mechanistically, circ-ZNF609 served as a sponge of miR-145-5p to elevate p70S6K1 expression. Moreover, miR-145-5p overexpression or p70S6K1 knockdown abrogated the oncogenic effects of circZNF609 in breast cancer. In addition, clinically, a strong negative correlation was observed between the expression of circZNF609 and miR-145-5p in breast cancer tissues ( $r = -0.597, P < 0.001$ ), whereas a positive correlation between circZNF609 and p70S6K1 expression ( $r = 0.319, P < 0.001$ ). Conclusion: These data suggest that circZNF609 contributes to breast cancer progression, at least partly, by modulating the miR-145-5p/p70S6K1 axis, and it may be a potential therapeutic target for breast cancer.

Color Codes:

- Targets
- Cancer terms
- Down regulation
- Over expression
- Therapeutic target
- Biomarker

- Developed gene target ranking scores in oncology in close collaboration with SDPO researchers incorporating scientific, epidemiological, and competitive intelligence data

Gene	target score (0-5)
Gene1	5
Gene2	4
Gene3	3
Gene4	2
Gene5	2
Gene6	2
Gene7	2
Gene8	2
Gene9	2
Gene10	1.5
Gene11	1.5

Improved drug target selection quality and efficiency



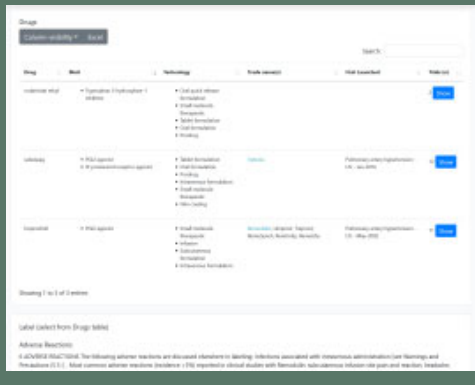
Top target selected and added to SDPO's drug development pipeline

(1) Sumitomo Dainippon Pharma Oncology, Inc.  
 All data shown in this presentation are for illustrative purposes only



