

VRL/SEC/EXCHANGE

17.04.2025

<b>National Stock Exchange of India Ltd.</b> 5 <sup>th</sup> Floor, Exchange Plaza Bandra (E), <b>Mumbai- 400 051</b>	<b>BSE Limited</b> 25 <sup>th</sup> Floor, Phiroze Jeejeebhoy Towers Dalal Street Mumbai <b>Script Code: 526953</b>
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**Sub.: Intimation under Regulation 30 of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015.**

**Ref.: US FDA Grants Qualified Infectious Disease Product Designation to Venus Remedies' VRP-034, a Novel Polymyxin B Formulation**

Dear Sir/ Madam,

Pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, kindly find enclosed herewith is a press release being issued by the Company on the captioned subject.

Kindly take the above information on your record.

Thanking you.

**Yours faithfully,  
for VENUS REMEDIES LIMITED**

**(Authorized Signatory)**

## **VENUS REMEDIES LIMITED**

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## PRESS RELEASE

### US FDA Grants Qualified Infectious Disease Product Designation to Venus Remedies' VRP-034, a Novel Polymyxin B Formulation

- VRP-034 is a novel supramolecular cationic (SMC) formulation of polymyxin B sulphate, uniquely developed to mitigate the nephrotoxic effects associated with conventional polymyxin B (PMB) therapy
- Key preclinical findings for VRP-034 included up to 70% reduction in nephrotoxicity compared to marketed PMB
- The QIDP designation by the United States Food and Drug Administration (US FDA) underscores the urgent global need for safer polymyxin-based therapies

**India, April 17, 2025**-- Venus Remedies Limited (NSE: VENUSREM, BSE: 526953), a leading pharmaceutical company specializing in critical care injectables, today announced that its investigational product **VRP-034** has been granted **Qualified Infectious Disease Product (QIDP)** designation by the United States Food and Drug Administration (US FDA) for the treatment of bloodstream infections caused by polymyxin B (PMB)-susceptible strains in adults.

Developed by Venus Medicine Research Centre (VMRC), the R&D division of Venus Remedies, VRP-034 is a novel supramolecular cationic (SMC) formulation of polymyxin B sulphate, uniquely developed to address the nephrotoxic effects associated with conventional polymyxin B therapy.

The QIDP designation, granted under the Generating Antibiotic Incentives Now (GAIN) Act, provides VRP-034 with significant regulatory benefits, including priority review, eligibility for fast track designation, and an additional five years of market exclusivity upon approval in the United States.

"Receiving QIDP designation for VRP-034 is a pivotal milestone in our efforts to combat antimicrobial resistance," said **Saransh Chaudhary**, CEO, Venus Medicine Research Centre. "QIDP recognition for VRP-034 underscores the urgent global need for safer polymyxin-based therapies and validates the strength of our scientific approach."

Venus Remedies' has developed the novel polymyxin-B formulation, VRP-034, using its proprietary Renal Guard technology. The company utilized kidney-on-a-chip technology (based on Organ-on-a-Chip model) to study established kidney injury biomarkers, including KIM-1, cystatin C, NAG, and NGAL, in response to polymyxin-B, an antibiotic used against multidrug-resistant Gram-negative bacteria. These insights directly contributed to the refining of its Renal Guard technology, forming the foundation of the novel formulation, VRP-034, designed specifically to minimize nephrotoxicity while preserving therapeutic efficacy.





Polymyxins, particularly PMB and colistin, are among the last-resort antibiotics used against Multidrug resistance (MDR) infections. However, their clinical use is severely limited by nephrotoxicity, which affects up to 60% of patients. VRP-034 offers a novel solution by preserving the pharmacokinetics and pharmacodynamics of PMB while significantly reducing oxidative stress and renal cell injury, as demonstrated in multiple *in vitro* and *in vivo* studies.

Key preclinical findings for VRP-034 include:

- Up to 70% reduction in nephrotoxicity compared to marketed PMB
- Robust efficacy against resistant pathogens in both *in vitro* and animal models
- Favorable safety profile across multiple toxicity studies using advanced renal biomarkers and human organ-on-a-chip models

This recognition by the US FDA strengthens Venus Remedies' commitment to innovation in the fight against AMR and underlines the company's dedication to addressing unmet needs in infectious disease therapy.

