

December 28, 2020

Sumitomo Dainippon Pharma Co., Ltd.

**Consolidated Subsidiary Myovant and Pfizer Enter Into Collaboration to  
Develop and Commercialize Relugolix**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura) announced today that on December 28, 2020 (local time), its consolidated subsidiary, Myovant Sciences Ltd. (NYSE: MYOV), has entered into a development and commercialization agreement (hereinafter, “the Agreement”) with Pfizer, Inc (NYSE: PFE) on relugolix (generic name) – a gonadotropin-releasing hormone (GnRH) receptor antagonist, in oncology and women’s health – in the U.S. and Canada. Pfizer will also receive an exclusive option to commercialize relugolix in oncology outside the U.S. and Canada, excluding certain Asian countries.

Under the terms of the Agreement, Myovant grants Pfizer the right to jointly develop and commercialize relugolix monotherapy tablet, ORGOVYX™, approved by the U.S. Food and Drug Administration (FDA) on December 18, 2020 for the treatment of adult patients with advanced prostate cancer and, if approved, relugolix combination tablet in women’s health in the U.S. and Canada. Myovant and Pfizer will begin co-promoting ORGOVYX for advanced prostate cancer in early 2021. Myovant and Pfizer will equally share profits and certain expenses for ORGOVYX and relugolix combination tablet with Myovant recording revenues.

Myovant will receive up to \$4.2 billion, including an upfront payment of \$650 million, \$200 million in potential regulatory milestones for U.S. Food and Drug Administration (FDA) approvals for relugolix combination tablet in women’s health, and tiered sales milestones upon reaching certain thresholds up to \$2.5 billion in net sales for prostate cancer and also for the combined women’s health indications. If Pfizer exercises the option to commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries, Myovant will receive \$50 million and be entitled to receive double-digit royalties on sales.

“We are thrilled to partner with Pfizer to unlock the full potential of ORGOVYX in advanced prostate cancer and relugolix combination tablet in uterine fibroids and endometriosis, advancing our mission to redefine care for women and for men,” said Lynn Seely, M.D., Chief Executive Officer, Myovant Sciences, Inc. “Pfizer is the ideal partner for Myovant given its impressive capabilities and track record across both oncology and women’s health. This transformative collaboration will significantly strengthen the upcoming launch of ORGOVYX and the potential launches of relugolix combination tablet in women’s health, while substantially enhancing our financial position and enabling us to expand our pipeline of potential new medicines.”

“We are excited to join forces with Myovant and combine our capabilities to bring ORGOVYX to

patients with advanced prostate cancer,” said Andy Schmeltz, Global President, Pfizer Oncology. “This strategic collaboration builds on our leadership in serving prostate cancer patients in the U.S. and aligns with our goal to deliver more breakthroughs across the prostate cancer treatment paradigm.”

“There continues to be a high unmet need among the millions of women who experience the common and debilitating symptoms associated with uterine fibroids and endometriosis,” said Nick Lagunowich, Global President, Pfizer Internal Medicine. “We believe our deep heritage and leadership in women’s health combined with our experienced women’s health field force will enable us to maximize these opportunities with Myovant, potentially bringing valuable new treatment options to these women.”

Sumitomo Dainippon Pharma is currently evaluating the impact that this matter will have on its consolidated financial results of the fiscal year ending March 31, 2021, and will promptly make a disclosure if there arises a need for revision of earnings forecast of such fiscal year or there occurs any other reportable event in relation to this matter.

For further details, please visit <https://www.myovant.com/>

## **Reference Information**

### **About Relugolix**

Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis.

The U.S. Food and Drug Administration (FDA) approved ORGOVYX™ (relugolix 120 mg tablet) on December 18, 2020 for the treatment of adult patients with advanced prostate cancer.

\*Details of the approval of ORGOVYX™ were disclosed on December 21, 2020.

(<https://www.ds-pharma.com/ir/news/pdf/ene20201219.pdf>)

Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review for women with uterine fibroids and is under development for women with endometriosis.

- Submitted Marketing Authorization Application\* to the European Medicines Agency in March, 2020, and New Drug Application to the FDA in May 2020 (Expected action date by FDA: June 1, 2021)

- Obtained positive results from global Phase 3 study (SPIRIT 1 and SPIRIT 2) for endometriosis, being planning to submit New Drug Application to the FDA in the first half of 2021

\*Myovant and Gedeon Richter Plc. (Headquarters: Budapest, Hungary) have entered into an

exclusive license agreement on the development and marketing of a relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside the U.S., which include Europe and Russia. Details of this matter were disclosed on March 31, 2020.

(<https://www.ds-pharma.co.jp/ir/news/pdf/ene20200331.2.pdf>)

### **About Myovant Sciences**

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. The company's lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction.

In December 2019, Sumitomo Dainippon Pharma made Myovant into a consolidated subsidiary under Sumitovant, a new subsidiary established through a strategic alliance with Roivant Sciences Ltd. (Headquarters: London, U.K.; Basel, Switzerland).

For more information, please visit the company's website at [www.myovant.com](http://www.myovant.com) [www.myovant.com](http://www.myovant.com). Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma and is the parent company of five biopharmaceutical companies: Myovant, Urovant, Enzyvant, Altavant and Spirovant. For further details of Sumitovant, please visit <https://www.sumitovant.com>.

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