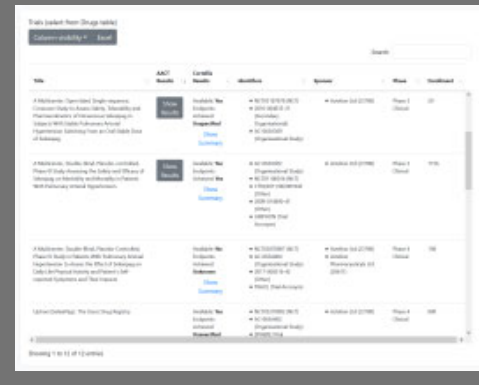
## Identify comp. drugs

Filter by indication / phase, MoA, company, route of admin



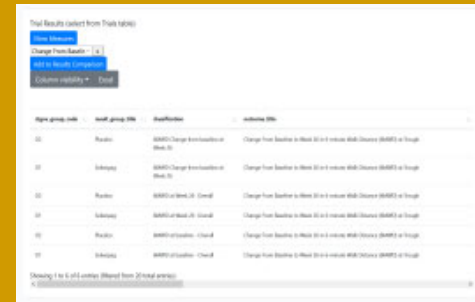
## View trials

Check results availability across data sources



## Compile results

Filter by endpoint of interest and add to aggregate table



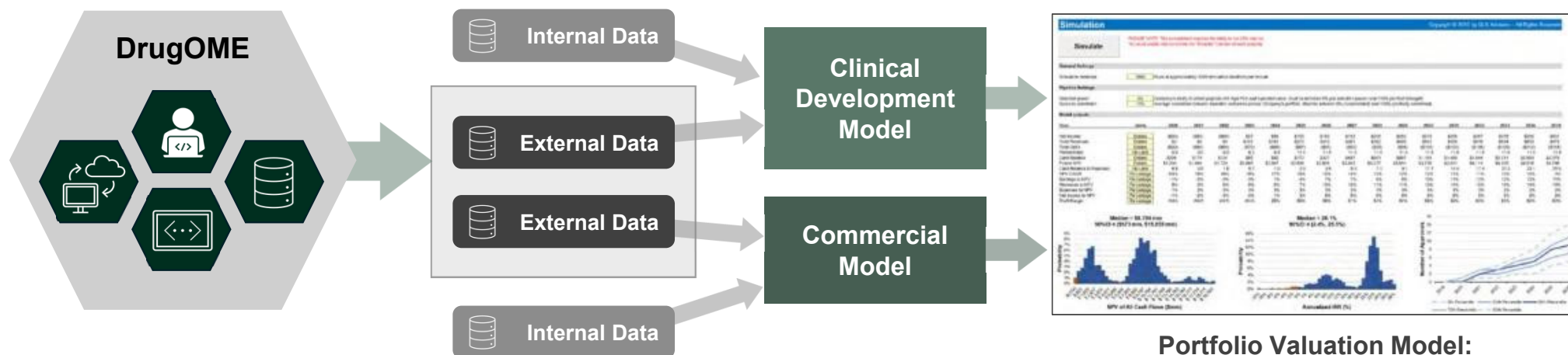
## Link to PR / Journal

When data unavailable in structure format, provide text summary + link



*Used to substantially reduce curation time in analyses for multiple indications of strategic significance just in the past several months*

# DrugOME Role in Maximizing Portfolio Value



**Portfolio Valuation Model:**  
Portfolio modeling must play a central role in strategic decision-making

- We are working in partnership with Clinical Development, Finance, Commercial, and Digital Innovators<sup>1</sup> to combine their internal data and data pipelines with DrugOME data sources and drug valuation algorithms into a holistic Sumitovant Drug Portfolio Valuation Model
- This guarantees alignment of the strategic decision-making of Sumitomo Dainippon Pharma Group with long-term generation of value, optimizing the value of Digital Transformation

(1) Dedicated Engineers  
All data shown in this presentation are for illustrative purposes only

# **Expectations for Sumitovant and Synergies in R&D**

**Toru Kimura**  
**Member, Board of Directors**  
**Senior Executive Officer, CSO**

## Aspirations of the Company

Aspire to establish a position as a “Global Specialized Player” in 2033 with ability to meet increasingly diversified needs for healthcare

### Global Specialized Player

#### Pharmaceuticals + Solutions

Medicine /  
Cell Therapy



Healthcare Solution  
(Frontier business)

#### Global leader in 3 areas

Psychiatry &  
Neurology

Oncology

Regenerative  
Medicine /  
Cell Therapy

Best in class focused on value



## Major Events in FY2020

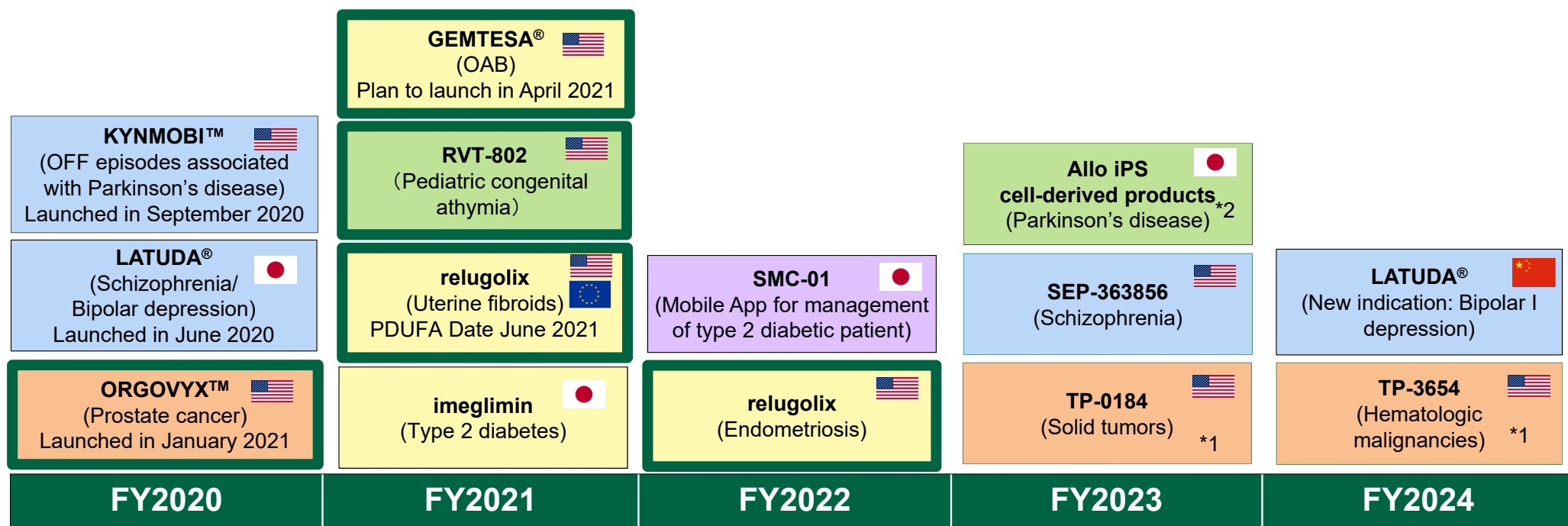
- **Sumitovant** **Successful clinical development of relugolix and vibegron**  
**Progress of new programs such as RVT-802**
- **Psychiatry & Neurology area** Started late clinical development of SEP-363856 and SEP-4199  
Created 7 new development candidate compounds in FY2020  
(IND-enabling studies in preparation; Some of which expected to be “Block-Busters”)
- **Oncology area** Did not meet the primary endpoint of napabucasin CanStem 303C study
- **Regenerative Medicine/Cell Therapy field** Transplanted our manufactured cells at investigator-initiated clinical study of Parkinson’s disease and clinical research of retinitis pigmentosa  
RVT-802 (Pediatric Congenital Athymia) is about to be re-submitted to the FDA
- **Frontier business** Started joint development of SMC-01 (mobile App for management of type 2 diabetic patient)  
Seeking of various opportunities expecting synergies with our pharmaceutical business

