

PROCLAIMSM National Patient Registry Analysis Shows Improved Median Overall Survival in Patients with Metastatic Melanoma Treated with High-Dose Interleukin-2 (HD IL-2)

Data Support Adoption of Stable Disease as Response Criterion, Raise Intriguing Hypotheses about Sequential Therapy and Utility of IL-2 as Salvage Option

Chicago, IL, May 31, 2014 – Prometheus Laboratories Inc. announced today that data from the PROCLAIMSM national patient registry retrospective cohort document an improvement in median overall survival (OS) in patients with metastatic melanoma who were treated with high-dose Proleukin[®] (aldesleukin) as compared to historical reference standards. The data, presented here today in a poster session during the 50th annual meeting of American Society of Clinical Oncology (ASCO), also suggest that response criteria for HD IL-2 immunotherapy should include stable disease (SD) in addition to complete and partial response (CR and PR), based on the survival outcomes observed in PROCLAIM.¹

“The PROCLAIM retrospective cohort data, encompassing 170 patients with metastatic melanoma, show a 16% overall response rate, as well as a 19% stable disease rate after high-dose interleukin-2 immunotherapy. Additionally, when analyzed for survival, the stable disease population and the partial responders had a similar overall survival advantage over patients with progressive disease,” said James Lowder, M.D., Senior Director of Medical Affairs at Prometheus Labs. “The availability of other effective agents contributes to the improved survival. The recognition of stable disease as a predictor of survival in melanoma patients makes it an important parameter to follow in combination and sequencing trials.”

In a poster presentation entitled, “Improved Median Overall Survival (OS) in Patients with Metastatic Melanoma (mM) Treated with High Dose (HD) IL-2: Analysis of the PROCLAIM 2007-2012 National Registry,” the PROCLAIM researchers presented an analysis of retrospective data from 170 patients with metastatic melanoma who received at least one dose of HD IL-2, which is marketed as Proleukin. Patients were followed for a median duration of 30.5 months. A majority of the patients (80%) were treated in 2010 and 2011. The overall response rate (ORR) for IL-2 was similar to historical data. Patients received HD IL-2 treatment for a median of 1 month (range 0.07-14 months). Of the 170 subjects, 98 were deceased and 72 were known to be alive. Median OS was 21 months for HD IL-2 compared to a median historical OS range of 10-15.9 months for other FDA-approved single-agent therapies, including HD IL-2 administered at the National Cancer Institute (NCI) in the past.^{2,3,4} Among patients with SD, median OS was 33.3 months, compared to 15.4 months in patients with progressive disease (PD). Median OS had not been reached for patients achieving CR and was 36.8 months for PR. There was no trend in OS between the 128 patients who received HD IL-2 as first-line therapy and the 42 who were treated with second-line HD IL-2. No deaths due to IL-2-related toxicity were reported.¹

The PROCLAIMSM national patient registry (www.proclaimregistry.com), an HD IL-2 observational database covering more than 35 participating sites, consists of a retrospective cohort of patients treated between 2007 and 2012, as well as an ongoing prospective cohort of over 600 patients. Issues such as sequential therapy and use of IL-2 as a salvage option in patients with metastatic melanoma are currently being explored in the prospective cohort.

“The median survival of approximately 20 months in this real-world cohort of patients treated with standard high-dose IL2 is impressive,” said lead investigator Gregory Daniels, MD, University of California, San Diego. “The short time on therapy -- a median of 1 month -- and the long duration of benefit without the need for additional treatment continue to be the hallmark and the bar set by IL-2. Future studies designed to understand rational combinations and the continued integration of immune therapy into anticancer treatment will change the oncology landscape.”

About Proleukin® (aldesleukin)

Proleukin for injection is a recombinant human interleukin-2 for treatment in adults with metastatic melanoma and metastatic kidney cancer. Proleukin therapy is a form of immunotherapy that enhances the body's natural immune system to help fight these types of cancer. Proleukin has been used for over 10 years in the treatment of metastatic melanoma and for 20 years in the treatment of metastatic kidney cancer (renal cell carcinoma). For complete prescribing information, please visit www.proleukin.com. Proleukin is a registered trademark of Novartis.

