

# Memorandum of Understanding for Strategic Alliance with Roivant Sciences

September 6, 2019

Sumitomo Dainippon Pharma Co., Ltd.



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may differ materially from those presented herein.

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# Overview of Memorandum of Understanding for Strategic Alliance

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# **Overview of Memorandum of Understanding**



■ In September 2019, we entered into memorandum of understanding with respect to stock acquisition for select Roivant subsidiaries, equity investment in Roivant, and acquisition of technology platforms

#### Overview of Memorandum of Understanding

• The two companies will continue to conduct necessary due diligence and engage in mutual consultations as required as they work toward the conclusion of a legally binding definitive agreement by the end of October 2019

Stock Acquisition of Subsidiaries

Acquires Roivant's interests in 5 of its subsidiaries

Obtaining Options

Obtains options to acquire Roivant's interests in 6 of its subsidiaries

Acquisition of Platforms and Cooperation

• Acquires Roivant's pharma-related technology platform & data technology talent emain Roivant subsidiaries

Subscription for Shares

11 companies subject to stock acquisition or option agreement collectively have over 25 innovative clinical programs

in Roivant Acquires over 10 % of Roivant shares

\* Memorandum of understanding is not-legally binding except for certain stipulations

#### ■ Consideration for stock acquisition and transfer of technologies

Acquires over 10% of Roivant shares

Approx. US \$3 billion (approx. 320 billion yen)

#### ■ Schedule

- Signing of definitive agreement: End of October 2019 (Scheduled)
- Stock acquisitions and transfer pharma-related technology platforms: Subject to customary closing conditions



#### **Overview of Roivant Sciences**



■ Name: Roivant Sciences Ltd.

■ Established: April 2014

■ **Headquarters**: London, UK / Basel, Switzerland

■ Representative: Vivek Ramaswamy,

Founder and CEO of Roivant Sciences, Inc.

■ Employees: More than 900 (consolidated)

#### **■** Businesses:

 Builds "Vants" as subsidiaries – nimble, focused companies that develop innovative medicines and healthcare technologies

Has pharma-related platform and data technology talent

# ROIVANT

#### **DrugOme Technology**

(Unique data analytics platform for accelerating pipeline acquisition and clinical development)

#### **Digital Innovation Technology**

(Platform for optimizing business processes through data analysis)

# 4 out of 5 Roivant subsidiaries subject to stock acquisition

#### **Myovant Sciences**

(Women's Health and Prostate Cancer)

#### **Urovant Sciences**

(Urology)

#### **Enzyvant Therapeutics**

(Pediatric Rare Diseases)

#### **Altavant Sciences**

(Respiratory Rare Diseases)

#### **Metavant Sciences**

(Cardiometabolic Diseases)

#### **Dermavant Sciences**

(Dermatology)

#### Sinovant Sciences

(Greater China Drug Development)

#### **Genevant Sciences**

(RNA Therapeutics)

#### **Cytovant Sciences**

(Asia Cell Therapies)

#### **Axovant Gene Therapies**

(Neurological Gene Therapies)

#### **Arbutus Biopharma**

(Hepatitis B)

#### **Respivant Sciences**

(Respiratory Diseases)

#### **Immunovant Sciences**

(Immunology)

#### **Aruvant Sciences**

(Hematological Gene Therapies)

#### **Alyvant**

(Tech-Enabled Pharma Commercialization)

#### **Datavant**

(Healthcare Data)

# **Leadership of Roivant Companies**



#### **President and Chief Executive Officer, Myovant**

- Former CMO at Medivation
- Led development of XTANDI® for metastatic castrationresistant prostate cancer

#### **Lynn Seely**



# **Chief Executive Officer, Altavant**

- Former Chief Development Officer at Roivant, held senior roles at Gilead and Pharmasset
- Led development of SOVALDI® / HARVONI®, the top selling cure for Hepatitis C

#### Bill Symonds



#### **President and Chief Executive Officer, Urovant**

- Former President and CEO at Avanir through \$3.5 billion USD sale to Otsuka in 2014
- Responsible for developing and executing the corporate strategy that led to the approval and commercialization of NUEDEXTA®

#### **Keith Katkin**

#### **Chief Executive Officer, Enzyvant**

- Former SVP, Global Franchise Head of Complement at Alexion
- More than two decades of experience in U.S. and global commercial leadership and marketing, including launching multiple medicines