**On-going active use of Sumitovant model for further advance of each pipeline**

## Expectations for Sumitovant and Synergies in R&D



# Product Launch Target (as of March 23, 2021)

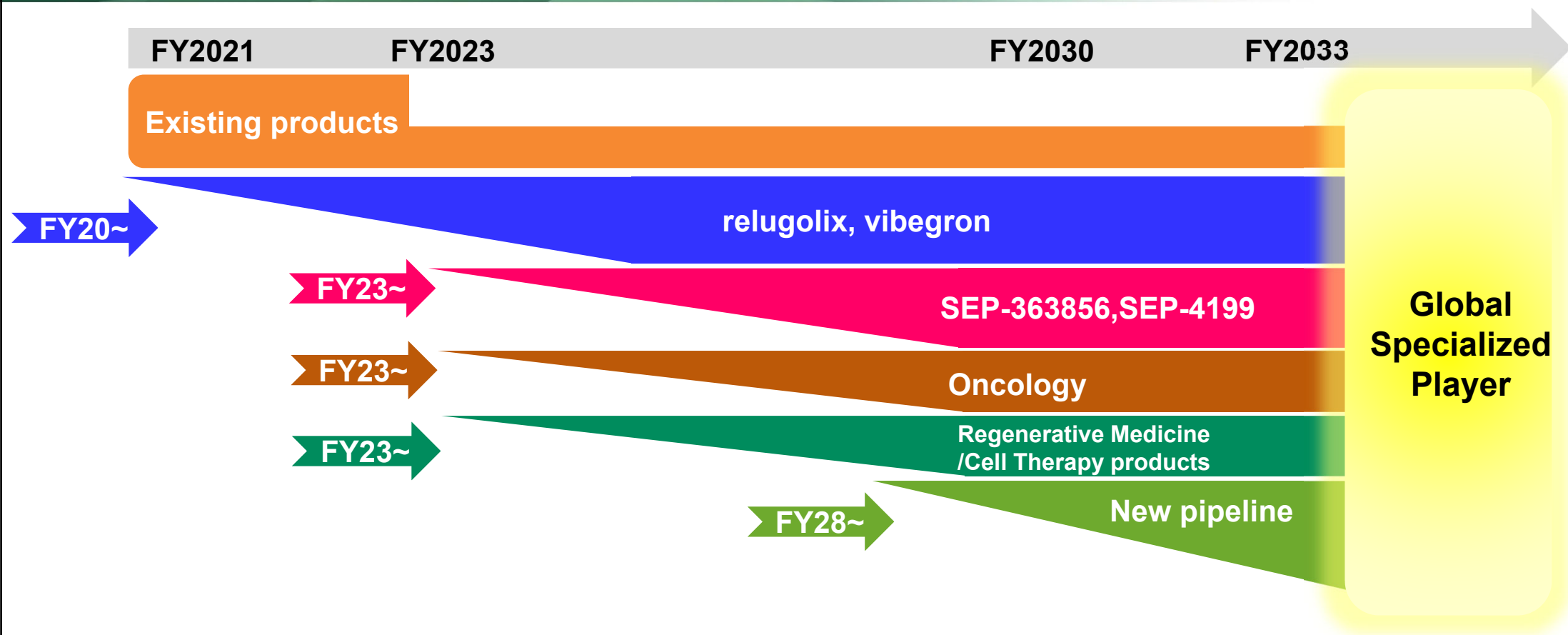


- : Psychiatry & Neurology
- : Oncology
- : Regenerative medicine / cell therapy
- : Others
- : Frontier business
- : Sumitovant's product

