

PHARMION SUBMITS EUROPEAN MARKETING AUTHORIZATION APPLICATION FOR THALIDOMIDE PHARMION(R) FOR UNTREATED MULTIPLE MYELOMA

Pharmion Corporation

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Pharmion Corporation (Nasdaq: PHRM) announced the submission of a marketing authorization application (MAA) with the European Medicines Agency (EMA) for Thalidomide Pharmion for the treatment of untreated multiple myeloma in the European Union (E.U.). The submission includes details of the Pharmion Risk Management Programme (PRMP) as a condition of supply following the approval of Thalidomide Pharmion.

"This submission represents the achievement of a significant milestone for Pharmion. We look forward to working with the EMA, as well as patient and Thalidomider groups as we proceed through the regulatory process," said Patrick J. Mahaffy, Pharmion's president and chief executive officer. "The data for Thalidomide in the treatment of untreated multiple myeloma are extremely positive and we believe that it is time for this very important and widely used drug to come under regulatory oversight."

Multiple myeloma, the second most common cancer of the blood, affects approximately 82,000 people in the E.U., and approximately 25,000 people in the E.U. are diagnosed with multiple myeloma each year.

"Our data demonstrate significant benefit when Thalidomide is added to today's standard of care in untreated elderly patients with multiple myeloma," said Philippe Moreau, Professor of Clinical Haematology at Nantes Faculty of Medicine and Chairman of the Intergroup Francophone du Myelome (IFM). "Based on these data, and particularly the unprecedented 21-month survival advantage demonstrated for the Thalidomide arm, we believe that Thalidomide, melphalan and prednisone should rapidly become the reference therapy for this patient population. We hope the EMA acts urgently to approve this very critical therapy," he added.

Thalidomide Pharmion has been designated as an Orphan Medicinal Product in the E.U. for the treatment of multiple myeloma, which, if approved, entitles the drug to ten years of market exclusivity for the approved indications.

The application is based upon a clinical data package comprised of four studies in more than 1400 patients. These studies, which include both first-line and induction therapy, include:

- IFM 99-06, a three-arm study conducted by IFM, demonstrated the superiority of melphalan/prednisone plus Thalidomide (MPT) over standard therapy of melphalan/prednisone (MP) or a combination of chemotherapies (vincristine/adriamycin/dexamethasone, or VAD) followed by melphalan and transplantation (MEL 100) in the treatment of newly diagnosed elderly multiple myeloma patients. A total of 447 patients were randomized to one of the three treatment arms. Following an interim analysis, recruitment was stopped on the recommendation of the study's Data Safety Monitoring Board (DSMB). At final analysis, the median overall survival in the MPT arm was approximately 53.6 months, compared to 32.2 and 38.6 months, respectively, for the MP and MEL 100 arms. Thalidomide treatment was well-tolerated by the majority of patients. The Thalidomide combination was associated with more venous thrombosis and pulmonary embolism. Patients taking thalidomide were also at more risk of peripheral neuropathy, neutropenia and constipation.(1)

- A study conducted by the Italian research group Gruppo Italiano Malattie Ematologiche dell'Adulto (GIMEMA) also demonstrated the superiority of melphalan/prednisone plus Thalidomide compared to melphalan/prednisone alone. In the randomized study of MPT versus MP alone in 255 elderly patients,

MPT had a superior response rate and a significantly higher two-year event-free survival rate (54 percent versus 27 percent).(2)

- MM-003, a Phase 3, multi-national, placebo controlled, randomized study of 470 patients, sponsored by Celgene Corporation and supported by Pharmion, compared Thalidomide plus dexamethasone versus dexamethasone and placebo in newly-diagnosed patients. In December 2005, an Independent Data Monitoring Committee reviewed the data as part of a pre-specified interim analysis and concluded that the study should be stopped as it had reached its efficacy stopping rule of $p < 0.0015$ for the primary endpoint of time to disease progression. At the final analysis there was also a significant ($p = 0.001$) improvement in response rate of Thalidomide plus dexamethasone of 69.4 percent, compared to dexamethasone and placebo of 51.1 percent. Of the Thalidomide treated patients, 43.8 percent experienced "Very Good" or "Complete Response" compared to 15.8 percent in the placebo arm ($p < 0.0001$). Time to disease progression was 97.7 weeks versus 28.3 weeks.(3)

- A Phase 3 study conducted by the Eastern Cooperative Oncology Group (ECOG) compared Thalidomide plus dexamethasone compared to dexamethasone alone in over 200 patients. The study demonstrated a statistically significant difference in response rates of 61.6 percent versus 39.6 percent ($p = 0.001$) at four months with Thalidomide plus dexamethasone compared to dexamethasone alone.(4)

The Company is seeking approval for the following indications: Thalidomide Pharmion in combination with melphalan and prednisone for the treatment of patients with untreated multiple myeloma aged 65 years or older or ineligible for high dose chemotherapy and Thalidomide Pharmion in combination with dexamethasone for induction therapy prior to high dose chemotherapy and bone marrow transplant, for the treatment of patients with untreated multiple myeloma. Thalidomide Pharmion must be prescribed and dispensed through the Pharmion Risk Management Programme.

Thalidomide Pharmion is approved in Australia, New Zealand, Turkey, Israel, South Korea and Thailand for the treatment of multiple myeloma after the failure of standard therapies.

In markets where Thalidomide Pharmion is not approved, such as the E.U., Thalidomide Pharmion is currently provided on a named patient/compassionate use basis and under an Autorisation Temporaire d'Utilisation (ATU) in France while the Company seeks an approval. Pharmion is the only provider of thalidomide outside of the U.S. with a comprehensive safety program in place. The Company holds exclusive marketing and distribution rights from Celgene Corporation for Thalidomide in markets outside of North America, Japan and certain other Asian countries. In May 2006, Thalomid(R) (thalidomide) was approved by the U.S. Food and Drug Administration (FDA) in combination with dexamethasone for the treatment of newly diagnosed multiple myeloma.