

41/LG/SE/APRIL/2022/GBSL

11th April 2022

To
The Manager (CRD)
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort, Mumbai - 400 001

To
The Manager
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex,
Bandra (E), Mumbai - 400 051

Scrip Code : 509079

Symbol : GUFICBIO

Dear Sirs,

Sub: Press Release - Gufic receives permission from CDSCO to manufacture and sale Isavuconazonium Sulfate API and Finished formulation Isavuconazole for Injection 200 mg/vial

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

The same is submitted for public dissemination and your records.

Thanking You,

Yours Faithfully,

For Gufic Biosciences Limited



Ami Shah
Company Secretary
Membership No. A39579



Encl: As above



GUFIC RECEIVES PERMISSION FROM CDSCO TO MANUFACTURE AND SALE ISAVUCONAZONIUM SULFATE API AND FINISHED FORMULATION ISAVUCONAZOLE FOR INJECTION 200 MG/VIAL

Gufic Biosciences Limited (Gufic) have received permission from Central Licensing Approving Authority, Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare for manufacture, sale and distribution of Isavuconazonium Sulfate API and finished formulation Isavuconazole for Injection 200 mg/vial. Isavuconazole for Injection 200 mg/vial is indicated for the treatment of patients having 18 years of age and older for the treatment of Invasive Aspergillosis and Invasive Mucormycosis

About Isavuconazole

Isavuconazole is a systemic antifungal drug of triazole class. The drug is used for the treatment of Invasive Aspergillosis and Invasive Mucormycosis in patients of 18 years of age and older. Isavuconazole has already been approved by US-FDA on March 06, 2015 and European Medicines Agency (EMA) on October 15, 2015. It has activity against Aspergillus, Mucorales and other rare mould infections, enabling physicians to treat the patients without a confirmed diagnosis. Isavuconazole has comparable efficacy, and is well tolerated, when compared to current treatments options. It has proven efficacy in invasive aspergillosis and mucormycosis, with better survival rates. Isavuconazole has a broad spectrum of activity, comparable efficacy, favourable safety profile, improved ease-of-use, which means that it is a valuable treatment option for those with possible invasive aspergillosis or mucormycosis, particularly in patients who may be immunocompromised, taking multiple therapeutic agents and/or unable to tolerate treatment with high organ toxicity.

About Invasive Fungal Infections (IFIs)

The incidence of IFIs has been increasing over the past few decades and represents a significant problem in immunocompromised individuals and a large proportion of critically ill patients. The changing epidemiology with increasing numbers of immunocompetent hosts includes the cases following natural disasters and large iatrogenic inoculation. This is attributed primarily to the overall increase in the number of patients irrespective of severe immunosuppression such as acquired immunodeficiency syndrome (AIDS), haematological malignancies, organ transplantation, etc. or apparent immunocompetent status with diabetes mellitus, chronic obstructive pulmonary disease (COPD), etc. The overall IFI incidence rate varies from 3% to 20%. The ongoing COVID pandemic has also brought the focus back on superinfections caused by secondary IFIs. Opportunistic pathogens such as Candida sp., causing candidiasis, Aspergillus sp., causing Aspergillosis and Mucorales causing Mucormycosis (Black Fungus) are the most common causative agents of these infections. Mucormycosis and Aspergillosis typically affect the immunocompromised or already critically ill individuals, both infections can be highly fatal, with mortality rates approaching 90%. The prevalence of mucormycosis is around 70 times higher in India than it is globally. Diabetes mellitus is the most common risk factor, followed by haematological malignancy and solid-organ transplant. Invasive aspergillosis and mucormycosis are also associated with lengthy hospital stays, and impose substantial healthcare costs, driven by prolonged treatment and management of treatment-related adverse events (AEs). This increases mortality rates and contributes to the economic burden of invasive aspergillosis and mucormycosis. There are only a limited number of approved therapies for the treatment of invasive aspergillosis and mucormycosis.

The second wave of COVID-19 in early 2021, had caused devastating chaos in India. Mucormycosis an invasive fungal infection in COVID patients had posed a big challenge towards the medical fraternity and a high death rate was reported in this scenario. There was an urgent need of an effective antifungal drug to fight this life-threatening condition. "It has become the need of the hour to have an effective and safe drug in the antifungal category to fight invasive fungal infections, we are optimistic that Isavuconazole will serve this purpose. Gufic has a unique legacy of bringing forward ground-breaking innovations in the field of infectious diseases and serving the mankind and improving lives. We are working relentlessly with regulatory authorities on our applications to do our best to bring innovative medicines to patients rapidly", said Mr. Nagesh Y, Chief Operating Officer of Gufic.

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 amongst the top 100 pharma companies in India and is also one of the largest manufacturers of Lyophilized injections in India and have a fully automated lyophilisation plant. Gufic's lyophilized product are available in Therapy areas like Antibiotic, Antifungal, Cardiac, Infertility, Antiviral and proton-pump inhibitor (PPI). Gufic is now augmenting its global focus by deepening its 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, Philippines-BFAD, Nigeria-NAFDAC, Cambodia-MOH, Kenya-PPB, Ethiopia-FMHACA, Thailand-MOH, Sri Lanka-NMRA, 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.