

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 13, 1999

LIGAND PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware 000-20720 77-0160744

(State or other (Commission File Number) (IRS Employer Identification No.)
jurisdiction of
incorporation)

10275 Science Center Drive, San Diego, California 92121

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 550-7500

ITEM 5. OTHER EVENTS.

On December 13, 1999, Ligand Pharmaceuticals Incorporated ("Ligand") announced that the Oncologic Drugs Advisory Committee of the FDA, by a vote of 13 to 2 (with one abstention), recommended marketing approval for Targretin(R) (bexarotene) capsules in the advanced-stage cutaneous T-cell lymphoma (CTCL) Stages IIb, III, IVa, IVb patient population as evaluated in Ligand's advanced-stage pivotal trial included in its new drug application. In a vote of 5 to 7 (with 4 abstentions), the committee declined to recommend marketing approval of Targretin capsules in the early-stage CTCL population as evaluated in its early-stage pivotal trial (Stages Ia, Ib, IIa).

On December 13, 1999, Ligand issued a press release which is filed herewith as Exhibit 99 and is incorporated herein by reference.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(c) Exhibits.

99.1 Press Release dated December 13, 1999

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LIGAND PHARMACEUTICALS INCORPORATED

Date: December 14, 1999 By: /s/ Paul V. Maier

Paul V. Maier
Senior Vice President, Finance
and Chief Financial Officer

INDEX TO EXHIBITS

99.1 Press Release dated December 13, 1999.

EXHIBIT 99.1

Paul V. Maier
(858) 550-7573

FDA ONCOLOGIC DRUGS ADVISORY COMMITTEE RECOMMENDS MARKETING APPROVAL
FOR LIGAND'S TARGRETIN(R) CAPSULES FOR TREATMENT OF ADVANCED-STAGE
CUTANEOUS T-CELL LYMPHOMA

-- ODAC DECLINES TO RECOMMEND FOR EARLY-STAGE PATIENTS --

SAN DIEGO, Calif. -- December 13, 1999 -- Ligand Pharmaceuticals Incorporated (Nasdaq: LGND) announced today that the Oncologic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA), by a vote of 13 to 2 (with one abstention), recommended marketing approval for Targretin(R) (bexarotene) capsules in the advanced-stage cutaneous T-cell lymphoma (CTCL) Stages IIb, III, IVa, IVb patient population as evaluated in Ligand's advanced-stage pivotal trial included in its new drug application (NDA). In a vote of 5 to 7 (with 4 abstentions), the committee declined to recommend marketing approval of Targretin capsules in the early-stage CTCL population as evaluated in its early-stage pivotal trial (Stages Ia, Ib, IIa).

The FDA is expected to consider the committee's recommendation for approval in its review of the NDA for Targretin capsules. While the FDA is not bound by the committee's decision, the agency usually follows committee advice. The FDA is expected to complete its review of the Targretin capsules NDA in December 1999. If Targretin capsule therapy is approved for marketing, it will be the first oral retinoid approved by the FDA specifically for the treatment of patients with CTCL.

"We are pleased with the panel's vote to recommend Targretin capsules approval for advanced-stage CTCL patients but disappointed that Targretin capsules was not also recommended at this time for the early-stage CTCL patient population," said David E. Robinson, Ligand Chairman, President and CEO. "We have worked closely with the FDA during this process, and we intend to have additional conversations with the FDA about the most appropriate patient populations for Targretin capsules following ODAC's recommendations including any additional information necessary for early-stage patients. The advanced-stage disease patient population, Stages IIb, III, IVa, IVb, are half or more of the prevalent patient population in the

US and Targretin capsules will represent a significant therapeutic option as a new oral oncologic agent for them."

OTHER COMMITTEE VOTES

Six questions were submitted to the committee for a vote. In addition to the primary questions of recommending approval of Targretin capsules in both early-stage and advanced-stage CTCL, the committee voted on four additional questions. The committee voted 11 to 4 (with one abstention) that a clinically meaningful tumor response rate using acceptable tumor response criteria had been adequately demonstrated and 0 to 14 (with two abstentions) that clinical benefit other than tumor response had been adequately demonstrated.

The committee voted as well on several other questions posed by the FDA including recommending an additional post approval/clinical study in advanced-stage patients.

"We are pleased that the FDA's ODAC panel has supported the conclusion from our data that Targretin capsules represent a positive risk benefit for advanced-stage CTCL patients," said Ligand Senior Medical Director and Physician Team Leader for the CTCL project, Richard C. Yocum, M.D. "The prompt and durable responses to Targretin capsule therapy are especially remarkable in this heavily-pretreated patient population with refractory CTCL and with few if any remaining treatment options. We look forward to continuing to work with the FDA to address requirements for approval in the early-stage disease patient population as well as commencing our dialogue on the recently submitted

Targretin gel NDA in early-stage disease."

TARGRETIN CAPSULES

The NDA for Targretin capsules was submitted by Ligand in June 1999 and was accepted for priority review by the FDA. Targretin has also received orphan drug designation in the U.S. In November 1999, Ligand submitted a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMA) seeking marketing clearance for Targretin capsules for the treatment of patients with CTCL. Ligand is conducting Phase II trials with Targretin capsules for the treatment of patients with moderate to severe plaque psoriasis and for the treatment of women with advanced breast cancer.

