Polynoma Presenting Interim Phase III Data for Its Investigational Melanoma Vaccine, Seviprotimut-L, at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting

-- MAVIS Study Identifies Most Responsive Patient Subpopulations, Supporting the Continued Study of Adjuvant Treatment in Localized Melanoma Patients --

SAN DIEGO, November 6, 2019 – 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., is presenting clinical data from MAVIS (Melanoma Antigen Vaccine Immunotherapy Study), its ongoing Phase III clinical study of seviprotimut-L, an investigational melanoma vaccine candidate, on November 8 at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, Maryland.

MAVIS is a multicenter, double-blind, placebo-controlled adaptive Phase III trial to assess the safety and efficacy of seviprotimut-L, with primary endpoints of recurrence-free survival (RFS) and overall survival (OS) in patients with American Joint Committee on Cancer (AJCC) Stage IIB/C, IIIA, IIIB/C melanoma at high risk of recurrence after definitive surgical resection.

Highlights of the data presented include:

- **Improved outcomes in Stage IIB/C patients**: Interim analysis of subgroups suggested enhanced RFS for seviprotimut-L among those with AJCC stage IIB/IIC melanoma, as well as those under age 60.
- **Favorable adverse event profile:** Seviprotimut-L was well-tolerated with treatment-emergent adverse events (AEs) similar to patients given placebo.

Treatment of Stage IIB/IIC melanoma is primarily limited to surgery, coupled with a "wait and see" approach. However, recurrence of the disease can occur following definitive resection of the melanoma. Many patients progress to more advanced stages following resection and 5-year survival rates fall sharply after a patient passes from localized Stage II melanoma into regional Stage III disease (98.4% to 63.6%). Five-year survival rates are distinctly lower (22.4%) for metastatic Stage IV.[1]

"The passage from Stage II to Stage III melanoma marks a critical point in time where survival is severely threatened. We find this initial data from MAVIS to be extremely encouraging and validating," said Melvin Toh, Chief Technology Officer at Polynoma and Vice President & Chief Scientific Officer at CK Life Sciences. "With promising evidence of efficacy and safety as seen in this analysis, seviprotimut-L has the potential to be an important new option for the adjuvant treatment of patients with localized melanoma."

The preliminary data from MAVIS also suggest that seviprotimut-L could serve as a breakthrough in the vaccine-based treatment of melanoma, where to date, no other vaccine has proven successful.

"The data show that vaccines are a potentially important new class of immunotherapy for the treatment of stage IIB/IIC melanoma, after surgery," said Craig L. Slingluff Jr., MD, Professor of Surgery and Director of the Human Immune Therapy Center and co-leader of the Cancer Therapeutics Program of the UVA Cancer Center. "These promising efficacy and safety data support continuing the study of seviprotimut-L in melanoma, particularly in Stage IIB/C patients and those under the age of sixty."

FURTHER DETAILS ON POSTER PRESENTATION:

- **Abstract P367:** A multicenter, double-blind, placebo-controlled trial of seviprotimut-L polyvalent melanoma vaccine in post-resection melanoma patients at high risk of recurrence.
- **Authors:** Craig L. Slingluff, Jr., MD; Brent A. Blumenstein, PhD; Karl D. Lewis, MD; Robert H. Andtbacka, MD, CM, FACS, FRCSC; John Hyngstrom, MD; Mohammed Milhem, MBBS; Svetomir N. Markovic, MD, PhD; Omid Hamid, MD; Leonel Hernandez-Aya, MD PhD; Tawnya Bowles, MD; Prejesh Philips, MD; Joel Claveau, MD; Sekwon Jang, MD; Jose Lutzky, MD, FACP; Anna Bar, MD; Peter Beitsch, MD.

- **Session Date and Time**: Friday, November 8th from 7:00 a.m. - 8:00 p.m. Eastern Standard Time

The data presented assessed the treatment effects of seviprotimut-L in patients with AJCCv7 stage IIB-III cutaneous melanoma after surgical resection. 347 patients ages 18-75, ECOG PS 0-1, were enrolled and randomized 2:1 to seviprotimut-L 40 mcg or placebo, administered intradermally every 2 weeks x 5, then monthly x 4, then every 3 months to month 24. Patients were stratified by stage (IIB/C, IIIA, IIIB/C).

By intent-to-treat (ITT) analysis, RFS was not significantly enhanced for seviprotimut-L in the full study population but trended slightly higher. However, interim efficacy analysis of subgroups based on pre-planned stratification suggested enhanced RFS for seviprotimut-L among Stage IIB/IIC melanoma patients (Hazard Ratio= 0.59, 95% CI [0.33,1.07]).

Age has been identified as a cause of decreased immune competence[2]; thus, outcomes were assessed as a function of age as an effect modifier. Effects estimates for patients aged less than 60 years are favorable to seviprotimut-L in the overall population (Hazard Ratio= 0.61, 95% CI [0.36, 1.05]) and in the Stage IIB/IIC population (Hazard Ratio= 0.239, 95% CI [0.083, 0.69]).

In the study, seviprotimut-L was well-tolerated with treatment-emergent adverse events (AEs) similar to placebo patients. There were no serious adverse events or Grade 4 or 5 adverse events in the 347 patients studied, and the vast majority of events were Grade 1-2 injection site reactions that were managed by topical cream/s or an over-the-counter antihistamine.

About MAVIS

MAVIS (Melanoma Antigen Vaccine Immunotherapy Study) is a multicenter, double-blind, placebo-controlled adaptive Phase III trial to assess the safety and efficacy 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 definitive surgical resection. MAVIS is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

For additional information about the trial, please visit https://clinicaltrials.gov/ct2/show/NCT01546571.

About Seviprotimut-L

Seviprotimut-L is an allogeneic, polyvalent, partially purified 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-specific 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 to IIIC melanoma, following definitive 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 over 1,000 patients. For additional information, please visit www.polynoma.com.

About CK Life Sciences

CK Life Sciences Int'l., (Holdings) Inc. (stock code: 0775) is listed on the Stock Exchange of Hong Kong. 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.ck-lifesciences.com.

About Melanoma

Skin cancer is the 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.[3] 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.[4] In 2019, an estimated 96,480 new cases of melanoma will be diagnosed in the U.S. alone, and an estimated 7,230 people in the U.S. will die from the disease.[5] Globally, there are approximately 350,000 cases of melanoma and nearly 60,000 deaths a year.[6]

While it still represents less than 5% of all cutaneous malignancies, melanoma accounts for the majority of skin cancer deaths.[4] 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 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.[7] The majority of melanoma cases are diagnosed at a localized stage.[8,9] 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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