Dr. Reddy's and Pharmazz, Inc. enter into licensing agreement to market first-in-class Centhaquine (Lyfaquin®) for hypovolemic shock in India

- *Centhaquine is a first-of-its-kind resuscitative agent to treat hypovolemic shock by increasing stroke volume and cardiac output due to an increase in (preload) venous blood return to the heart and a decrease in (afterload) due to arterial dilatation*
- *India is the first global territory in which Centhaquine (Lyfaquin®) is being launched immediately*
- *The partnership marks Dr. Reddy's latest strategic collaboration to bring innovative products and novel molecules to India*

Hyderabad, India; March 22, 2024 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; hereafter referred to as "Dr. Reddy's"), a global pharmaceutical company, has entered into a license agreement with Pharmazz, Inc. ("Pharmazz"), a U.S. based biopharmaceutical company developing and commercialising drug products to treat critically ill patients, to commercialise the first-in-class innovative drug Centhaquine in India. Developed by Pharmazz, Centhaquine is a resuscitative agent presently indicated for the treatment of hypovolemic shock by the Drugs Controller General of India (DCGI).

As per the agreement, Dr. Reddy's has received exclusive rights to market and distribute Centhaquine in India. Pharmazz will be entitled to upfront payments and royalties. Dr. Reddy's will market the product under the brand name Lyfaquin®, which it shall own. In addition to India, Dr. Reddy's also receives marketing rights for Lyfaquin® from Pharmazz for Nepal.

M.V. Ramana, Chief Executive Officer, Branded Markets (India and Emerging Markets), Dr. Reddy's, said: *"The partnership with Pharmazz and launch of this first-in-class drug marks the latest in our effort to enter into strategic collaborations to bring novel molecules to India to meet genuine unmet patient needs. The clinical studies for Lyfaquin® have demonstrated significantly better and promising outcomes, making it as a potential add-on drug in the management of hypovolemic shock and enhancing the current standard of care for its treatment in India."*

Dr. Prof. Anil Gulati, M.D., Ph.D., inventor, CEO, and Chairman of the Board of Directors of Pharmazz, said: *"India's emergence as a hub for developing and introducing innovative medicines is a remarkable achievement. It reflects the country's growing capabilities in research and development within the pharmaceutical sector. It is a large step for Pharmazz to partner with Dr. Reddy's, a leading global pharmaceutical company from India. For patients with hypovolemic shock, I believe Dr. Reddy's is the best partner for Pharmazz to market Centhaquine, an innovative, first-in-class novel resuscitative agent, in India."*

Hypovolemic shock is a life-threatening and often a fatal condition[1]. Severe loss of blood or fluids due to traumatic haemorrhage, postpartum haemorrhage, gastrointestinal bleeding, post-surgical bleeding, diarrhoea or vomiting can cause hypovolemic shock, which may lead to multi-organ failure and death. India has a high prevalence of these conditions and high mortality due to these conditions[2]. Data from various Indian studies and registries suggests a mortality rate of around 10 to 15% in traumatic haemorrhages despite the existing standard of care[3]. This suggests a need for a novel resuscitative agent which can improve the existing standard of care.

About Centhaquine (Lyfaquin® in India): Centhaquine is a frontline therapy used along with the standard of care and is well-positioned to a critical unmet need as a pharmacologically active resuscitative agent. A decrease in the volume of blood circulation from blood or fluid loss due to trauma, gastrointestinal bleeding, major surgery, postpartum hemorrhage, diarrhea, or vomiting can cause hypovolemic shock. About 1.9 million people worldwide die because of hemorrhagic shock every year, most dying within the first 6 hours. Centhaquine activates venous alpha2B adrenergic receptors to increase cardiac preload and activates central alpha2A adrenergic receptors to decrease cardiac afterload. Thereby, Centhaquine converts the venous unstressed blood volume to stressed blood volume and improves cardiac output and blood circulation, making it an ideal candidate for the resuscitation of patients with hypovolemic shock.

Centhaquine was approved in India by Drugs Controller General of India following a successful phase III clinical trial. The results of are published in a manuscript entitled "A Multicentric, Randomized, Controlled Ph III Study of Centhaquine (Lyfaquin®), as a Resuscitative Agent in Hypovolemic Shock Patients". The manuscript is published in DRUGS and is available at: https://link.springer.com/article/10.1007/s40265-021-01547-5

Pharmazz received permission from the U.S. Food and Drug Administration (FDA) to conduct a Phase III clinical trial of centhaquine in hypovolemic shock patients. It assesses the safety and efficacy of centhaquine in patients with hypovolemic shock. The Phase III randomized double-blind, placebo-controlled study will be conducted in 430 patients where patients will receive either an intravenous infusion of 0.01 mg/Kg of centhaquine or a placebo. All patients will receive the standard of care. A 28-day all-cause mortality is the primary endpoint.

Currently, Centhaquine is also under development for septic shock.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com.

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About Pharmazz Inc: Pharmazz is a privately held company developing novel products in critical care medicine. Pharmazz, Inc. obtained marketing authorization for two of its first-in-class drug molecules, Centhaquine and Sovateltide, for hypovolemic shock and ischemic stroke, respectively, in India. In addition, the U.S. Food and Drug Administration (FDA) has approved two phase III INDs for Centhaquine as an agent for hypovolemic shock and Sovateltide for cerebral ischemic stroke. Additional information may be found on the Company's website, www.pharmazz.com.

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[1] https://researchoutreach.org/articles/centhaquine-new-resuscitative-agent-haemorrhagic-shock/
[2] Road Accidents in India 2021, Govt. of India. Ministry of Road Transport and Highways/Health Management Information System, MOHFW, Govt. of India/ National Family Health Survey (NFHS 4), MOHFW, Govt. of India/Maternal and Child Health in India, MOHFW, Govt. of India/National Health Profile 2019, 14th issue, GovPostpartum Hemorrhage; a Major Killer of Woman: Review of Current Scenario. ObstetGynecol Int J 2016; 4(4): 00116.
[3] Indian J Crit Care Med.2016;20(4):216–25./World J Surg. 2021;45(2):380–9.

and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2023. The company assumes no obligation to update any information contained herein.