

Valeo Pharma Announces Filing of a New Drug Submission-COVID 19 With Health Canada for Sabizabulin for the Treatment of Hospitalized COVID-19 Patients

written by Raj Shah | January 26, 2023

- In the final analysis of the Phase 3 clinical study conducted by Veru Inc., sabizabulin showed a 51.6% reduction in deaths compared to placebo in hospitalized adult patients with moderate to severe COVID-19 who are at high risk for ARDS
- Sabizabulin also showed a significant reduction of days in ICU, days on mechanical ventilation and days in the hospital

January 26, 2023 ([Source](#)) – [Valeo Pharma Inc.](#) (TSX: [VPH](#)) (OTCQB: [VPHIF](#)) (FSE: [VP2](#)) (“**Valeo**” or the “**Company**”), a fast-growing Canadian pharmaceutical company, announced today that Health Canada has accepted for review Veru’s New Drug Submission (“NDS-CV”) for sabizabulin for COVID-19. Sabizabulin is a novel dual antiviral and anti-inflammatory agent being developed for the treatment of hospitalized moderate to severe COVID-19 adult patients at high risk for acute respiratory distress syndrome (ARDS) and death.

“Health Canada’s filing acceptance of Veru’s NDS-CV application

for sabizabulin is the first important regulatory milestone in the drug approval process. Given the current number of hospitalized COVID-19 patients and the burden on provincial healthcare systems, there is a need to continually seek innovative treatment options,” said Steve Saviuk, CEO. “We will continue working closely with Veru to ensure, if approved, access to sabizabulin at the earliest possible time.”

The Phase 3 COVID-19 clinical trial of sabizabulin was a double-blind, randomized, placebo controlled trial conducted in 204 hospitalized COVID-19 patients with moderate to severe COVID-19 (\geq WHO 4-supplemental oxygen) at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Patients in both treatment groups were allowed to receive standard of care treatment, including remdesivir, dexamethasone, anti-IL6 receptor antibodies and JAK inhibitors. Based on a planned interim analysis of the first 150 patients randomized, the Independent Data Monitoring Committee unanimously recommended to halt the study early for clear clinical efficacy and no safety concerns were identified. Treatment with sabizabulin 9 mg once daily, an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and antiviral properties, resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths compared to placebo. The results of the interim analysis were published in The New England Journal of Medicine (NEJM) Evidence. In the final analysis of all 204 patients, sabizabulin demonstrated a statistically significant 51.6% relative reduction in deaths compared to placebo. Sabizabulin was well tolerated.

Valeo previously announced in September 2022 that Veru and Valeo had entered into an agreement under which Valeo is the commercial partner for Veru’s product candidate sabizabulin for COVID-19 in Canada.

About Valeo Pharma

Valeo Pharma is a fast growing Canadian pharmaceutical company dedicated to the commercialization of innovative prescription products in Canada with a focus on Respiratory/Allergy, Ophthalmology and Hospital Specialty Products. Headquartered in Kirkland, Quebec Valeo Pharma has all the necessary capabilities and a complete infrastructure to register and 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.

SOURCE Valeo Pharma Inc.

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