\*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

\*2 Launch schedule is based on our goal pending agreement with partners

## R&D Strategic Synergies



Sumitovant products will be main source of revenue for the next 10 years including R&D expense  
→ In the meantime, development and launch of products for Post-Latuda will be progressing  
→ Contributing to health care as a “Global Specialized Player” after 2033

## Base of Research and Development

### Sumitovant R&D

- Flexible system for each project regardless of disease area or location
- Active use of digital technology for asset exploration and clinical trial

Myovant Sciences (U.S.)  
(Women's health and prostate cancer)

Urovant Sciences (U.S.)  
(Urological disease)

Enzyvant Therapeutics (U.S.)  
(Pediatric rare disease)

Spirovant Sciences (U.S.)  
(Cystic fibrosis [gene therapy])

Altavant Sciences (U.S.)  
(Respiratory rare disease)

Sumitomo Dainippon Pharma Co., Ltd. (Japan) Psychiatry & Neurology area, Oncology area, Regenerative/Cell therapy field, Infectious disease area, and etc.

Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)  
Clinical development in China

Sunovion Pharmaceuticals Inc. (U.S.)  
Psychiatry & Neurology, Respiratory areas

Sumitomo Dainippon Pharma Oncology, Inc. (U.S.) Oncology area

# New Development Organization Model (ex. Enzyvant)



Basel



**Alexander Solyom**  
Senior Medical Director,  
Clinical Development



California

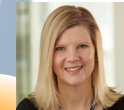


**Sarah Kulke**  
Vice President Medical Affairs

**Jim Luterman**  
SVP, Head of Early-Stage  
Development and Partnering



Massachusetts



**Rachelle Jacques**  
CEO

**Andrea Ashford-Hicks**  
Senior Biopharmaceutical  
Executive



**Jeb Ledell**  
Chief  
Operating  
Officer

North  
Carolina



**Kevin Healy**  
Vice President Regulatory  
Affairs and Quality






Sumitomo Dainippon  
Pharma group:  
R&D system that expands  
globally in each area



**Smitovant : Build a flexible system for each Vant  
Business structure that is not captured by location  
Pioneer in remote work**

# Sumitovant Biopharma Pipeline Summary

Sumitovant has a diverse development pipeline spanning numerous modalities & indications that address significant unmet patient need. Two - thirds of pipeline are modality other than small molecule

	Compound	Modality	Indication	Therapeutic Area	Phase
	relugolix	Small Molecule	Advanced Prostate Cancer	Oncology	FDA Approved
		Small Molecule (Combo)	Symptoms of Uterine Fibroids	Women's Health	NDA Accepted; MAA Filed
			Symptoms of Endometriosis	Women's Health	Phase 3
	MVT-602	Oligopeptide	Female Infertility	Women's Health	Phase 2
	vibegron	Small Molecule	Overactive Bladder	Urology	FDA Approved
			Overactive Bladder in Men w/ BPH	Urology	Phase 3
	URO-902	Gene Therapy	Overactive Bladder	Urology	Phase 2a
	RVT-802*	Regenerative Therapy	Pediatric Congenital Athymia	Rare Disease	BLA resubmission
	rodatristat ethyl	Small Molecule	Pulmonary Arterial Hypertension	Respiratory	Phase 2b
	ALTA-2530	Recombinant Protein	Bronchiolitis Obliterans Syndrome	Respiratory	Preclinical
			Chemical Lung Injury (in partnership w/ BARDA & NIAID)	Respiratory	Preclinical
	SP-101*	Gene Therapy (AAV)	Cystic Fibrosis	Respiratory	Preclinical
	SP-102*	Gene Therapy (LVV)	Cystic Fibrosis	Respiratory	Preclinical

\* For RVT-802, SP-101, and SP-102, refer to the reference material slides

## Digital Synergies in R&D



- Active utilizing of Real World Data
- Strengths in exploring targets for drug discovery, asset discovery, and speeding up clinical development through utilizing of digital technologies (→ DrugOME)
- Digital platform development power in close contact with the field (→ Digital Innovation)

