

Malignant Melanoma Fact Sheet

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Growing Incidence of Melanoma

Skin cancer is the most common form of cancer in the United States. In 2007, The American Cancer Society estimates that approximately 8,110 deaths will occur from melanoma and another 59,940 cases of melanoma are expected to be diagnosed in this country. In Europe, Globocan 2002 reports that 59,400 new cases of melanoma will be diagnosed, and approximately 16,000 deaths will result each year from melanoma. Unfortunately, these numbers are expected to continue to increase each year, particularly among Caucasian men and the elderly.

When detected early, melanoma can be cured easily. However, once the cancer has spread beyond the skin to distant sites, the melanoma is classified as stage IV malignant melanoma, the most advanced form of this cancer. Current therapies are ineffective at extending overall patient survival, which at this stage is typically only about six to nine months.

Few Therapy Options

Stage IV malignant melanoma is the most difficult skin cancer to treat and patients are usually treated with one or more of the following:

- Surgery to remove tumors and cancer that has spread to other parts of the body
- Radiation therapy
- Chemotherapy with dacarbazine (DTIC) alone or in combination with other chemotherapy drugs or in combination with immunotherapy agents such as interferon alpha and/or interleukin-2
- Novel, unapproved therapies administered in a clinical trial

Response to treatment largely depends upon the stage of melanoma, disease site and the extent to which the cancer has spread. Unfortunately, none of the current therapies have proven to be very effective at extending overall patient survival. Accordingly, many physicians believe that the best alternative for most stage IV melanoma patients is to enroll in a clinical trial in order to receive an investigational therapeutic.

Growing Market Opportunity

As the number of patients diagnosed with malignant melanoma continues to rise, there is a growing unmet medical need for new therapy options. Cancer drugs which are able to extend patient survival, even by only a few months, typically cost several thousand dollars per month of therapy. For these reasons, many biopharmaceutical companies are targeting malignant melanoma as an attractive market opportunity for their product development efforts.

This Corporate Fact Sheet contains forward-looking statements involving risks and uncertainties, including expectations regarding financial goals and product development efforts. SciClone's actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in SciClone's filings made with the Securities and Exchange Commission.

8,110

patients expected to die from
melanoma in 2007 in the U.S.

59,940

patients expected to be
diagnosed with melanoma in 2007
in the U.S.

6-9 months

expected survival for patients
diagnosed with stage IV
malignant melanoma

3x tumor response

**3 months longer
survival**

for stage IV malignant melanoma
patients treated with

thymalfasin and DTIC
versus
DTIC and interferon alpha

Source: SciClone Pharmaceuticals and Sigma-Tau, phase 2 trial results presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO). June 2007.

Thymalfasin for Malignant Melanoma

SciClone, together with our European partner Sigma-Tau S.p.A, completed a phase 2 trial evaluating thymalfasin (ZADAXIN®) in combination with chemotherapeutic agents for the treatment of 488 patients with stage IV malignant melanoma. Based on these positive results, SciClone intends to meet with the FDA and the EMEA and begin a planned phase 3 registration trial in the first quarter of 2008.

In this phase 2 clinical trial, a total of 488 patients with stage IV malignant melanoma were enrolled in 64 sites throughout Europe. Patients were randomized to one of five treatment arms, received six cycles of therapy for six months and were observed for twelve months following therapy. The following therapy combinations were evaluated:

1. DTIC + Interferon alpha (control)
2. Thymalfasin 3.2 mg + DTIC
3. Thymalfasin 1.6 mg + DTIC + Interferon alpha
4. Thymalfasin 3.2 mg + DTIC + Interferon alpha
5. Thymalfasin 6.4 mg + DTIC + Interferon alpha

Phase 2 Trial Met Primary Endpoint

The phase 2 trial achieved its primary endpoint and results showed that thymalfasin 3.2 mg without interferon in combination with DTIC tripled the overall response rate and extended overall survival by nearly 3 months compared to treatment with DTIC and interferon alpha.

All patients in the thymalfasin treatment arms reported greater overall tumor response and longer median and progression free survival than those in the control arm. Patients treated with the 3.2 mg dose of thymalfasin in combination with DTIC without interferon alpha showed a tumor response of 12.1%, compared to 4.1% for patients in the control group treated with DTIC and interferon alpha. This same group reached a median survival of 9.3 months, compared to 6.6 months for the control group.

Phase 2 Trial Data (Intent-to-Treat)			
Treatment Arm	N=	Overall Tumor Response	Median Survival (months)
DTIC + Interferon alpha (control arm)	97	4.1%	6.6
Thymalfasin (3.2 mg) + DTIC	99	12.1%	9.3
Thymalfasin (1.6 mg) + DTIC + Interferon alpha	97	7.2%	9.3
Thymalfasin (3.2 mg) + DTIC + Interferon alpha	97	10.3%	8.5
Thymalfasin (6.4 mg) + DTIC + Interferon alpha	98	6.1%	10.2

Source: SciClone Pharmaceuticals and Sigma-Tau, phase 2 trial results presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO), June 2007.

Thymalfasin (ZADAXIN)

Phase 2 Melanoma Trial

Objective: Receive U.S., European and other international approvals for thymalfasin in combination with DTIC as a treatment for patients with stage IV malignant melanoma

Design:

- Randomized, open label trial in 64 sites throughout Europe
- 488 patients diagnosed with stage IV malignant melanoma
- Five treatment arms received six cycles of therapy for six months and were observed for twelve months after therapy
- Primary endpoint met: overall tumor response
- Secondary endpoints: survival, duration of response, time to disease progression and immunological response

Intellectual Property: U.S. Orphan Drug designation

Next Milestones: Expect to begin phase 3 registration trial in 1Q08

Mechanism of Action in Melanoma

Suppression of the growth of immune-sensitive tumors such as melanoma have been shown to be dependent on a strong immune response, including a number of activated effectors such as tumor-infiltrating lymphocyte cells (TILs) and specific anti-melanoma cytotoxic T lymphocytes (CTLs). It is also important to increase the presentation of cancer-specific antigens to the immune system through sustained expression of these molecules along with MHC Class I, as cancers avoid the immune system by decreases in this presentation.

Thymalfasin's potential beneficial role in the treatment of melanoma derives from its demonstrated activation of these various arms of the immune system, including increases in TILs, CTLs, and expression of MHC Class I and tumor-specific antigens. Thymalfasin's multiple activities arise through activation of Toll-like receptor 9 and signaling through increases in the nuclear factor NfKB through Myd88 and IKKb. Evaluation of thymalfasin's utility in melanoma animal models has confirmed effective anti-tumor activity.