Spectrum Pharmaceuticals and GPC Biotech Receive Clearance From FDA to Initiate Phase 3 Registrational Trial of Satraplatin

Primary Endpoint for Accelerated Approval Will Be Time to Disease Progression
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IRVINE, CA--(MARKET WIRE)--Sep 2, 2003 -- Spectrum Pharmaceuticals, Inc. (NasdaqSC:SPPI) and GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX 30) today announced that they have received written confirmation from the FDA (U.S. Food and Drug Administration) that they may initiate a Phase 3 registrational trial with satraplatin plus prednisone in patients with hormone-refractory prostate cancer who have failed prior treatment with chemotherapy. This notification is the culmination of the satisfactory completion of both a Special Protocol Assessment (SPA) and an "End of Phase 2" meeting with the FDA.

GPC Biotech and Spectrum Pharmaceuticals requested a review of the Phase 3 clinical trial protocol under an SPA, part of procedures published by the FDA in 2002 to encourage a meaningful dialogue between the Agency and a drug developer prior to the initiation of registrational studies. Under this SPA program, the FDA evaluates whether the protocol for a clinical trial is adequate to meet scientific and regulatory requirements for marketing approval of the drug by the FDA. The satraplatin Phase 3 clinical trial protocol has now successfully completed this SPA process.

In addition, the Satraplatin Joint Development Committee, composed of senior executives of Spectrum Pharmaceuticals and GPC Biotech, held an "End of Phase 2" meeting with the FDA. The purposes of this type of meeting include: assessing the safety of the drug regimen to be tested in the Phase 3 trial, evaluating the Phase 3 plan, and identifying any additional information that will be needed to support a marketing application. The combination of this meeting and the SPA provided GPC Biotech and Spectrum Pharmaceuticals the opportunity to hold comprehensive and meaningful discussions with the FDA about the many components that will eventually be part of its U.S. NDA (New Drug Application) filing.

The satraplatin registrational Phase 3 study will assess the safety and efficacy of satraplatin in combination with prednisone as a second-line chemotherapy regimen in patients with hormone-refractory prostate cancer (HRPC). This will be a multicenter, global, randomized study. It is modeled on the smaller Phase 3 trial successfully conducted by the EORTC (European Organization for Research and Treatment of Cancer), the results of which were presented at the ASCO (American Society of Clinical Oncology) Annual Meeting in June 2003 and reported in a press release dated June 3, 2003. The GPC Biotech/Spectrum Pharmaceuticals Phase 3 registrational trial will compare satraplatin plus prednisone versus prednisone alone. Prednisone is a synthetic hormone often used to treat advanced prostate cancer.

The primary endpoint of the registrational trial for accelerated approval will be the time to disease progression. The study's objectives also will include the evaluation of pain control and survival, as well as an assessment of drug safety in this patient population.

"We are pleased to have received clearance from the FDA to proceed with the Phase 3 study. Our discussions with the FDA have been very constructive in developing the trial design, and we will continue to work closely with the Agency throughout the trial process," said Marcel Rozencweig, M.D., Senior Vice President, Drug Development of GPC Biotech and Chairman of the Satraplatin Joint Development Committee. "Hormone-refractory prostate cancer represents an area of major unmet medical need. For patients with this disease who fail one chemotherapeutic regimen, there are currently no approved treatment options." Dr. Rozencweig continued, "Together with our colleagues at Spectrum Pharmaceuticals, GPC Biotech is moving forward aggressively with the development and registrational plans for satraplatin."

"GPC Biotech has done exactly what we expected when we chose the Company as our co-development partner for satraplatin," stated Luigi Lenaz, M.D., President of the Oncology Division of Spectrum Pharmaceuticals and member of the Satraplatin Joint Development Committee. "Under Dr. Rozencweig's leadership, we have received clearance from the FDA to begin a well designed phase 3 clinical trial for satraplatin in hormone refractory prostate cancer, which is designed to meet the scientific and regulatory requirements for marketing approval of the drug by the FDA. We plan to continue working closely with our partner, GPC Biotech, and the FDA in the clinical development and registration of satraplatin."

Prostate cancer is the most common cancer among men in the U.S. Over 220,000 new cases are projected for 2003, and an estimated one in six men is expected to develop prostate cancer in his lifetime. An estimated 100,000 patients in North America, Europe and Japan combined have hormone-refractory prostate cancer. For those patients failing hormone therapy, treatment

currently involves a limited number of options, including chemotherapy. These options are usually only marginally effective. For those patients who fail first-line chemotherapy, there are currently no approved treatment regimens.

About Satraplatin

Satraplatin is a member of the platinum family of compounds, but unlike platinum compounds currently on the market, satraplatin is orally administered. Phase 2 trials have been successfully completed in HRPC, as well as in other tumor types, including ovarian and small cell lung cancer. Results from a randomized, 50-patient study in HRPC were presented at the ASCO Annual Meeting in June 2003. These data demonstrated statistical significance in time to disease progression, doubling progression-free survival. A registrational Phase 3 trial in HRPC is expected to begin in the near future. Satraplatin has already been studied in over 600 patients. Additional information on satraplatin can be found on the Company's website at www.spectrumpharm.com.

Spectrum Pharmaceuticals' primary focus is to develop in-licensed drugs for the treatment and supportive care of cancer patients. The Company's lead drug, satraplatin, is a phase 3 oral, anti-cancer drug being co-developed with GPC Biotech AG. Elsamitrucin, a phase 2 drug, will initially target non-Hodgkin's lymphoma. Eoquin™ is being studied in the treatment of superficial bladder cancer, and may have applications as a radiation sensitizer. The Company is actively working to develop, seek approval for and oversee the marketing of generic drugs in the U.S. Spectrum also has a pipeline of pre-clinical neurological drug candidates for disorders such as attention-deficit hyperactivity disorder, schizophrenia, mild cognitive impairment and pain, which it is actively seeking to out-license or co-develop. For additional information, visit the Company's web site at www.spectrumpharm.com.

This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These risks are described in further detail in the Company's reports filed with the Securities and Exchange Commission.

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