Utilizing the  
characteristics of both parties,  
**to achieve speeding up R&D  
and improving the probability  
of success**



- Experience in creating many products and accumulated in-house data
- Strengths in the utilizing of digital technologies in the early stages of drug discovery, mainly in Psychiatry & Neurology area
- Active utilizing of digital technology to improve success rate of clinical trial

## Drug Discovery Utilizing DX



- Flexible and efficient development organization for each asset and disease
- Rapid and flexible clinical development utilizing digital technology
- Exploring promising assets using digital technology



Bringing R&D transformation by combining the strengths of both companies and demonstrating synergies



- High expertise in each area and achievements in continuous product creation
- An integrated system that can manage from discovery stage to marketing approval
- Achievements of global expansion ahead of other domestic second-tier companies



# Appendix

## Appendix (Development Compound of Sumitovant)

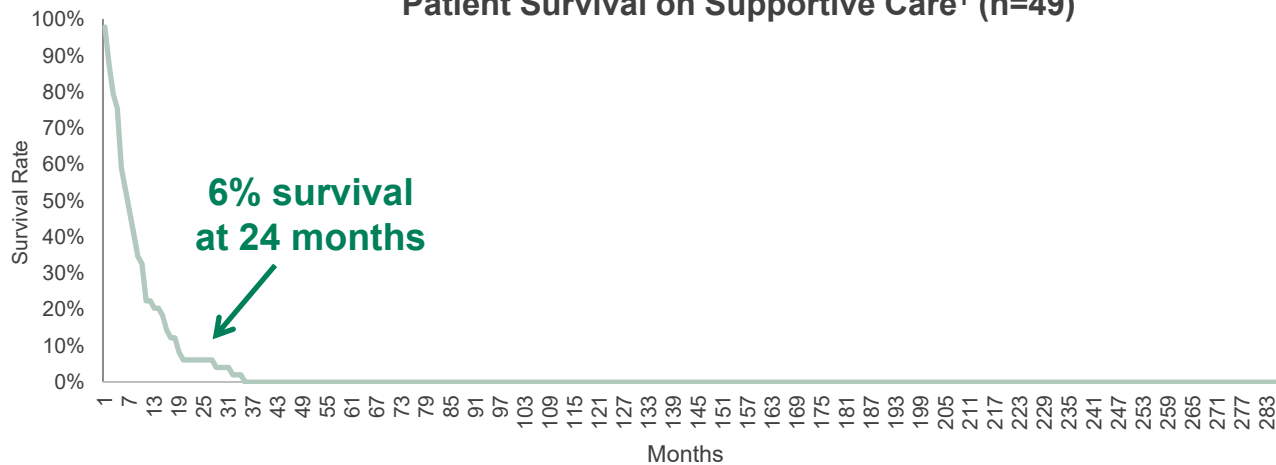
# Pediatric Congenital Athymia: Overview

**Congenital athymia is an ultra-rare immune disorder with no currently approved treatment options and a high unmet need**

- Children who have congenital athymia are born without a thymus, making them severely immunodeficient and unable to fight infections
- Children with congenital athymia may have repeated, often life-threatening infections because they do not have enough working T cells to fight them off
- Patients with congenital athymia historically do not survive past the age of two, most often due to infections



**Patient Survival on Supportive Care<sup>1</sup> (n=49)**



(1) Supportive care options for congenital athymia patients include IV immunoglobulin and isolation

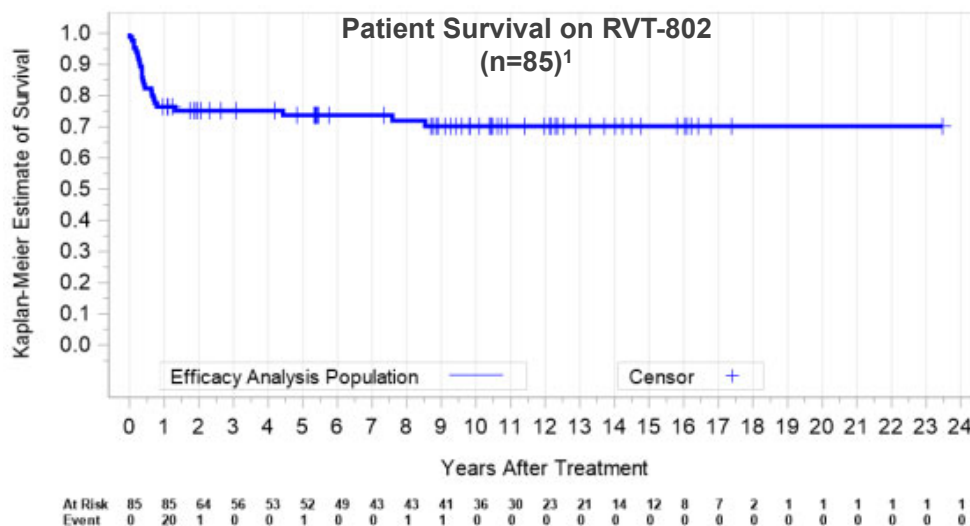
# RVT-802: Investigational Regenerative Therapy for the Treatment of Pediatric Congenital Athymia



