



March 17, 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:

**“Akston Biosciences and Biolexis Collaborate to Launch a
Room Temperature Stable 2nd Generation COVID-19 Vaccine in 130+ Countries”**

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

Manjula Ramamurthy
Company Secretary



Encl. As above

Strides Pharma Science Limited

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Akston Biosciences and Biolexis Collaborate to Launch a Room Temperature Stable 2nd Generation COVID-19 Vaccine in 130+ Countries

- ⇒ ***Biolexis has in-licensed AKS-452, a room temperature stable COVID-19 vaccine developed on Akston's proprietary Fc fusion protein platform***
- ⇒ ***Biolexis will launch AKS-452 as "AmbiVax-C™" for global markets where the cold chain elimination would contribute to improving immunization coverage and reducing vaccine wastage***
- ⇒ ***Phase I and II studies of AmbiVax-C™ were completed in the Netherlands with greater than 90% seroconversion and a favorable safety profile***
- ⇒ ***AmbiVax-C™ is currently undergoing clinical trials in India for Emergency Use Authorization (EUA) as a prime vaccine followed by planned studies for booster shot approval***

BEVERLY, Massachusetts, and BANGALORE, India – March 17, 2022 – Akston Biosciences Corporation, a developer of new classes of biologic therapeutics, and Biolexis, a division of Stelis Biopharma Limited (Stelis), announced today that they have entered into a licensing, manufacturing and commercialization agreement for Akston's AKS-452, a protein subunit COVID-19 vaccine. Under the agreement, Biolexis gains the right to manufacture and commercialize AKS-452 (branded as AmbiVax-C™) in India and over 130 countries in Asia, Latin America, and Africa largely covering the low-and-middle-income countries (LMICs). Biolexis will also leverage the capabilities of Strides Group for launching this vaccine across regions where the group has a deep market presence and established relationships.

AKS-452 or AmbiVax-C™ is a first-of-its-kind thermostable COVID-19 vaccine developed for all parts of the world. AmbiVax-C™ is a SARS-CoV-2 protein subunit vaccine designed to induce a Th1/Th2 mixed immune response in patients against the Receptor Binding Domain (RBD) of the novel coronavirus spike protein. As the primary locus for infection, the RBD is highly conserved among mutated forms of the virus. The studies on AmbiVax-C™ have demonstrated robust antibody neutralization of variants, including Delta and Omicron, and the vaccine has been evaluated in multiple safety and efficacy studies in Netherlands and India across hundreds of subjects.

AmbiVax-C™ does not include mRNA technology, viral vectors, or a weakened SARS-CoV-2 virus and has been engineered to use established, low-cost antibody manufacturing techniques, such that a single production line could be capable of producing over one billion doses per year. AmbiVax-C™ is a two-shot vaccine injected over 28 days, with the first shot being supported by an adjuvant. The stability studies conducted on AmbiVax-C™ have demonstrated thermostability at room temperature for over six months at 25° Celsius (77° Fahrenheit) and maintains potency for one month at 37° Celsius (99° Fahrenheit). Being shelf-stable at these temperatures, AmbiVax-C™ has the potential to eliminate challenges in maintaining the cold chain, especially in low-and-middle-income countries where a significant population lacks dependable access to vaccines as a result of insufficient infrastructure to support the cold chain requirements of mRNA COVID-19 vaccines. AmbiVax-C™ would offer a flexible, reliable, and economically viable vaccine alternative in these regions, allowing the acceleration of immunization and longevity of immunity with the booster shots.

Commenting on the partnership, **Arun Kumar, Founder, Strides Group**, added, *"We are very excited to partner with Akston on AmbiVax-C™, which is a first-of-its-kind COVID-19 vaccine developed for all parts of the world. While the vaccine has demonstrated good outcomes with its safety profile and over 90% seroconversion in clinical and bridging studies, its room temperature stability offers a unique value to the global population, making it more accessible across the World. As AmbiVax-C™ expects to receive EUA as a prime vaccine in H1 of 2022, we will leverage our group capabilities to manufacture, fill-finish, and*

commercialize AmbiVax-C™ across all the markets. We also remain on course to get the vaccine qualified as a booster to itself and other approved vaccines in different regions.”

Todd Zion, Ph.D., President & CEO of Akston Biosciences, said, “We are very pleased to be working closely with Biolexis and Strides Group, which has the experience, know-how, and capability to produce our vaccine at scale. Just as importantly, the group can supply the vaccine to countries that need a practical and affordable way to protect their populations during this worldwide pandemic.”

AmbiVax-C™ has completed Phase I and II studies at the University Medical Centre Groningen (UMCG) in the Netherlands. The recent Phase II trial data showed a greater than 90% seroconversion rate after two 45 µg doses (100%) or a single 90 µg dose (96%) in healthy adults at 56 days. It was well tolerated with a safety profile comparable to approved vaccines.

An EUA determining Phase II/III clinical trial is currently underway in India for over 1,600 subjects. The bridging study of 100 subjects has already been completed with a favorable safety profile and greater than 90% seroconversion achieved on day 28 post two vaccines doses. Approval from the Subject Expert Committee (SEC) on vaccines of the Central Drugs Standard Control Organization (CDSCO), India, has been received to begin the dosing of the remaining 1,500 subjects. The studies are expected to conclude in April 2022 with a potential EUA within the H1 of 2022. Besides this, additional studies are also being pursued to qualify AmbiVax-C™ as a booster to itself or other approved vaccines.

About Akston Biosciences

Akston Biosciences Corporation leverages its novel fusion protein platform to develop and manufacture new classes of biologics, including vaccines, ultra-long-acting insulins, and autoimmune disease therapies. Founded by the team that developed the world’s first clinical glucose-responsive insulin at SmartCells, Inc. (sold to Merck & Co.), Akston has partnered with Dechra Pharmaceuticals PLC (DPH) to commercialize once-a-week canine and feline insulin therapies. It operates a GMP biologics manufacturing cleanroom facility and research laboratory at its Beverly, Mass. location. Additional information is available at www.akstonbio.com.

About Strides

Strides, listed on the BSE (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bengaluru, India. The Company mainly operates in the regulated markets, 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 www.strides.com.

About Stelis

Stelis Biopharma Limited (Stelis) is a leading global biopharmaceutical Contract Development and Manufacturing Organization (CDMO) with a complete and integrated end-to-end offering. It is equipped with a world-class Process Development (PD) and manufacturing infrastructure for both drug substance (mammalian and microbial-based therapeutic proteins, viral vectors) and drug product (lyophilized vials, liquid vials, pre-filled syringes, cartridges and devices). Stelis has three state-of-the-art facilities, with ~900,000 square feet of PD and manufacturing space. More details are available at www.stelis.com.

About Biolexis

Biolexis Private Limited (Biolexis) is an emerging biotech and vaccine company with the capabilities to develop and commercialize products for the Global markets. The Company is a wholly-owned subsidiary of Stelis and is focused on building and in-licensing a portfolio of advanced biosimilars, peptides, and vaccines. The Company endeavors to attain leadership in commercializing its portfolio of products with a high focus on quality, affordability, and accessibility. Besides in-licensing AmbiVax-C™ from Akston, 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 Lantus®), Insulin Lispro (biosimilar to Eli-Lilly's Humalog®), Insulin Aspart (biosimilar to Novo Nordisk's Novolog®), a recently filed peptide for diabetes and a novel anti-hemorrhoid.

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