News Release

- ORGANON

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ORGANON & LILLY ENTER COMMERCIALIZATION AGREEMENT IN EUROPE FOR TWO MIGRAINE MEDICINES

Organon becomes the sole distributor and promoter of EMGALITY[®] (galcanezumab) and RAYVOW[™] (lasmiditan) in Europe, building on strong commercial expertise in central nervous system disorders

Expands Organon's European product portfolio in a condition that primarily affects women¹

JERSEY CITY, N.J., December 18, 2023 – Organon (NYSE: OGN), a global healthcare company with a focus on women's health, announced an agreement with Eli Lilly and Company (Lilly) to become the sole distributor and promoter for the migraine medicines EMGALITY[®] (galcanezumab) and RAYVOW[™] (lasmiditan) in Europe.*

EMGALITY[®], a humanized monoclonal antibody calcitonin gene-related peptide (CGRP) antagonist, is indicated for the prophylaxis of migraine in adults who have at least four migraine days per month. RAYVOW[™] is a first-in-class serotonin 5-HT_{1F} receptor agonist approved for the acute treatment of the headache phase of migraine attacks, with or without aura in adults.

"This commercialization agreement aligns seamlessly with Organon's suite of central nervous system treatments in our Established Brands portfolio and, most importantly, it further bolsters our offerings to women, who are disproportionately impacted by migraine," said Kevin Ali, Organon CEO. "Our strong commercial expertise and proven track record in this therapeutic area will help enable us to bring these important treatments to more patients across Europe who need them."

Migraine is the third most common disease worldwide¹ causing recurrent moderate-tosevere headaches, often accompanied by other debilitating symptoms, including nausea, vomiting, and sensitivity to light and sound² that can negatively interrupt an individual's daily living including family life, career, education, relationships, and earnings.³ The disease is three times more common in women than in men and is one of the leading causes of disability in women.⁴

"Lilly is committed to helping people living with migraine, a debilitating neurological disease," said Ilya Yuffa, executive vice president of Eli Lilly and Company and president of Lilly International. "We are confident this collaboration with Organon will help even more people throughout Europe gain access to our innovative migraine treatments."

Under the terms of the agreement, Organon will become the sole distributor and promoter of EMGALITY[®] and RAYVOW[™] in Europe. Lilly will remain the marketing authorization holder and will manufacture the products for sale.

Total consideration to be paid to Lilly includes an upfront payment of \$50 million and sales-based milestone payments. The transaction is expected to close in Q1 2024 upon completion of review with relevant country-specific authorities.

About EMGALITY®

EMGALITY[®] is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) and was approved by the European Medicines Agency (EMA) in November 2018.

Indications and Usage in EU:

Therapeutic indications: EMGALITY® is indicated for the prophylaxis of migraine in

adults who have at least 4 migraine days per month. Posology and method of administration: EMGALITY[®] should be initiated by physicians experienced in the diagnosis and treatment of migraine.

Posology: The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose. Patients should be instructed to inject a missed dose as soon as possible and then resume monthly dosing. The treatment benefit should be assessed within 3 months after initiation of treatment. Any further decision to continue treatment should be taken on an individual patient basis. Evaluation of the need to continue treatment is recommended regularly thereafter.

Method of administration:

Subcutaneous use.

A patient may self-inject galcanezumab by following the Instructions for Use. Galcanezumab is to be injected subcutaneously in the abdomen, thigh, back of the upper arm, or in the gluteal region. After training, patients may self-inject galcanezumab if a healthcare professional determines that it is appropriate. Comprehensive instructions for administration are given in the Package Leaflet.