**Development Phase:** Received Complete Response Letter to BLA (BLA resubmission in 2021)

**Modality:** Tissue-based Regenerative Medicine

- One-time therapy that uses cultured thymus tissue engineered to generate a functioning immune response when implanted in pediatric patients with congenital athymia
- Granted Breakthrough Therapy, Regenerative Medicine Advanced Therapy, Rare Pediatric Disease and Orphan Drug designations by the FDA, as well as Advanced Therapy Medicinal Product classification and Orphan Drug designation by the EMA



- In 85 RVT-802 treated patients with congenital athymia, Kaplan-Meier estimated survival rates at Year 1 and Year 2 were **76%** and **75%**, respectively<sup>1</sup>
- After treatment with RVT-802 it usually takes 6 to 12 months to establish thymic function<sup>1</sup>
- For patients who survived one year after treatment, the probability of surviving to 7.3 years was **95%**<sup>1</sup>

(1) Data on file

## Appendix (Development Compound of Sumitovant)

### SP-101: Next-Generation Gene Therapy Technology for Cystic Fibrosis



Existing products used to treat cystic fibrosis address specific protein defects (such as improving CFTR protein dysfunction) and are only helpful to patients with Class II-VI mutations

In many cases, these therapies provide limited benefit with no cure

**Development Phase:** Preclinical

**Modality:** Gene therapy (Inhaled)

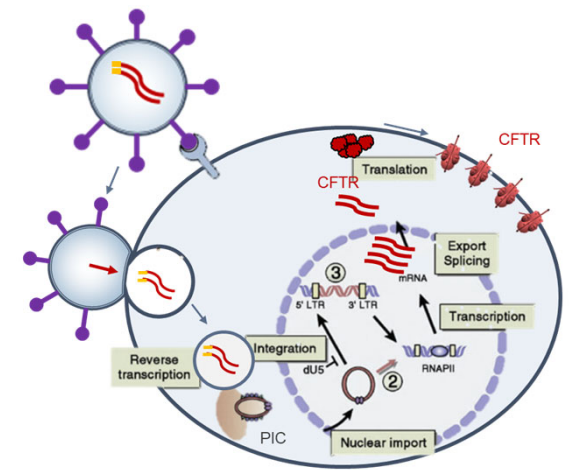
- Engineered adeno-associated virus (AAV) capsid (AAV2.5T) that has high tropism (binding) to airway epithelial cells
- A proprietary, synthetic promoter/enhancer (SP183) maximizes expression of cystic fibrosis transmembrane conductance regulator (CFTR)
- A small molecule augments improves trafficking of the vector from endosomes to the nucleus
- These components boost transduction efficiency by 1,000-10,000x vs AAV2

# SP-102: Next-Generation Lentiviral Vector Technology for Potential One-Time Curative Dose for Cystic Fibrosis

**Development Phase:** Preclinical

**Modality:** Gene therapy (One-time dose)

- Engineered lentiviral vector with a GP64 glycoprotein that confers high tropism (binding) to airway epithelial cells to deliver fully functional CFTR transgenes to replace the mutated, defective CFTR
- CFTR transgenes from lentiviral vectors integrate into the genome, thus allowing for life-long expression after a one-time, potentially curative dose
- Preclinical data showed robust transduction of human airway epithelial cells



## Appendix (Regenerative Medicine/Cell Therapy Field)



### Regenerative Medicine/Cell Therapy Business Plan (as of March 23, 2021)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	In preparation to resubmit BLA
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	In progress: pre-clinical study

**Aim to start clinical study in FY2021**

**Aim to launch in FY2023\***

\* Launch schedule is based on our goal pending agreement with partners. Revision since the announcement of Jan. 2021 is shown in red.



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows