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Stellar Achieves Robust Viral Clearance for Manufacturing Process

LOS ANGELES, May 24, 2018 /PRNewswire/ -- Stellar Biotechnologies, Inc. (Nasdaq: SBOT), a leading manufacturer of a key protein utilized in multiple immunotherapy development pipelines targeting Alzheimer's, lupus and cancer, among other diseases, today announced that third-party trial results have demonstrated that the company's KLH manufacturing methods achieve robust viral clearance. This clearance step is a key quality assurance milestone under Stellar's initiatives to increase the scalability and throughput capacity of its manufacturing processes.

Results from testing completed by Texcell, a contract testing organization for viral safety, demonstrated that Stellar's manufacturing process for its most widely used formulation effectively removes three representative viruses, and meets suggested regulatory criteria for robustness. While routine quality testing has never detected the presence of viruses in Stellar KLH, one of the principal approaches to control the potential presence of viruses in biological products is to purposely introduce viruses in a test environment and demonstrate the capacity of the production process to remove them.

Stellar Executive Vice President of Corporate Development, Gregory T. Baxter, PhD, said that the company aims to roll out manufacturing optimizations ahead of the next phase of its customers' clinical studies, and will continue to routinely test for viruses and validate the viral removal of its manufacturing processes as needed.

"KLH is a key component for the success of multiple immunotherapies under development and Stellar is committed to expanding our manufacturing capacity and validating our quality systems as our customers advance toward pivotal Phase 3 clinical studies," said Dr. Baxter.

To produce Stellar KLH, hemocyanin protein is extracted from its native source using Stellar's patented process and then purified and manufactured into various grades and formulations. Due in part to its controlled aquaculture source and manufacturing methods, Stellar KLH has been shown to produce a vigorous primary and secondary immune responses. Researchers interested in obtaining Stellar KLH, or obtaining technical specifications for research or GMP-grade KLH, may contact Stellar business development department at (805)488-2800 or KLHinfo@stellarbiotech.com.

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About Stellar Biotechnologies

Based north of Los Angeles at the Port of Hueneme, [Stellar Biotechnologies, Inc.](#)

(Nasdaq: SBOT) is the leader in sustainable manufacture of [Keyhole Limpet Hemocyanin \(KLH\)](#), an important immune-stimulating protein used in wide-ranging therapeutic and diagnostic markets. KLH is both a key pharmaceutical ingredient in many new immunotherapies (targeting cancer, immune disorders, Alzheimer's and inflammatory diseases) as well as a finished product for measuring immune status. Stellar is unique in its proprietary methods, facilities, and KLH technology. The company is committed to meeting the growing demand for commercial-scale supplies of GMP grade KLH, ensuring environmentally sound KLH production, and developing KLH-based active immunotherapies. Stellar KLH is a trademark of Stellar Biotechnologies.

Stellar Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," or "continue" and variations or similar expressions. Readers should not unduly rely on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from the forward-looking statements. Such risks include, but may not be limited to: general economic and business conditions; technology changes; competition; changes in strategy or development plans; availability of funds and resources; anticipated requirements for operating capital; governmental regulations and the ability or failure to comply with governmental regulations; changes in trade policy and international law; the timing of Stellar's or its partners' anticipated results, including in connection with clinical trials; the ability to meet the goals of Stellar's joint ventures and strategic partnerships; and other factors referenced in Stellar's filings with securities regulators. For a discussion of further risks and uncertainties related to the Stellar's business, please refer to Stellar's public company reports filed with the U.S. Securities and Exchange Commission and the British Columbia Securities Commission. All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, Stellar assumes no obligation to update such statements. This press release does not constitute an offer or solicitation of an offer for sale of any securities in any jurisdiction, including the United States.

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