About RAYVOW[™] (lasmiditan)

RAYVOW[™] is an oral treatment that binds to 5-HT_{1F} receptors with high affinity and is approved by the EMA for the acute treatment of the headache phase of migraine attacks, with or without aura in adults. Its therapeutic effects in the treatment of migraine are presumably mediated by agonist effects at the 5-HT_{1F} receptor; however, the precise mechanism is unknown. RAYVOW[™] is not indicated for preventive treatment of migraine. RAYVOW[™] can be prescribed to patients in oral doses of 50 mg, 100 mg, and 200 mg as needed. No more than 200 mg should be taken in 24 hours.

Indications and Usage in EU:

RAYVOW[™] is indicated for the acute treatment of the headache phase of migraine attacks, with or without aura in adults.

Posology and method of administration:

Posology: In general, recommended initial dose in adults is 100 mg lasmiditan for acute treatment of migraine attacks. If necessary, the dose can be increased to 200 mg for greater efficacy or can be decreased to 50 mg for greater tolerability. If the migraine headache recurs within 24 hours of an initial response after taking 50 mg or 100 mg lasmiditan, a second dose of the same strength may be taken. The second dose should not be taken within 2 hours of the initial dose. No more than 200 mg should be taken in 24 hours.

If a patient does not respond to the first dose, it is unlikely that a second dose will be of benefit in the same attack. Lasmiditan may be taken with or without food. Method of administration: Oral use.

About Organon

Organon is a global healthcare company formed to focus on improving the health of women throughout their lives. Organon offers more than 60 medicines and products in women's health in addition to a growing biosimilars business and a large franchise of established medicines across a range of therapeutic areas. Organon's existing products produce strong cash flows that support investments in innovation and future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, visit <u>www.organon.ca</u> and connect with us on <u>LinkedIn</u>.

Cautionary Note Regarding Forward-Looking Statements

Some statements and disclosures in this news release are "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "potential," "may," "expects," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "will," or words of similar meaning. These forward-looking statements include, but are not limited to, statements about the expected timing for the completion of the transaction between Organon and Eli Lilly and Company, Organon's ability to obtain required licenses and commercialize EMGALITY[®] and RAYVOW[™] in Europe during the expected timeframe, and the expected benefits of the commercialization agreement. Such statements are based on Organon's current plans and expectations and are subject to a number of risks and uncertainties that could cause its plans and expectations, including actual results, to differ materially from the forward-looking statements. Risks and uncertainties include, but are not limited to, the timing and impact of any required regulatory reviews or approvals, any failure to satisfy the conditions to closing the commercialization transaction, an inability of Organon to fully execute on its commercialization plans for EMGALITY[®] and RAYVOW[™] and/or an inability to obtain required licenses to commercialize such assets, efficacy, safety, or other quality concerns with respect to marketed products, including market actions such as recalls, withdrawals, or declining sales; general industry conditions and competition; the impact of pharmaceutical industry regulation and health care legislation and trends toward health care cost containment; new products and patents attained by competitors; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. Organon undertakes no obligation to publicly update any forwardlooking statement, whether as a result of new information, future events or otherwise.

Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Organon's filings with the Securities and Exchange Commission ("SEC"), including Organon's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent SEC filings, available at the SEC's Internet site (www.sec.gov).

*RAYVOW™ is marketed and distributed in the United States as REYVOW[®]

References: 1. American Brain Foundation, Migraine overview, available: <u>Migraine - American Brain</u> <u>Foundation</u>. Last accessed: November 2023. **2.** National Institute of Neurological Disorders and Stroke, Migraine, available: <u>Migraine | National Institute of Neurological Disorders and Stroke (nih.gov)</u>. Last accessed: November 2023. **3.** Buse DC. *et al.* Life With Migraine: Effects on Relationships, Career, and Finances From the Chronic Migraine Epidemiology and Outcomes (CaMEO) Study, Headache: *The Journal of Head and Face Pain*, 2019;59:1286-1299 doi: 10.1111/head.13613. **4.** Pavlović JM. The impact of midlife on migraine in women: summary of current views. *Womens Midlife Health*. 2020;6(1):11. doi:10.1186/s40695-020-00059-8