November 14, 2022

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
Scrip code: 532531

The National Stock Exchange of India Limited
Exchange Plaza, Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051
Scrip code: STAR

Dear Madam/ Sir,

Sub: Press Release

Please find attached Press Release issued by the Company titled:

"Stelis receives a positive recommendation from European Medicines Agency (EMA) granting market authorization for KaulivTM, a recombinant human teriparatide biosimilar to treat osteoporosis."

Thanks & Regards,
For **Strides Pharma Science Limited,**

MANJULA RAMAMURTHY
Digitally signed by MANJULA RAMAMURTHY
Date: 2022.11.14 08:08:28 +05'30'

Manjula Ramamurthy
Company Secretary

Encl. As above

PRESS RELEASE

Stelis receives a positive recommendation from European Medicines Agency (EMA) granting market authorization for Kauliv™, a recombinant human teriparatide biosimilar to treat osteoporosis.

- ⇒ ***Kauliv™ is the first In-house biosimilar product developed by Stelis Biopharma.***
- ⇒ ***A biosimilar to Forsteo® (Innovator Product), which leads the treatment of osteoporosis market and remains a gold standard with over $800 million in world sales for 2021.***
- ⇒ ***Stelis has already licensed Kauliv™ across 20 markets worldwide and will commence commercial sales starting FY24 as country-specific registrations complete.***

Bengaluru, India, 14 November 2022: Stelis Biopharma Limited (Stelis or Company), the biologics arm of Strides Pharma Science Limited (Strides, BSE: 532531 NSE: STAR), today announced that its product division Biolexis has a major success with its first biosimilar product Kauliv™ receiving a positive recommendation from European Medicines Agency (EMA) for granting of market authorization. Kauliv™ is a recombinant human teriparatide injection intended for the treatment of osteoporosis.

The Company informed that EMA's Committee for Medicinal Products for Human Use (CHMP) had adopted a positive opinion, recommending granting marketing authorization for Kauliv™ on November 11, 2022.[1]

Kauliv™ is a biosimilar to Forsteo® (innovator product), indicated for both men and postmenopausal women with osteoporosis who are at high risk for having broken bones or fractures. The product is developed on a recombinant *Escherichia coli* host platform, similar to the innovator. Kauliv™ provides reusable and disposable pen[2] device options to cater to the global market demand. Forsteo® (innovator product) is currently the market leader among the treatment options of bisphosphonates and Selective Estrogen Receptor Modulators (SERMs) and remains a gold standard drug for the treatment of osteoporosis with >$800 million global sales in a total market size of >$1.5 billion.

Kauliv™ will be available as a 20 µg/80 µl solution for injection. At the molecular level, teriparatide binds to the human parathyroid hormone receptor with a similar affinity as the human parathyroid hormone and effect a similar molecular signaling mechanism to act on bone metabolism.

For the European markets, Kauliv™ will utilize a 'CE' marked reusable pen device developed based on the clinically proven Autopen® platform by Owen Mumford Limited (a United Kingdom-based medical device design and manufacture company).

Stelis will manufacture this product at its USFDA and EU authority-approved facilities in Bangalore, India, and will scale the opportunity globally through a B2B model. The Company has already licensed Kauliv™ across 20 countries, and the commercialization of the product will generate incremental revenues for Company starting FY24 after country-specific registrations are completed.

About Stelis

Stelis Biopharma Limited (Stelis) is an emerging global biopharmaceutical CDMO with a complete, integrated, end-to-end offering. The Company also operates a product division (operated under Biolexis Private Limited) where it is building a portfolio of leading biologics and biosimilar products with cost leadership through efficient processes and low-cost devices. The Company endeavors to attain leadership in commercializing its portfolio of products with a high focus on quality, affordability, and accessibility. Biolexis has a proprietary platform technology to develop and commercialize recombinant insulin and insulin analogs with high purity and consistent quality. The current programs of the Company include Rh-Teriparatide (biosimilar to Forteo® and Forsteo®), Insulin glargine (biosimilar to Sanofi's

[1] https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-7-10-november-2022
[2] *Currently, the positive recommendation from EMA referred to above is for the reusable pen*

Lantus®), Insulin Lispro (biosimilar to Eli-Lilly's Humalog®), Insulin Aspart (biosimilar to Novo Nordisk's Novolog®), and a recently filed peptide for diabetes. Biolexis will operate as a standalone products business and is being carved out from Stelis, which will only operate as a pure-play CDMO business.

About Strides

Strides, a global pharmaceutical company headquartered in Bengaluru, India, is listed on the BSE (532531) and National Stock Exchange of India Limited (STAR). The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy and an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India (Chennai, Puducherry, and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi), and the United States (New York). The Company focuses on "difficult to manufacture" products sold in over 100 countries. Additional information is available at the Company's website at www.strides.com.

For queries related to Stelis, feel free to write to ankit@stelis.com

For questions about Strides, please reach out to Sandeep.baid@strides.com