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AIVITA gets IND nod for Phase 1B melanoma trial

January 17, 2019 | News

Trial will investigate AIVITA's platform cancer immunotherapy in combination with anti-PD-1 checkpoint inhibitors



AIVITA Biomedical, Inc., a biotech company specializing in innovative stem cell applications, announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a Phase 1B clinical trial investigating the Company's ROOT OF CANCER technology in patients with metastatic melanoma. The trial marks the first time AIVITA's cancer immunotherapy technology will be tested in combination with checkpoint inhibitors.

AIVITA's open-label, single-arm, phase 1B treatment study will establish the safety of administering anti-PD1 monoclonal antibodies in combination with AV-MEL-1 in patients with measurable metastatic melanoma. The study will also track the efficacy of the treatment for the estimated 14 to 20 patients.

AIVITA's personalized patient-specific platform cancer technology uniquely and selectively targets the patient's tumor-initiating cells, which seed tumor growth, metastases and tumor recurrence. Previously, this treatment was tested in two Phase 2 trials in patients with advanced melanoma and approved for Phase 3 testing. These clinical studies demonstrated the efficacy of the approach in a randomized trial, yielding a 72% 2-year survival rate and a 54% 5-year survival rate.

AIVITA's ROOT OF CANCER technology is currently the subject of two ongoing multi-center Phase 2 trials in the USA, one in patients with a primary diagnosis of advanced ovarian cancer and another in patients with newly diagnosed glioblastoma.

The Company is also applying to commercialize the treatment of melanoma patients in Japan and is considering Japanese strategic partners for this program, having just received an enabling approval of its manufacturing, quality systems and safety by Japan's PMDA.