The NDA is based on the results from two multi-center, multinational clinical trials involving 152 patients with CTCL. The dose regimen recommended in the NDA is a single daily oral dose of Targretin capsules at an initial dose level of 300 milligrams per square meter (mg/m²) of body surface area, administered with a meal. In both clinical trials, this initial dose level provided efficacy that exceeded the protocol-defined targets of response rates.

Ligand has the worldwide rights to Targretin. If approved in the respective territories, Ligand expects to market and sell Targretin capsules in the U.S., Canada and selected European markets through its specialty oncology sales and marketing group. In Spain, Portugal, Greece, and Central and South America, Ferrer Internacional, S.A., will market and distribute, if approved in the respective jurisdictions, Targretin as well as certain other Ligand oncology products.

CTCL BACKGROUND

Affecting an estimated 16,000 to 20,000 people in the U.S., CTCL is a cancer of T-lymphocytes (white blood cells involved in the body's immune system). T-cell lymphomas, of which CTCL is a subclass, represent approximately 10% of the non-Hodgkin's lymphomas (NHL), which affect approximately 300,000 individuals in the U.S.

CTCL ordinarily manifests itself initially in the skin, but over time may progress to involve other organs. The prognosis for CTCL is based in part on the stage of the disease when diagnosed. CTCL is most commonly a slowly progressing cancer, and many patients live with the complications of CTCL for 10 or more years after diagnosis. Some patients, however, have a much more aggressive form of this disease, and the median survival for late-stage patients is less than three years.

Currently available approved treatment options for CTCL are limited. CTCL continues to be a devastating, highly-symptomatic, very visible, chronic malignancy often characterized by years of deforming symptomatic skin lesions that culminate in ulceration with secondary infection and visceral tumor invasion. Nearly all patients have symptoms relating to skin lesions that may itch and cause pain, bleeding, infection, or disfigurement. New therapies which are preferably both effective and without toxicity overlapping with currently available treatment modalities are needed for the treatment of patients with CTCL.

BACKGROUND INFORMATION ON TARGRETIN

Discovered by Ligand scientists, Targretin (pronounced tar-GRET-tin), generically known as bexarotene, is a synthetic compound representing a novel class of retinoids that selectively activate retinoid X receptors (RXRs). This subclass of retinoid receptors has biologic activity distinct from that of retinoic acid receptors (RARs). The RXR selective retinoids have a biological activity that is different from that of the endogenous retinoid 9-cis-retinoic acid (alitretinoin), the active substance in Panretin(R) gel and capsules. Panretin is a pan agonist that activates with RAR and RXR receptor subtypes. RXRs play an important role in the control of a variety of cellular functions. Ligand's pre-clinical research has indicated bexarotene may be useful in the treatment of CTCL, psoriasis, some solid tumors, and

tamoxifen-resistant breast tumors; bexarotene has also proven effective in the treatment and prevention of breast cancer in pre-clinical models.

LIGAND PHARMACEUTICALS INCORPORATED

Ligand Pharmaceuticals Incorporated discovers, develops and markets new drugs that address critical unmet medical needs of patients in the areas of cancer, skin diseases, and men's and women's hormone-related diseases, as well as osteoporosis, metabolic disorders and cardiovascular and inflammatory diseases. Ligand's first two drugs -- Panretin(R) gel and ONTAK(R) -- were approved for marketing in the U.S. in early 1999 and are being marketed through its specialty cancer and HIV-center sales force in the U.S. In addition to Targretin(R) capsules which is currently under review by the FDA, Ligand has three additional oncology-related products in late-stage development, Targretin(R) gel, Panretin(R) capsules, and Morphelan(TM) (licensed from Elan). Ligand's proprietary drug discovery and development programs are based on its leadership position in gene transcription technology, primarily related to Intracellular Receptors (IR) and Signal Transducers and Activators of Transcription (STATs).

Except for the historical information contained herein, this news release may contain certain forward looking statements by Ligand and actual results could differ materially from those described as a result of factors including, but not limited to, the following. There can be no assurance that the Targretin capsules NDA will be approved by the FDA for the treatment of patients with CTCL or any other indication in a timely manner or at all; that, if approved, Targretin capsules or any other Ligand product will be accepted by physicians for prescribing, by patients for use and by insurance companies / agencies for reimbursement; that Ligand will be able to successfully commercialize Targretin capsules or any other product; that any other regulatory approval for Targretin capsules or regulatory approval for any other Ligand product will be granted in a timely manner, or at all; that regulatory filings will be made in a timely manner or at all. Additional information concerning these and other factors affecting Ligand's business can be found in press releases as well as in Ligand's public periodic filings with the Securities and Exchange Commission, available via our website at <http://www.ligand.com>. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release.

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Note: Panretin(R) and Targretin(R) are registered trademarks of Ligand Pharmaceuticals Incorporated, and ONTAK(R) is a registered trademark of Seragen, Inc., a wholly owned subsidiary of Ligand.

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