



June 24, 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:

**“Biolexis and Akston Biosciences Announce Encouraging Top-Line Results from Phase II/III  
Trial of their Thermostable 2nd Gen COVID-19 Vaccine”**

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

A handwritten signature in blue ink that reads 'Manjula R.'.

**Manjula Ramamurthy**  
**Company Secretary**



Encl. As above

**Strides Pharma Science Limited**

CIN: L24230MH1990PLC057062

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## Biolexis and Akston Biosciences Announce Encouraging Top-Line Results from Phase II/III Trial of their Thermostable 2<sup>nd</sup> Gen COVID-19 Vaccine.

- ⇒ **Results of 100 subjects bridging study and 1,500 subjects placebo-controlled trial of Akston's AKS-452 announced.**
- ⇒ **Interim analysis shows a 91% seroconversion rate.**
- ⇒ **Statistically-significant high antibody titers were maintained for six months in the bridging study.**
- ⇒ **The vaccine was well tolerated, with no significant safety issues reported.**
- ⇒ **AKS-452 is shelf-stable for over six months at room temperature at 25° C and maintains potency for one month at 37° C.**
- ⇒ **Biolexis has licensed AKS-452 and plans to launch it as "AmbiVax-C™" in global markets.**
- ⇒ **Vaccine to be produced at Stelis Biopharma, the biotech CDMO division of Strides Group.**

**BEVERLY, Mass., and BANGALORE, India – June 24, 2022** – Akston Biosciences Corporation and Biolexis, a Strides Group Company, today announced results from a Phase II/III clinical trial in India of the SARS-CoV-2 vaccine, AKS-452, in which 1,600 healthy volunteers participated – 100 in an open-label bridging study and 1,500 in Phase II/III, double-blind, placebo-controlled trial.

An interim analysis of this data shows no significant safety issues and a 91% seroconversion rate at Day 56. Volunteers in the bridging study had antibody titers that persisted at statistically-significant high levels through six months, with serum taken from them showing protection against variants of concern. The results will be submitted as a prime vaccine in India for Emergency Use Authorization (EUA). Later clinical studies are planned to support approval for use as a booster shot to itself and other approved vaccines. Earlier studies in the Netherlands have demonstrated robust antibody neutralization of variants, including Delta and Omicron.

Akston and Strides group have already signed a licensing, manufacturing, and commercialization agreement to launch this vaccine worldwide as AmbiVax-C™. Under the agreement, Biolexis (The vaccine and biosimilar arm of Strides group) has the right to manufacture and commercialize AmbiVax-C™ in India and over 130 countries in Asia, Latin America, and Africa, mainly covering the low-and-middle-income countries (LMICs) where a significant population lacks dependable access to vaccines as a result of insufficient infrastructure to support the cold chain requirements of other COVID-19 vaccines. The vaccine is a reliable, accessible alternative in these regions, allowing immunization and longevity of immunity with the boosters against the Covid variants of concern. The partnership will leverage the capabilities of Strides Group, which has an "in Africa for Africa" strategy and will offer the vaccine to countries with a deep market presence and established relationships.

**Arun Kumar, Founder of Strides Group**, added, *"We are pleased to know the encouraging results from the India studies of AmbiVax-C™, particularly the high seroconversion rate that the Vaccine demonstrated. This vaccine differentiates itself by allowing room-temperature stability, higher efficacy, and safety and can offer accessibility and affordability through the economical supply chain and infrastructure requirements. As we progress to receiving the approval, we will continue exploring opportunities to fast-track its launch for the global markets."*

**Todd Zion, Ph.D., President & CEO of Akston Biosciences**, said, *"The latest clinical data demonstrate the potential of this low-cost protein vaccine intended specifically for those most in need. We are very pleased to be working closely with Biolexis and Strides Group, which can supply the vaccine at scale to*

*countries that need a practical and affordable way to protect their populations during this worldwide pandemic.”*

The Phase II/III trial, managed by Ahmedabad-based Veeda Clinical Research Limited, evaluated the safety, tolerability, and humoral immunogenicity profile, i.e., SP/RBD-specific IgG titers. Of the 1,500 healthy volunteers, 1,125 received the two 90 µg doses 28 days apart, with the first dose including AKS-452 and an adjuvant, while the second dose consisted of only AKS-452. The remaining 375 also received two doses, with the first dose including placebo and the adjuvant, while the second dose consisted only of placebo.

AKS-452 does not include mRNA technology, viral vectors, or a weakened SARS-CoV-2 virus. It 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. Stability studies have demonstrated thermostability at room temperature for over six months at 25° Celsius (77° Fahrenheit) and maintenance of potency for one month at 37° Celsius (99° Fahrenheit).

### **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. It was founded by the team that developed the world's first clinical glucose-responsive insulin at SmartCells, Inc. (sold to Merck & Co.). Besides out-licensing AmbiVax-C™ to Biolexis, 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](http://www.akstonbio.com).

### **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, has an “in Africa for Africa” strategy, and an institutional business to service donor-funded needs. 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](http://www.strides.com).

### **About Stelis**

Stelis Biopharma Limited (Stelis) is an emerging global biopharmaceutical CDMO with a complete and integrated end-to-end offering. It is equipped with world-class Process Development (PD) and manufacturing infrastructure for both drug substances (mammalian and microbial-based therapeutic proteins and other emerging modalities) and drug products (lyophilized vials, liquid vials, pre-filled syringes, cartridges, and devices). Stelis offers the complete spectrum of services, from cell line tech transfer to clinical and commercial manufacturing, with in-house capability to convert drug substances to stable formulations and fill and finish in all formats. Stelis has three state-of-the-art facilities, with ~85,000 square meters of PD and manufacturing space and over 800 highly talented professionals. Its facilities are highly automated to increase accuracy, efficiency, and speed at every process stage. Additional details are available at [www.stelis.com](http://www.stelis.com).

### **About Biolexis**

Biolexis Private Limited (Biolexis) is an emerging biotech and vaccine company capable of developing and commercializing 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.

**About Veeda Clinical Research Limited**

Veeda Clinical Research Limited ("Veeda") is one of the largest independent, full-service clinical research organizations headquartered in Ahmedabad, India. Veeda offers a range of bioequivalence studies and early and late phase clinical trials. Veeda has completed several regulatory inspections and is approved by USFDA, UK MHRA, ANVISA (Brazil), and WHO. Veeda has experience in conducting complex clinical studies. Visit <https://www.veedacr.com/>

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