Valeo Pharma Inc. Enters into an Agreement for Enerzair® Breezhaler® and Atectura® Breezhaler® in Canada

written by Raj Shah | March 29, 2021 March 29, 2021 (<u>Source</u>) -

- Valeo to commercialize Enerzair® Breezhaler® and
 Atectura® Breezhaler®, 2 innovative asthma therapies approved by Health Canada
- Positions Valeo as one of the leading Canadian Respiratory companies
- Almost 4 million Canadians afflicted with asthma¹; Canadian market for asthma medication exceeds \$700M annually²

Valeo Pharma Inc. (CSE: VPH) (OTCQB: VPHIF) (FSE: VP2) ("Valeo" or the "Company"), a Canadian pharmaceutical company, announced today that it has entered into a Commercialization and Supply Agreement (the "Agreement") with Novartis Pharmaceuticals Canada Inc. ("Novartis") for the Canadian commercialization by Valeo of two asthma therapies, Enerzair® Breezhaler® (indacaterol (as acetate), glycopyrronium (as bromide) and mometasone furoate)³ and Atectura® Breezhaler® (indacaterol (as acetate) and mometasone furoate)⁴.

Under the Agreement, Valeo will be responsible for medical and

commercial activities for Enerzair® Breezhaler® and Atectura® Breezhaler® for an initial 8 year period.

At present, almost 4 million Canadians are living with asthma¹, a serious health issue affecting all age groups. Patients with severe asthma live in fear of potential exacerbations which remain highly prevalent even with today's most advanced therapies. Asthma related exacerbations are concerning because of their associated mortality burden and also because of the increased risk of side effects from the use of systemic corticosteroids. Furthermore, there is growing evidence highlighting the lack of symptom control currently achieved in asthma. 39% of patients remain uncontrolled, despite available dual LABA/ICS medications, primarily due to low adherence, treatment misuse and poor inhaler technique. There is an urgent need to add effective maintenance treatment options to more efficiently address symptoms as well as asthma related long-term complications and mortality.

"We are extremely pleased to be partnering with Novartis to launch these two asthma drugs in the coming weeks. Breezhaler® Commercializing Enerzair® Atectura® Breezhaler® will immediately position Valeo as one of the leading Canadian respiratory companies providing first inclass and best in-class asthma therapies. The Canadian asthma maintenance market exceeds \$700M annually," said Steve Saviuk, CEO of Valeo. "This partnership is perfectly aligned with Valeo's vision and mission of building a Canadian anchor pharmaceutical company by driving therapeutic innovation to patients in need. We look forward to building a long and mutually beneficial relationship with Novartis that will help both companies fulfill their respective missions."

"This agreement with Valeo Pharma fits with our overall strategy to provide innovative medicines that have the potential to improve health outcomes," said Andrea Marazzi, Head, Country Pharma Organization, Novartis Pharmaceuticals Canada Inc. "Valeo's commitment and focus to bring

Enerzair[®] Breezhaler[®] and Atectura[®] Breezhaler[®] to Canadians, combined with our strong respiratory experience, brings a solution that will help make asthma control a more attainable goal for some Canadians."

Commenting on this commercial agreement with Novartis, Frederic Fasano, Valeo's recently appointed President and COO said, "Enerzair" Breezhaler" and Atectura Breezhaler are both benefitting from an extensive phase III clinical trial program including more than 7,500 asthma patients. The efficacy of both treatments on symptoms, lung function and rate of exacerbations have been demonstrated and this will provide Canadian patients with a significant improvement over current standards of care." He added, "This significant addition to our expanding product portfolio is key to achieving our growth objectives. It will

The Enerzair® Breezhaler® and Atectura® Breezhaler® will both be available in the hydrofluoroalkane/chlorofluorocarbon (HFA/CFC) - free Breezhaler® device.

provide the basis for the upscaling of our organization and set

the stage for future international expansion."

Atectura, Enerzair and Breezhaler are registered trademarks.

References:

1: Government of Canada. Asthma and Chronic Obstructive Pulmonary Disease (COPD) in Canada, 2018. Report from the Canadian Chronic Disease Surveillance System. Available from: https://www.canada.ca/en/public-health/services/publicatio

<u>ns/diseases-conditions/asthma-chronic-obstructive-pulmonary-</u>disease-canada-2018.html#a1.

- 2: IQVIA CDH June 2020
- 3: Novartis Pharmaceuticals Canada Inc., ENERZAIR® BREEZHALER® Product Monograph, dated July 22, 2020
- 4: Novartis Pharmaceuticals Canada Inc., ATECTURA® BREEZHALER® Product Monograph, dated May 5, 2020
- 5: Buhl R et al. Respiratory Medicine (2020)

About Energair® Breezhaler®

Enerzair® Breezhaler® is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta₂-agonist and a medium or high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous 12 months³. This formulation combines the bronchodilation of indacaterol acetate (a LABA) and the glycopyrronium bromide (a LAMA) with mometasone furoate (an ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler® device.

About Atectura® Breezhaler®

Atectura® Breezhaler® is indicated as a once-daily maintenance treatment of asthma in adults and adolescents 12 years of age and older with reversible obstructive airways disease.

Atectura[®] Breezhaler[®] should be prescribed for patients not adequately controlled on a long-term asthma control medication, such as ICS or whose disease severity clearly warrants treatment

with both a LABA and an ICS⁴. Atectura[®] Breezhaler[®] combines the bronchodilation of indacaterol acetate (a LAMA) with the anti-inflammatory mometasone furoate (an ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler[®] device.

About Novartis Pharmaceuticals Canada

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. In 2020, the company invested \$45 million in research and development in Canada. Located in Dorval, Quebec, Novartis Pharmaceuticals Canada Inc. employs approximately 1,000 people in Canada and is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. For further information, please consult www.novartis.ca.

About Valeo Pharma

Valeo Pharma is a pharmaceutical company dedicated to the commercialization of innovative prescription products in Canada with a focus on Respirology, Neurodegenerative Diseases, Oncology and other specialty products. Headquartered in Kirkland, Quebec, Valeo Pharma has the full capability and complete infrastructure to register and properly manage its growing product portfolio through all stages of commercialization. For more information, please visit www.valeopharma.com and follow us on LinkedIn and Twitter.

Forward Looking Statements

This press release contains forward-looking statements about

Valeo's objectives, strategies and businesses that involve risks and uncertainties. These statements are "forward-looking" because they are based on our current expectations about the markets we operate in and on various estimates and assumptions. Actual events or results may differ materially from those anticipated in these forward-looking statements if known or unknown risks affect our business, or if our estimates or assumptions turn out to be inaccurate.

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