GUFIC
BIOSCIENCES LIMITED

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5th April 2022

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

Scrip Code : 509079

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

Symbol : GUFICBIO

Dear Sirs,

Sub: Press Release - Gufic receives DCGI nod for Thymosin Alpha - 1

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

GUFIC BIOSCIENCES LIMITED MUMBAI

Encl: As above

GUFIC RECEIVES DCGI NOD FOR THYMOSIN ALPHA - 1

Gufic Biosciences Limited (Gufic) have received DCGI approval for Thymosin Alpha-1 **(Immunocin α - A Brand of Gufic for the said drug)** as an add-on therapy for the treatment of moderate-to-severe COVID-19 patients requiring ventilator support (NIV as well as Mechanical Ventilation). **Immunocin α** , an Immuno-modulator drug, significantly reduced the risk of death in the Phase 3 Clinical trial in adult patients with moderate-to-severe COVID-19.

The medical armamentarium urgently needs many more tools to fight the COVID-19 pandemic, which is a leading cause of mortality and a strain on the social wellbeing and healthcare system all around the world. "Looking at the convincing results, we are optimistic that **Immunocin α** can become an important drug amongst the global efforts to fight the COVID-19 pandemic and will add to Gufic's unique legacy of bringing forward breakthroughs in infectious diseases when they are needed most. Gufic has been relentlessly committed to saving and improving lives. We will continue to work with regulatory agencies on our applications and do everything we can to bring novel molecules to patients as quickly as possible," said Dr. Adarsh Shetty, General Manager - Medical Affairs of Gufic. As the virus is still circulating widely and the therapeutic interventions available to people with COVID-19 are limited, **Immunocin α** will prove to be a valuable addition to the treatment regime of COVID-19.

More about **Immunocin α Phase 3 Study**

Immunocin α Phase 3 Study was a, Multi-centric, Randomized, Placebo-Controlled, Double-Blind study in hospitalized adult patients with laboratory-confirmed moderate-to-severe COVID-19. The primary objective of the study was to assess and compare the efficacy of Thymosin α-1 (Tα1) in combination with Standard of Care Treatment (SOC) versus placebo with SOC. The clinical results are as summarized below

1. All the first 105 patients who had taken at least one dose of study medication were taken into analysis. This study was designed to explore efficacy of **Immunocin α** as a primary objective, in patients with moderate and severe COVID-19.
2. Statistically significant (p value - 0.03) difference between two arms has been observed with respect to all cause mortality, where **Immunocin α** Arm has 11.1% Death rate compare to 38.5% in Placebo Arm, with absolute risk difference of 27.4%.
3. 96% patients in study arm have shown improvement after 7 days of treatment with **Immunocin α** along with SOC in WHO's 8 point Ordinal score Vs 57% in placebo arm group.
4. WHO Ordinal scale Comparison of the mean change from baseline on both arms shown to be statistically significant for moderate and severe COVID-19 (p-value Moderate- 0.002, Severe-0.001).
5. **Immunocin α** treatment compared to placebo, has shown 2 days less hospitalization and 4 less ventilator days in moderate and severe COVID-19 patients respectively.

About Thymosin α-1

Thymosin α 1 (**Immunocin α**) is an endogenous polypeptide hormone secreted by thymic epithelial cells. As an immunomodulatory therapy, Thymosin α 1 has been investigated in many diseases involving immune dysfunction (such as sepsis, cystic fibrosis, and hepatitis viral infection) and is associated with an improved patient outcome. Thymosin α 1 increase T cell numbers by promoting T cell development and proliferation, enhance their function and prevents & corrects lymphopaenia.

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 and have a fully automated lyophilization 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.