Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Date: October 16, 2024

To,

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Ltd.
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
Mumbai-400 051

Dear Sir/Madam,

Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Shilpa Medicare Limited ("SML")'s CDMO customer receives Fast-Track Designation for its investigational drug candidate

One of SML's, NASDAQ listed US based, CDMO customers has announced that its investigational drug candidate for treatment of Glioblastoma (GBM) has been granted Fast Track Designation by the USFDA. The drug is currently in a Phase 1A clinical trial designed to evaluate the safety and tolerability of the synthetically lethal investigational drug candidate in a broad range of solid tumors, including GBM. A phase 1b/2a clinical trial for recurrent GBM is targeted to start in late 2024/early 2025.

About GBM
GBM affects nearly 13,000 patients annually in the US and approximately 300,000 globally, with a mortality rate of 94%. Current standard of care therapies result in a life expectancy in GBM patients of less than 15 months. A major limitation to development of new drugs in the treatment of GBM is the need for potential drugs to have the ability to cross the blood brain barrier (BBB) as well as the ability to counteract the inherent and adaptive resistance of GBM cancer cells to the current standard of care in GBM. This resistance is largely derived from the expression of the DNA repair enzyme MGMT. The activity of drug under development is agnostic to MGMT expression, meaning it does not depend on the under or over-expression of MGMT in GBM and has shown in-vivo, preclinical activity in both types of GBM models.

No new drug for GBM has been approved in over two decades. The drug under development demonstrates synthetic lethality when combined with agents that cause DNA damage repair deficiency. Additionally, the drug under development has shown that it causes double-stranded breaks in the DNA of recurrent GBM (rGBM) cancer cells in multiple in-vivo models and is currently being advanced in early clinical stage studies.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

SML has partnered with the customer to provide **end-to-end solution for development of API and formulation for this challenging drug where no drug of choice has been developed for over two decades**. SML along with its 100% subsidiary Shilpa Pharma Lifesciences Limited ("SPL") has already completed the developmental quantities and are now working on GMP grade material. SML is currently the only partner with whom the customer is working on the project.

For Shilpa, this is the **second CDMO contract where the partner has received Fast Track Designation for its product review, showcasing Shilpa's capabilities of developing difficult molecules addressing un-met patient needs**. The FDA's Fast Track process is designed to facilitate development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients sooner.

About Shilpa:
Shilpa is an integrated pharmaceutical group with business interests in niche Oncology & Non-oncology APIs, Peptides, Polymers, differentiated finished dosage formulations including orally dispersible films & transdermal patches along with carefully crafted biological portfolio. Shilpa also provides end-to-end CDMO services to global pharmaceutical companies across all its business segments based on its strong R&D and manufacturing capabilities backed by four R&D units and seven manufacturing facilities.

For SHILPA MEDICARE LIMITED

RITU TIWARY

Digitally signed by RITU TIWARY
Date: 2024.10.16 14:14:28 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer