Valeo Pharma Enters into Canadian Commercial Services Agreement with Veru for Sabizabulin in Hospitalized Adult Patients with Covid-19 at High Risk for Acute Respiratory Distress Syndrome (ARDS)

written by Raj Shah | September 14, 2022

- **In a Phase 3 cinical study interim analysis, sabizabulin showed a 55.2% reduction in deaths compared to placebo in hospitalized adult patients with moderate-severe COVID-19 who are at high risk for ARDS**
- **Sabizabulin also showed significant reduction of days in ICU, days on mechanical ventilation and days in the hospital**
- **Veru submitted a request for emergency use authorization to FDA in June 2022**
- **Veru plans to request that Health Canada utliize the NDS-CV (a prioritized, COVID specific review and authorization submission) through the ACCESS Consortium regulatory pathway**

September 14, 2022 (Source) – Valeo Pharma Inc. (TSX: VPH) (OTCQB: VPHIF) (FSE: VP2) ("**Valeo**" or the "**Company**"), a Canadian pharmaceutical company, announced today that it has entered into

a Commercial Services Agreement with Veru Inc. (**Veru**) for sabizabulin for COVID-19 in Canada. Sabizabulin is a novel dual antiviral and anti-inflammatory agent being targeted for the treatment of hospitalized moderate-severe COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS) and death.

“Provincial healthcare systems across the country are still battling with high numbers of COVID-19 hospitalized patients and related deaths. In a pivotal Phase 3 study, sabizabulin demonstrated a statistically significant and clinically meaningful 55.2% reduction in deaths compared to placebo. It also showed a significant reduction of days in ICU, days on mechanical ventilation and days in hospital,” said Steve Saviuk, CEO, Valeo. “Veru plans to pursue an expedited review process with the Canadian healthcare authorities with the objective of making sabizabulin available in Canada at the earliest time possible.”

The sabizabulin Phase 3 COVID-19 clinical trial was a double-blind, randomized, placebo-controlled trial conducted in 204 hospitalized COVID-19 patients with moderate to severe COVID (≥ 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 halted the study 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 of the Phase 3 COVID-19 study have been published in *The New England Journal of Medicine (NEJM) Evidence*.

In June 2022, Veru submitted a request for emergency use authorization to the US FDA. Veru will be working with Health Canada and plans to submit its application via the "NDS CV" submission type – which has been created for New Drug Submissions (NDSs) that seek approval on the basis of any of the specific requirements including COVID (CV). Veru will be requesting that Health Canada utilize the ACCESS Consortium regulatory pathway which supports increased harmonization across a number of global health authorities.

About Veru

Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate cancers.

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin. Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

About Valeo Pharma Inc.

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.

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