#### **Rachelle Jacques**

#### **Roivant's Business Model**







**Smaller is generally better** 





**Align incentives** 





Focus on value, rather than historical strategic commitments





Recruit top talent from within and beyond biopharma





Use data and deploy technology in all areas of the business

# **Key Pipelines of Roivant Companies**



Product Code	Code Company Proposed Indication		Development Stage		
RVT-802	Enzyvant	Pediatric congenital athymia			
Relugolix	Myovant	Uterine fibroids, endometriosis, prostate cancer			
Vibegron	Urovant	Overactive bladder, overactive bladder in men with BPH			
Tapinarof	Dermavant	Psoriasis	Phase 3		
Lefamulin		Community-acquired pneumonia			
Derazantinib		Intrahepatic cholangiocarcinoma			
SNV-003	Sinovant	Delayed graft function			
		Acute kidney injury			
Naronapride		Constipation			
Rodatristat ethyl	Altavant	Pulmonary arterial hypertension			
ARU-1801	Aruvant	Sickle cell disease			
AXO-LENTI-PD	Axovant	Parkinson's disease			
CVT-DC-01	Cytovant	Acute myeloid leukemia (AML)			
Tapinarof	Dermavant	Atopic dermatitis	Phase 2		
IMVT-1401	Immunovant	Myasthenia gravis			
		Graves' ophthalmopathy			
RVT-1501	Metavant	Diabetes			
MVT-602	Myovant	Female infertility			
RVT-1601	Respivant	Idiopathic pulmonary fibrosis (IPF) with chronic cough			
Vibegron	Urovant	IBS-associated pain			



# **Stock Acquisition of Subsidiaries of Roivant**



■ Acquires controlling interest in (4 out of 5 companies):

Myovant Sciences ~46% ownership: Listed on New York Stock Exchange

Urovant Sciences ~75% ownership: Listed on Nasdaq

Enzyvant Therapeutics
 Privately held by Roivant

Altavant Sciences
 Privately held by Roivant

Obtains options to acquire Roivant's ownership interests in six additional subsidiaries

#### **Significance of Acquisition**

- Acquisition of controlling interests in Roivant subsidiaries with numerous innovative compounds
  - Relugolix (uterine fibroids, endometriosis, prostate cancer)
  - Vibegron (overactive bladder (OAB), OAB in men
     with benign prostate hyperplasia, IBS-associated pain)
  - RVT-802 (pediatric congenital athymia)
  - Rodatristat ethyl (pulmonary arterial hypertension (PAH))

+α

Potential future post-LATUDA® assets

# Pipelines of Subsidiaries to Be Acquired



Product	Characteristics	Indication	Phase	Plan	Originator	Development
Relugolix		Uterine fibroids	Phase 3 complete	NDA submission FY2019 (U.S.)	Takeda Pharmaceutical Company Ltd.	Myovant
	Oral, once-a-day, small molecule GnRH (gonadotropin-releasing hormone) receptor antagonist	Endometriosis	Phase 3	Phase 3 results FY2019-2020		
	amagemen	Prostate cancer	Phase 3	Phase 3 results FY2019		
Vibegron		Overactive bladder (OAB)	Phase 3 complete	NDA submission FY2019 (U.S.)	Merck Sharp & Dohme Corp.	Urovant
	Oral, once-a-day, small molecule beta-3 adrenergic receptor agonist	OAB in men with BPH	Phase 3	Phase 3/Part 1 results FY2019		
		IBS-associated pain	Phase 2a	Phase 2a results FY2019-2020		
RVT-802	<ul> <li>Treatment of infants with congenital athymia by culturing thymus tissue obtained during cardiac surgery and implanting the cultured thymus tissue into quadriceps</li> <li>Granted Breakthrough Therapy,</li> <li>Regenerative Medicine Advanced Therapy,</li> <li>Orphan Drug designations and Rare</li> <li>Pediatric Disease by the US Food and</li> <li>Drug Administration (FDA)</li> </ul>	Pediatric congenital athymia	Applied (U.S.)	Approval decision FY2019 (U.S.)	Duke University	Enzyvant
Rodatristat ethyl	Prodrug of orally administered tryptophan hydroxylase (TPH) inhibitor	Pulmonary arterial hypertension (PAH)	Phase 2a	Phase 2a results FY2019-2020	Karos Pharmaceuticals, Inc.	Altavant

# **Overview of Relugolix**



■ Originator: Takeda Pharmaceutical Company Ltd.

■ **Development**: Myovant Sciences

■ **Development Stage**: Phase 3

(uterine fibroids, endometriosis, prostate cancer)

■ Characteristics:

 Oral, once-a-day, small molecule GnRH (gonadotropinreleasing hormone) receptor antagonist

 Reduces sex hormone levels by inhibiting pituitary GnRH receptors and suppresses estrogen and progesterone in women and testosterone in men

■ Plan:

Uterine fibroids: NDA submission FY2019 (U.S.)

• Endometriosis: Phase 3 topline results FY2019-2020

Prostate cancer: Phase 3 topline results FY2019

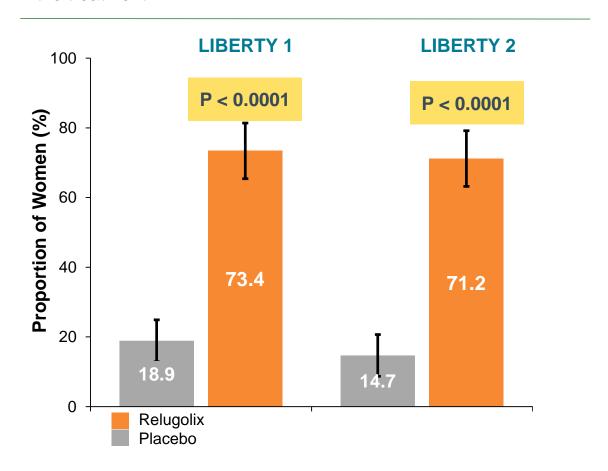
#### ■ Uterine Fibroids Phase 3 Study Results:

 Design of clinical trial: Double-blind placebo-controlled study

Combination of relugolix (40mg), estradiol (1.0mg) and norethindrone acetate (0.5mg), once-a day

- Efficacy: Achieved primary endpoint
- Safety: Well tolerated compared to placebo
- Plan: NDA submission in FY2019 in the U.S. based on these clinical studies

**Primary Endpoint**: Proportion of women who had a menstrual blood loss (MBL) of less than 80mL and at least a 50% reduction in menstrual blood loss from baseline during the last 35 days of the treatment



# **Overview of Vibegron**



**Originator**: Merck Sharp & Dohme Corp.

**Development**: Urovant Sciences

**Development Stage**: Phase 3 (overactive bladder (OAB),

OAB in men with BPH)

Phase 2a (IBS-associated pain)

#### Characteristics:

- Oral, once-a-day, small molecule beta-3 adrenergic receptor agonist
- Selectively acts on beta-3 adrenergic receptor and increases urine accumulation function by relaxing the bladder, which potentially improves symptoms of urinary urgency, frequent urination and urge incontinence

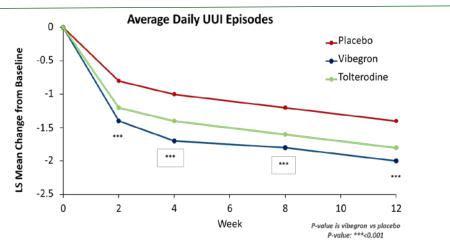
#### ■ Plan:

- OAB: NDA submission FY2019 (U.S.)
- OAB in men with BPH: Phase 3 Part 1 results FY2019
- IBS-associated pain: Phase 2a topline results FY2019-2020

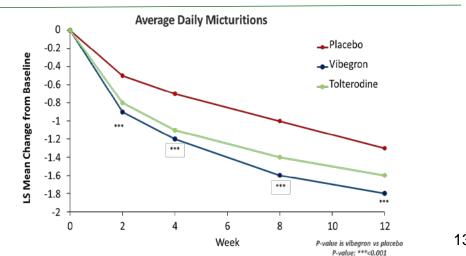
#### **OAB Phase 3 Study Results:**

- Design of clinical trial: Double-blind placebo-controlled study (Vibegron: 75mg, once-a-day)
- Efficacy: Achieved both primary endpoints
- Safety: Well tolerated compared to placebo
- Plan: NDA submission in FY2019 in the U.S. based on this study

**Co-Primary Endpoint:** Change in the average number of urge urinary incontinence episodes per 24 hours from baseline



**Co-Primary Endpoint:** Change in the average number of micturitions per 24 hours from baseline



# Pharma-Related Technology Platforms Transfer and Alliance



#### Significance of Pharma-Related Technology Platforms Transfer and Alliance

- Bolster efficiency of drug development
- Accelerate digital transformation







#### Roivant's technology to acquire

- DrugOme Technology
   (Unique data analytics platform for accelerating pipeline acquisition and clinical development)
- **Digital Innovation Technology** (Platform for optimizing business processes through data analysis)

# **Alliance**

Mutual utilization of technologies and services

#### Healthcare IT subsidiaries

- Datavant
  - (Platform with de-identification and linking technology of multiple external healthcare data to facilitate their use)
- Alyvant

(Platform for increasing efficiency of sales and marketing activities for pharmaceutical products through big data analytics)



