Polynoma Receives FDA Fast Track Designation for its Melanoma Cancer Vaccine Seviprotimut-L

SAN DIEGO, June 23, 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., announces that the U.S. Food and Drug Administration (FDA) has granted its application for Fast Track designation of seviprotimut-L, its melanoma cancer vaccine for the adjuvant treatment of stage IIB/IIC melanoma patients post-resection to improve recurrence-free survival.

"The Fast Track designation by the FDA provides further validation of seviprotimut-L as a potential new and important cancer vaccine for patients with localized melanoma," said Alan Yu, Chairman of Polynoma and Vice President & Chief Operating Officer at CK Life Sciences. "We look forward to advancing seviprotimut-L in a pivotal trial as an adjuvant treatment of melanoma."

Fast Track is designed to facilitate the development and expedite the review of drugs which treat serious or life-threatening conditions and fill an unmet medical need. The FDA defines filling an unmet medical need as "providing a therapy where none exists or providing a therapy which may be potentially better than available therapy,"[1] based on criteria such as:

- Showing superior effectiveness, or improved effect on serious outcomes;
- Avoiding serious side effects of an available therapy;
- Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment;
- Ability to address anticipated public health need.

Benefits of Fast Track designation include more frequent communication with the FDA, a rolling submission of the marketing application, and eligibility for Priority Review and Accelerated Approval, if relevant criteria are met.

The interval between progression from Stage II to Stage III/IV 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 five-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]

Final analysis of clinical data from Part B1 of MAVIS (Melanoma Antigen Vaccine Immunotherapy Study), a Phase III study of seviprotimut-L was presented at the American Society of Clinical Oncology (ASCO) ASCO20 Virtual Scientific Program, held online May 29-31, 2020.

Highlights of the presentation are as follows:

- **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.[3]
- **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.

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.

POLYNOMA

Media Contact:

Jessica Yingling, Ph.D.
+1 (858) 344-8091
jessica@litldog.com

REFERENCES

1. U.S. Food & Drug Administration. Fast Track. Accessed June 12, 2020 at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track
2. Melanoma Research Alliance. Melanoma Survival Rates. Accessed May 7, 2020 at https://www.curemelanoma.org/about-melanoma/melanoma-staging/melanoma-survival-rates/.
3. 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/.
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/.