

112/LG/SE/MAY/2023/GBSL

May 30, 2023

To,
BSE Limited,
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort, Mumbai - 400 001
Scrip Code: 509079

To,
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex,
Bandra (E), Mumbai - 400 051
Scrip Symbol: GUFICBIO

Dear Sir/Madam,

Sub.: Press Release - Gufic receives DCGI nod for Dalbavancin API and formulation

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

The same is submitted for public dissemination and for your record.

Thanking You,

Yours truly,

For Gufic Biosciences Limited

Ami Shah
Company Secretary & Compliance Officer
Membership No. A39579

Encl.: As above



GUFIC RECEIVES DCGI NOD FOR DALBAVANCIN API AND FORMULATION

Gufic Biosciences Limited (Gufic) have received approval from the Drug Controller General of India (DCGI) for both Dalbavancin API and Formulation which shall be used in the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adult patients caused by susceptible isolates of certain Gram-positive microorganisms Dalbavancin was developed with a purview of improved alternative to the currently available glycopeptides like Teicoplanin and Vancomycin, which are common intravenous agents for ABSSSI associated with Methicillin Resistant Staphylococcus aureus (MRSA). This molecule will add value to therapeutic armamentarium in Gufic's anti-microbial portfolio.

Additionally, Gufic has applied for a process patent for the injection formulation of Dalbavancin in India. Dr. Adarsh Shetty, General Manager – Medical Affairs at Gufic emphasized Gufic's unwavering dedication and resolve, stating “Gufic has been relentlessly committed to saving and improving lives. We will continue to work and put our efforts with regulatory agencies on our applications and do everything we can to bring novel molecules to surpass the developing resistance and infections,”. As the resistance to Dalbavancin is rare (<1% of isolates) this molecule will undoubtedly comply the dearth of current and upcoming strategy in management of infections.

About Dalbavancin

“Dalbavancin is a novel 2nd generation glyco-lipopeptide, with broad-spectrum activity against gram-positive organisms, including some of the more resistant isolates. Its unique pharmacokinetic profile, ease of use and excellent safety profile should be a valuable addition to the antimicrobial armamentarium used to treat infections because of gram-positive infections” said Mr. Mitesh Patel, Research Head-Formulation & Development at Gufic.

Dalbavancin in ABSSSIs has positive effect when implemented in community hospital settings due to its once-a-week dosing for outpatient treatment of patients. In Phase 3 trial named The Diverse, an early clinical response was seen in 84.4% patients treated with Dalbavancin compared to 83.5% in the Vancomycin–Linezolid group. Wherever the long-term venous access and outpatient parenteral antibiotic therapy (OPAT), is required it can stand out as an effective molecule. The use in such cases allows earlier hospital discharge, thus reducing the length of stay and cost. The safety of Dalbavancin is well established in multiple studies, said Dr. Adarsh Shetty.

About Gufic

Gufic is engaged in the Research and Development, manufacturing, marketing, distribution and sale of pharmaceutical and allied products. Gufic is known and respected for innovative and high quality pharmaceutical and Herbal products along with a wide range of Active Pharmaceutical Ingredients (APIs). Gufic is one of the fastest growing company among the top 100 pharma companies in India and is also one of the largest manufacturers of Lyophilized injections in India having a fully automated lyophilization plant. The lyophilized products are available in Therapeutic areas like Antibiotic, Antifungal, Cardiac, Infertility, Antiviral and Proton-Pump Inhibitor (PPI). Gufic is now augmenting its global focus by deepening the presence in the priority markets of India, Germany, Switzerland, South Africa, Russia, Canada, Europe and other key countries within the emerging market territories. Gufic aims at providing lifesaving drugs to people at affordable prices with no compromise in its quality. Gufic is a WHO-GMP, EU GMP, ANVISA Brazil, Russian GMP, Health Canada, Ukraine GMP, Australia TGA, Colombia INVIMA and Uganda NDA approved company with a total capacity of 48 million lyophilized vials per annum.