Iovance Biotherapeutics Announces Clinical Data for Lifileucel in Advanced Mucosal Melanoma at the European Society for Medical Oncology (ESMO) Congress

October 16, 2023

SAN CARLOS, Calif., Oct. 16, 2023 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today announced the publication of an abstract reporting clinical data for lifileucel which will be presented at the European Society for Medical Oncology ESMO Congress 2023, October 20-24, 2023 in Madrid, Spain.

The abstract reports outcomes of a subset of 12 patients with advanced mucosal melanoma treated with lifileucel in the pooled consecutive cohorts from the C-144-01 trial. All patients had progressed on or after immune checkpoint inhibitor therapy. Patients with mucosal melanoma, which is rare and difficult to treat, have worse outcomes after anti–PD-1 therapy compared to patients with other melanoma subtypes.

The ORR assessed by an independent review committee (IRC) using RECIST v1.1 was 50% (95% CI: 21%–79%). At median study follow-up of 35.7 months, median duration of response (DOR) was not reached (NR; 95% CI: 12.5 months–NR), median progression free survival (PFS) was NR (95% CI: 1.4 months–NR), and median overall survival (OS) was 19.4 months (95% CI: 7.9 months–NR). Treatment emergent adverse events (TEAEs) were consistent with known safety profiles of lymphodepleting chemotherapy and interleukin-2 (IL-2).

The clinically meaningful and durable activity for lifileucel in the subgroup of patients with the rare and difficult-to-treat mucosal melanoma subtype, as well as in the total population of 153 patients treated in the C-144-01 trial, support the potential benefit of lifileucel as a one-time treatment that is differentiated from other immunotherapies for advanced melanoma.

Additional details will be presented in a mini-oral presentation at ESMO:

- Mini Oral Session – Melanoma and Other Skin Tumours: 1086MO – Lifileucel tumor-infiltrating lymphocyte (TIL) cell therapy in patients (pts) with advanced mucosal melanoma after progression on immune checkpoint inhibitors (ICI): Results from the phase 2 C-144-01 study
    - Saturday, October 21, 3:15 PM - 3:20PM CEST (9:15 AM – 9:20 AM EDT)

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer. For more information, please visit www.iovance.com.

Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, may support registrational studies and subsequent approvals by the FDA; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from

the FDA or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA (including from the prior pre-BLA meeting with the FDA); the risk that the FDA may not approve or may delay approval for our BLA submission for lifileucel in metastatic melanoma; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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