✓ Acquires data technology talent



#### **Overview of Platforms**



# **DrugOme**

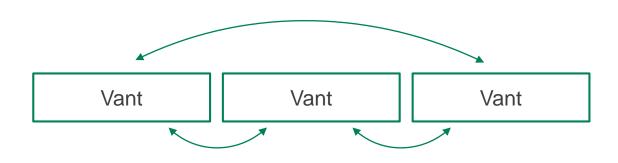
✓ Data science-driven platform with centralized database for accelerating pipeline acquisition and clinical development

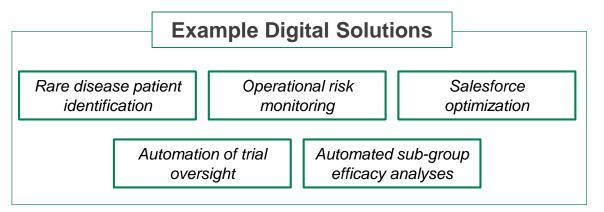


# New asset idea generation Interactive map of asset landscape Toxicology risk assessment Clinical trial enrollment

# **Digital Innovation**

- ✓ Increasing work efficiency through the use of healthcare IT by Digital Innovators (technologists) at each Vant
- ✓ Digital solutions are shared across Vants

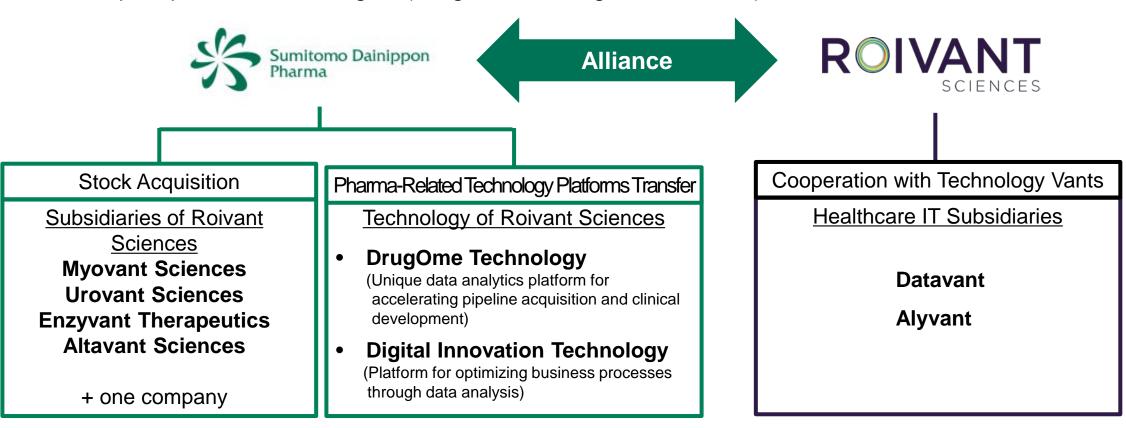




# **Summary**



- To acquire promising, future post-LATUDA® compounds
- To acquire platform technologies (DrugOme and Digital Innovation) and talent



- Obtains options to acquire Roivant's interests in six additional companies, which will remain owned by Roivant until exercise
- Determine exercise of options by FY2024

# **Significance of Strategic Alliance**



Acquire post-LATUDA® assets, early stage assets, platform technology (DrugOme and Digital Innovation), and talents. Realize to major change of Sumitomo Dainippon Pharma Group for sustainable growth

## **Key Issues**

**Expand post-LATUDA® assets** 

Expand pipeline by continued creation of innovative new drugs

Meet needs for preventive medical care and for digital technologies

Reinforce profitability of North America and Japan business
Expand presence in China and Asia

Enhance organizational capabilities to address changes in external environment

#### **Major Revolution to Achieve Sustainable Growth**

- Obtains multiple blockbuster products: relugolix and vibegron (planned NDA submissions in FY2019 in the U.S.), etc.
- Pipeline acquisition: possibility of acquiring over 25 innovative clinical programs
- Improves R&D productivity by utilizing DrugOme to enhance the capability of pipeline acquisition and R&D
- Possibility of acquiring gene therapy assets
- Adds to pipeline in Japan: multiple early-stage assets of rodatristat ethyl, etc.
- Introduces framework and talent that accelerate digital transformation to whole group
- Transformation to a flexible and speedy organizational culture

#### **Our Vision**



Aspire to establish a position as a "Global Specialized Player" with ability to meet increasingly diversified needs for healthcare



# Mid-term Business Plan 2022 Re-build Business Foundation

Establishment of growth engine



Building of flexible and efficient organization

# **Accelerating our growth**

Sustainable growth driver after LATUDA® LOE

Transformation into a new business model based on data technology by DrugOme and Digital Innovation



Innovation today, healthier tomorrows