Polynoma Presenting Final Analysis of MAVIS Phase III Part B1 Data of Its Investigational Melanoma Vaccine, Seviprotimut-L, at ASCO20 Virtual Scientific Program

Study data show a durable recurrence-free survival clinical benefit in patients with localized melanoma, supporting the potential use of seviprotimut-L as an adjuvant treatment

SAN DIEGO, May 13, 2020 – 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 final analysis of clinical data from Part B1 of MAVIS (Melanoma Antigen Vaccine Immunotherapy Study), a Phase III study of seviprotimut-L, an investigational melanoma vaccine candidate, at the American Society of Clinical Oncology (ASCO) Virtual Scientific Program, to be held online May 29-31, 2020. The study abstract is one of 12 abstracts selected for discussion in the Melanoma/Skin Cancers poster discussion session.

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**: Final analysis of subgroups confirmed the findings from the interim analysis, suggesting enhanced RFS for seviprotimut-L in patients with AJCC Stage IIB/IIC melanoma, particularly those under age 60, and those with ulceration, whose lesions are considered more serious because they have a greater risk of metastasis.[1]
- **Early evidence of survival benefit in Stage IIB/C patients:** For Stage IIB/IIC melanoma patients under 60, there was a trend toward improved overall survival for those treated with seviprotimut-L.
- **Favorable adverse event profile:** Seviprotimut-L was well-tolerated with treatment-emergent adverse events (AEs) similar to patients given placebo. There were no treatment-related serious adverse events.

Melanoma is the most diagnosed cancer among 25 to 29 year-olds in the United States, and passage from Stage II to Stage III melanoma marks a critical therapeutic intervention point to improve survival. 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 (22.5%) for metastatic Stage IV.[2]

"The final analysis of this part of the study reinforces the findings from our interim analysis last year, suggesting improved outcomes with seviprotimut-L in Stage IIB/IIC melanoma patients, particularly in those aged under 60. Furthermore, the latest findings extend the benefit to include disease with ulceration," said Melvin Toh, Chief Technology Officer at Polynoma and Vice President & Chief Scientific Officer at CK Life Sciences. "With a median patient follow-up of more than 48 months, the data show a durable RFS clinical benefit of seviprotimut-L in Stage IIB/IIC melanoma. We believe seviprotimut-L will be an important new option for the adjuvant treatment of patients with localized melanoma and look forward to advancing seviprotimut-L into the definitive part of the MAVIS Study."

"These data show promise for seviprotimut-L as a vaccine-based treatment of melanoma," 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 findings support moving forward with a pivotal trial testing seviprotimut-L as an adjuvant treatment for patients with Stage IIB/C melanoma, with stratification by age."

FURTHER DETAILS ON POSTER PRESENTATION AND DISCUSSION SESSION:

Abstract 10017: Final analysis of relapse-free survival in a multicenter, double-blind, placebo-controlled trial of seviprotimut-L polyvalent melanoma vaccine after resection of high-risk melanoma.

- **Poster:** 366
- **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 L. Bowles, MD; Prejesh Philips, MD; Sekwon Jang, MD; Jose Lutzky, MD, FACP; Anna Bar, MD; Peter D. Beitsch, MD

Poster Discussion Session

- **Session Title:** Melanoma/Skin Cancers
- **Presentation Title:** Adjuvant/Neoadjuvant Approaches
- **Discussant:** Kenneth F. Grossmann, MD, PhD | Huntsman Cancer Institute, University of Utah
- **Poster and Discussion:** will be available "on demand" on the ASCO website starting May 29 at 8:00 am EDT

The data being 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 toward benefit (Hazard Ratio "HR" = 0.88). Subgroup analysis based on planned stratification revealed the HR for the Stage IIB/IIC subset to be 0.65 (number of patients, "N" =111, 95% CI [0.37, 1.17]), favoring seviprotimut-L.

