Polynoma Receives Special Protocol FDA for a Pivotal Phase 3 Clinical Study of Assessment (SPA) Agreement from the U.S. Seviprotimut-L, a Melanoma Cancer Vaccine

Seviprotimut-L is in clinical development as a potential adjuvant treatment for patients 60 years and younger with Stage IIB or IIC melanoma

Polynoma's recently published clinical data from MAVIS in JITC supports further study of seviprotimut-L in Stage IIB/IIC melanoma, especially in younger patients and those with ulcerated melanomas

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SAN DIEGO, Jan. 11, 2022 /PRNewswire/ -- Polynoma LLC, a U.S. immuno-oncology focused biopharmaceutical company and wholly-owned subsidiary of Hong Kong-listed CK Life Sciences Int'l., (Holdings) Inc., today announced that it has reached an agreement with the U.S.
Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) on a pivotal Phase 3 clinical study of seviprotimut-L, Polynoma's melanoma cancer vaccine, for the adjuvant treatment of patients 60 years and younger with Stage IIB or IIC melanoma following de nitive surgical resection to improve recurrence-free survival. Seviprotimut-L previously received Fast Track designation from the U.S. FDA.

Final analysis of Part B1 data from Melanoma Antigen Vaccine Immunotherapy Study (MAVIS) was recently published in the *Journal for ImmunoTherapy of Cancer (JITC).* A subgroup analysis of patients receiving seviprotimut-L with AJCC Stage IIB/IIC melanoma, under age 60 with a median follow-up time of 45.8 months (3.8 years), showed clinically signi cant improvement in recurrence-free survival (RFS), reducing the risk of disease recurrence

or death by 68% (HR=0.32; 95% CI, 0.121, 0.864) compared to patients receiving placebo. Additionally, RFS was more favorable in patients under age 60 with ulcerated melanomas (HR 0.21; 95% CI:
0.065-0.702), and there was a trend toward improved overall survival (OS) (HR 0.34; 95% CI: 0.117, 0.975) for patients that received seviprotimut-L compared to those receiving placebo. Seviprotimut-L was extremely well tolerated, with adverse events (AEs) similar to patients that received placebo; there were no immune-mediated AEs or other treatment-related serious AEs observed.

"Vaccination with seviprotimut- L has an advantage of having very low toxicity, without signi cant immune-related adverse events and no signi cant increase in toxicity over placebo," said Craig L. Slingluff, Jr., MD, Professor of Surgery and Director of the Human Immune Therapy Center and lead author of the *JITC* research paper on MAVIS. "If de nitive evaluation of this vaccine therapy con rms clinical bene t in patients with Stage IIB/IIC melanoma, particularly those aged 60 and younger, the low toxicity of this approach will be a valuable option for these patients."

"This SPA agreement with the U.S. FDA for our planned pivotal trial provides important guidance for the regulatory path towards approval of seviprotimut-L as an adjuvant treatment in Stage IIB/IIC melanoma," said Alan Yu, Chairman of Polynoma and Vice President & Chief Executive Of cer at CK Life Sciences. "We believe results from this trial will support seviprotimut-L as the rst choice in treating younger patients with localized melanoma."

About FDA Special Protocol Assessment

The SPA process is a procedure by which the FDA provides a clinical trial sponsor with an of cial evaluation and written guidance on the design of a proposed protocol intended to form the basis for a new drug application. A SPA does not ensure the receipt of marketing approval or that the approval process will be faster than conventional regulatory procedures. Final marketing approval depends on ef cacy and safety results and an evaluation of the

overall bene ts and risks of treatment after review of the data from the development program in its totality. For more information on Special Protocol Assessments, please visit: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-protocolassessment-guidance-industry.

About MAVIS

MAVIS (Melanoma Antigen Vaccine Immunotherapy Study) is a multicenter, double-blind, placebo-controlled adaptive Phase 3 trial to assess the safety and ef cacy of seviprotimut-L, with primary endpoints of recurrence-free survival (RFS) and overall survival (OS) in patients with melanoma at high risk of recurrence after de nitive surgical resection. For additional information about the trial, please visit https://clinicaltrials.gov/ct2/show/NCT01546571.

About Seviprotimut-L

Seviprotimut-L is an allogeneic, polyvalent, partially puri ed shed melanoma antigen vaccine derived from three proprietary human melanoma cell lines. Seviprotimut-L stimulates humoral and cellular immune responses. Melanoma-associated antigens (MAAs) found in seviprotimut-L are taken up by antigen-presenting cells (e.g., dendritic cells) which then activate the production of antigen-speci c cytotoxic T-lymphocytes (CTLs) as well as develop antibody responses against MAAs. These CTLs and antibodies then recognize and act on tumor cells expressing the MAAs on their surfaces, causing cell death. Seviprotimut-L is currently in development for the adjuvant treatment of patients with Stages IIB and IIC melanoma, following de nitive resection.

About Polynoma

Polynoma LLC is a U.S. immuno-oncology focused biopharmaceutical company headquartered in San Diego, California. A wholly-owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc., Polynoma's lead asset is a novel polyvalent antigen vaccine, seviprotimut-L, for the prevention of recurrence of melanoma. The vaccine has been safely administered in more than 1,000 patients. For additional information, please visit www.polynoma.com.

About CK Life Sciences

CK Life Sciences Int'l., (Holdings) Inc. is listed on the Stock Exchange of Hong Kong (stock code: 0775). With a mission of improving the quality of life, CK Life Sciences is engaged in the business of research and development, manufacturing, commercialization, marketing, sale of, and investment in, products and assets which fall into three core categories: nutraceuticals, pharmaceuticals and agriculture-related. Regarding pharmaceutical research and development, CK Life Sciences' operations are focused on conducting research and development into cancer vaccines and pain management solutions. CK Life Sciences is a member of the CK Hutchison Group. For additional information, please visit www.cklifesciences.com.

About Melanoma

Skin cancer is one of the most commonly diagnosed cancers in the U.S. and around the world. Of those skin cancers, melanoma is the most serious and deadly form.[1] Historically, melanoma was a rare cancer, but in the last 50 years its incidence has risen faster than almost any other cancer and it is projected to continue to rise across the world.[2] In 2021, an estimated 106,110 new cases of melanoma will be diagnosed in the U.S. alone, and an estimated 7,180 people in the U.S. will die from the disease.[3] Globally, there are approximately 350,000 cases of melanoma and nearly 60,000 deaths a year.[4]

While it still represents less than 5% of all cutaneous malignancies, melanoma accounts for the majority of skin cancer deaths.[2] Most early skin cancers are diagnosed and treated by removal and microscopic examination of the cells. For melanoma, the primary growth and surrounding normal tissue are removed and sometimes a sentinel lymph node is biopsied to determine stage. Melanomas with deep invasion or that have spread to lymph nodes or distant organs may be treated with surgery, immunotherapy, chemotherapy, and/or radiation therapy.

Melanoma is the most diagnosed cancer among 25- to 29-year-olds in the United States and the third and fourth most common for 15- to 29-year-old males and females, respectively.[5] The majority of melanoma cases are diagnosed at a localized stage.[6,7] Stage IIB melanomas

are more than 2.0 millimeters and less than 4.0 millimeters thick, with ulcerated (broken) skin or more than 4.0 millimeters without ulceration. Stage IIC melanomas are more than 4.0 millimeters thick with broken skin/ulceration.

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