Important Safety Information

Therapy with Proleukin for injection should be restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing. Extreme caution should be used in patients with a normal thallium stress test and a normal pulmonary function test who have a history of cardiac or pulmonary disease.

Proleukin should be administered in a hospital setting under the supervision of a qualified physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Proleukin administration has been associated with capillary leak syndrome (CLS), which is characterized by a loss of vascular tone and extravasation of plasma proteins and fluid into the extravascular space. CLS results in hypotension and reduced organ perfusion, which may be severe and can result in death. CLS may be associated with cardiac arrhythmias (supraventricular and ventricular), angina, myocardial infarction, respiratory insufficiency requiring intubation, gastrointestinal bleeding or infarction, renal insufficiency, edema, and mental status changes.

Proleukin treatment is associated with impaired neutrophil function (reduced chemotaxis) and with an increased risk of disseminated infection, including sepsis and bacterial endocarditis. Consequently, preexisting bacterial infections should be adequately treated prior to initiation of Proleukin therapy. Patients with indwelling central lines are particularly at risk for infection with gram-positive microorganisms. Antibiotic prophylaxis with oxacillin, nafcillin, ciprofloxacin, or vancomycin has been associated with a reduced incidence of staphylococcal infections.

Proleukin administration should be withheld in patients developing moderate to severe lethargy or somnolence; continued administration may result in coma.

About Interleukin-2

Interleukin-2 (IL-2) is a protein that occurs naturally in the body and plays an important role in activating the immune system. The immune system protects the body from foreign substances, cells, and tissues by responding to and resisting diseases. Proleukin therapy is a genetically engineered or recombinant version of IL-2. Proleukin therapy possesses the same properties as naturally occurring IL-2 and helps activate the immune system to recognize and eliminate certain kinds of cancer cells.

About Prometheus Laboratories Inc.

Prometheus Laboratories Inc. is committed to improving lives through the development and commercialization of novel pharmaceutical and diagnostic products that enable physicians to provide greater individualized patient care. Prometheus is a leader in applying the principles of personalized medicine to the diagnosis and treatment of gastrointestinal diseases and is applying these principles to oncology. Its strategy includes the marketing and delivery of pharmaceutical products complemented by proprietary diagnostic testing services. By integrating therapeutics and diagnostics, Prometheus believes it can provide physicians with more targeted solutions to optimize care for their patients. Prometheus became part of Nestlé Health Science in July 2011. The corporate offices of Prometheus are located in San Diego, California. For more information about Prometheus, please visit www.prometheuslabs.com.

About Nestlé Health Science

Nestlé Health Science, a wholly-owned subsidiary of Nestlé, intends to spearhead the development of science-based nutritional solutions. Building on its core HealthCare Nutrition business, the company has ambitions to address conditions in the area of Gastrointestinal Health, Metabolic Health and Brain Health. Nestlé Health Science employs around 3,500 people worldwide and has its headquarters in Vevey, Switzerland. For more information, please visit www.nestlehealthscience.com.

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- ¹ Daniels G, Wong MKK, Kaufman HL, et al. Improved median overall survival (OS) in patients with metastatic melanoma (mM) treated with high dose (HD) IL-2: analysis of the PROCLAIM 2007-2012 national registry. Presented at the 50th annual meeting of the American Society of Clinical Oncology (ASCO), Chicago, IL, May 31, 2014. Abstract 9054
 - ² Smith FO, Downey SG Klapper JA et al. Treatment of metastatic melanoma using interleukin-2 alone or in conjunction with vaccines. Clin Cancer Res 2008 14:5610-18.
 - ³ Hodi FS, O'Day SJ, McDermott DF. Improved survival with ipilimumab in patients with metastatic melanoma. N Eng J Med 2010 363:711-723.
 - ⁴ Sosman JA, Kim KB, Schuchter L, et al. Survival in BRAF V600–mutant advanced melanoma treated with vemurafenib. N Engl J Med 2012;366:707-14.