Age has been identified as a cause of decreased immune competence;[3] thus, outcomes were assessed as a function of age as an effect modifier. Final efficacy analysis of subgroups confirmed treatment with seviprotimut-L enhanced RFS for patients less than 60 years overall (N=191, HR=0.64, 95% CI [0.38, 1.08]) and among Stage IIB/IIC melanoma patients (N=52, HR=0.32, 95% CI [0.12, 0.86]).

Furthermore, in a multivariable RFS model, for Stage IIB/IIC patients less than 60 years with ulceration, the HR was 0.209 (N=38, 95% CI [0.07,0.61]). For OS, for patients less than 60, HR = 0.41 [0.33,1.14] (n=191, 19 deaths) and for those ≥60, HR = 0.92 [0.39,2.12] (n = 156, 24 deaths).

In the study, seviprotimut-L was well-tolerated with treatment-emergent adverse events (AEs) similar to placebo patients. There were no treatment-related serious adverse events (SAEs) 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. 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.ck-lifesciences.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.[4] 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.[5] In 2020, an estimated 100,350 new cases of melanoma will be diagnosed in the U.S. alone, and an estimated 6,850 people in the U.S. will die from the disease.[6] Globally, there are approximately 350,000 cases of melanoma and nearly 60,000 deaths a year.[7]

While it still represents less than 5% of all cutaneous malignancies, melanoma accounts for the majority of skin cancer deaths.[5] 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.[8] The majority of melanoma cases are diagnosed at a localized stage.[9,10] 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.

REFERENCES

1. ACFP Cherobin, AJA Wainstein, EA Colosimo, EMA Goulart, and FV Bittencourt. An Bras Dermatol. Prognostic factors for metastasis in cutaneous melanoma. 2018;93(1):19-26. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5871357/.
2. Melanoma Research Alliance. Melanoma Survival Rates. Accessed May 7, 2020 at https://www.curemelanoma.org/about-melanoma/melanoma-staging/melanoma-survival-rates/.
3. Weyand CM, Goronzy JJ. Aging of the Immune System. Mechanisms and Therapeutic Targets. Ann Am Thorac Soc. 2016;13 Suppl 5(Suppl 5):S422–S428. doi:10.1513/AnnalsATS.201602-095AW. https://www.ncbi.nlm.nih.gov/pubmed/28005419.

4. Guy GP, Thomas CC, Thompson T, Watson M, Massetti GM, Richardson LC. Vital signs: Melanoma incidence and mortality trends and projections—United States, 1982–2030. MMWR Morb Mortal Wkly Rep. 2015;64(21):591-596. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584771/.
5. Matthews NH, Li W, Qureshi AA, Weinstock MA, and Cho E. Cutaneous Melanoma: Etiology and Therapy. Chapter 1: Epidemiology of Melanoma. https://www.ncbi.nlm.nih.gov/books/NBK481860/pdf/Bookshelf_NBK481860.pdf.
6. American Cancer Society. Key Statistics for Melanoma Skin Cancer. Accessed May 7, 2019 at https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html.
7. Karimkhani C, Green AC, Nijsten T, Weinstock MA, Dellavalle RP, Naghavi M, Fitzmaurice C. The global burden of melanoma: results from the Global Burden of Disease Study 2015. https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.15510.
8. Melanoma Research Alliance. Melanoma Statistics. Accessed May 7, 2020 at https://www.curemelanoma.org/about-melanoma/melanoma-statistics-2/.
9. National Cancer Institute. SEER Cancer Statistics Review 1975-2010. Melanoma of the Skin (Invasive). https://seer.cancer.gov/archive/csr/1975_2010/results_merged/sect_16_melanoma_skin.pdf
10. Enninga E, Moser J, Weaver A, Markovic S, Brewer J, Leontovich A, Hieken T, Shuster L, Kottschade L, Olariu A, Mansfield A, Dronca R. Cancer Med. Survival of cutaneous melanoma based on sex, age, and stage in the United States, 1992–2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5633552/.