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FOR IMMEDIATE RELEASE

PROVECTUS RECEIVES GUIDANCE FROM FDA ON PATHWAY TO APPROVAL FOR PHASE 3 TRIAL OF PV-10 FOR METASTATIC MELANOMA
-Additional End-of-Phase 2 Meeting Not Required-
-Company to Submit for Special Protocol Assessment-

KNOXVILLE, TN, January 18, 2012 -- Provectus Pharmaceuticals, Inc. (OTCBB: PVCT, <http://www.pvct.com>), a development-stage oncology and dermatology biopharmaceutical company, has received guidance from the U.S. Food and Drug Administration ("FDA") to submit its Phase 3 protocol for review, either via standard review or a request for Special Protocol Assessment ("SPA"). This guidance was in response to Provectus's request of a final end-of-Phase 2 meeting to achieve consensus on design of a planned pivotal Phase 3 randomized controlled trial ("RCT") of PV-10 for metastatic melanoma. The FDA indicated that an additional end-of-Phase 2 meeting with Provectus is not required.

Provectus is seeking consensus on a design that will qualify for Special Protocol Assessment and supports approval of PV-10 for its melanoma indication. The Company intends to pursue the SPA path, which would represent an agreement from the FDA that the Phase 3 study design endpoints, statistical analyses and other components of the planned clinical trials are acceptable to support approval of the product.

Craig Dees, Ph.D., CEO of Provectus said, "Following our third meeting with the Agency in October, we believed that significant progress had been achieved in defining the threshold the FDA will require for approval in melanoma, which is a rapidly evolving therapeutic area. Using recommendations of senior FDA officials from that meeting, including those related to patient population and primary endpoint, we intend to request SPA review of our protocol, which we expect will be submitted before the end of the first quarter. While SPA can occur over as little as 45 calendar days, it is important to note that this is frequently an iterative process, and could take longer as we work with the Agency to reach ultimate agreement on study design."

Dr. Dees continued, "We also continue to assess whether a second Phase 3 RCT, tailored to meet the regulatory requirements of Australia, would be helpful in accelerating approval in that important market, and whether emerging results from ongoing immunologic mechanism of action studies can be used to support accelerated approval in the U.S. We are fortunate to have the necessary resources to allow sufficient flexibility in our development plan to maximize likelihood of approval in the major melanoma markets in the U.S., Australia and the European Union."

More information about the Special Protocol Assessment is contained in the Appendix to this press release.

About Provectus Pharmaceuticals, Inc.

Provectus Pharmaceuticals specializes in developing oncology and dermatology therapies. Its novel oncology drug PV-10 is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, significantly reducing potential for systemic side effects. Its oncology focus is on melanoma, breast cancer and cancers of the liver. The Company has received orphan drug designations from the FDA for its melanoma and hepatocellular carcinoma indications. Its dermatological drug PH-10 also targets abnormal or diseased cells, with the current focus on psoriasis and atopic dermatitis. Provectus has recently completed Phase 2 trials of PV-10 as a therapy for metastatic melanoma, and of PH-10 as a topical treatment for atopic dermatitis and psoriasis. Information about these and the Company's other clinical trials can be found at the NIH registry, www.clinicaltrials.gov. For additional information about Provectus please visit the Company's website at www.pvct.com or contact Porter, LeVay & Rose, Inc.

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FORWARD-LOOKING STATEMENTS: The forward-looking statements contained herein are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. The company undertakes no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date thereof.

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Appendix

About the Special Protocol Assessment (Summarized from the Guidance for Industry: Special Protocol Assessment, U.S. FDA, May 2002):

In conjunction with the 1997 reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA agreed to specific performance goals for special protocol assessment (SPA). These goals provide that, upon request from a sponsor, FDA will evaluate within 45 days certain submitted protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Protocols eligible for SPA include those for phase 3 trials intended to provide the primary basis for an efficacy claim and where the trial has been the subject of discussion at an end-of-phase 2 meeting with the review division.

Special protocol assessment is designed to evaluate individual protocols primarily in response to specific questions posed by sponsors. While more general drug development issues (such as the number of trials needed or adequacy of supportive evidence for a given efficacy claim) are factors in assessing the overall adequacy of a proposed protocol, such issues are not considered part of the SPA program. Typical issues reviewed under SPA can include the proposed protocol design, study conduct and execution, data analysis, and implications for labeling. The Agency's assessment will be based primarily on the questions posed by the sponsor, the underlying data, assumptions, information described by the sponsor, and relevant Agency policies and guidance documents.

After receiving a written request for SPA, the review division will decide whether the submission is appropriate for such assessment. If it is concluded that SPA is appropriate, the review division will proceed with assessment. The Agency can communicate with the sponsor regarding concerns with the protocol before issuing a SPA letter. In such cases, the sponsor can choose to submit a revised protocol, which the Agency will consider to be a new request, and will act on the revised protocol within 45 days.

The Agency can seek advisory committee review of a clinical protocol or can obtain advisory review from selected advisory committee members, special government employees, or other consultants. Advisory committee discussion of protocols submitted for special protocol assessment generally will not be open to the public. A special protocol assessment letter, including comments from the review team based on advice from the advisory committee or selected advisory committee members, should be sent to the sponsor within 45 calendar days of the advisory committee member review of the protocol.

If the sponsor requests a meeting with the Agency after receipt of a SPA letter, the request will be handled as a request for a Type A (critical path) meeting, and will be scheduled to take place within 30 calendar days after receipt of the written request for the meeting. At the Type A meeting, the Agency and sponsor should discuss any remaining issues and uncertainties regarding the protocol. If the Agency believes that meeting with the sponsor would be the best way to resolve outstanding issues regarding a SPA, it can suggest that the sponsor request such a meeting.

The PDUFA goals for SPA and agreement state that once agreement is reached on the design, execution, and analyses proposed in a reviewed protocol, the Agency will not later alter its perspective on these issues unless public health concerns unrecognized at the time of assessment become evident.

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