Provectus Biopharmaceuticals Opens Patient Enrollment; Begins Phase 3 International FDA Comparative Clinical Trial of PV-10 for Melanoma

Interim Data Expected When 50% of Events Achieved

Wednesday April 15, 2015

KNOXVILLE, Tenn.--(BUSINESS WIRE)--Provectus Biopharmaceuticals, Inc. (NYSE MKT: PVCT, www.pvct.com), a clinical-stage oncology and dermatology biopharmaceutical company ("Provectus" or the "Company"), enters phase 3 and has opened enrollment of patients for its phase 3 international FDA comparative clinical trial of PV-10 for melanoma. The Company is seeking 225 patients and enrollment has begun at St. Luke's University Hospital and Health Network, Bethlehem, PA, the first study site to be opened, with additional sites to be added in the coming weeks and months.

The study is an international multicenter, open-label, randomized controlled trial (RCT) of single-agent intralesional PV-10 versus systemic chemotherapy with dacarbazine (DTIC) or temozolomide (TMZ) to assess treatment of locally advanced cutaneous melanoma in patients who are BRAF V600 wild-type and have failed or are not otherwise candidates for ipilimumab or another immune checkpoint inhibitor. Subjects in the comparator arm will receive the Investigator's choice of dacarbazine or temozolomide as determined by Investigator preference and/or local availability of the agent. Effectiveness will be assessed by comparison of progression-free survival (PFS) between all intent-to-treat (ITT) subjects in the two study treatment arms. The Primary Outcome Measure is progression-free survival (PFS) to be assessed every 12 weeks up to 18 months

The Secondary Outcome Measures include complete response rate (CRR) and its duration (to be assessed every 12 weeks up to 18 months); and Overall survival (OS) to be assessed every 12 weeks up to 18 months.

Safety and tolerability will be assessed by monitoring the frequency, duration, severity and attribution of adverse events and evaluating changes in laboratory values and vital signs. For more details on the study, please visit https://www.clinicaltrials.gov/ct2/show/NCT02288897 Top-line results from the phase 2 trial have been posted on clinicaltrials.gov, for the study entitled "Phase 2 study of Intralesional PV-10 for Metastatic Melanoma," [NCT00521053]. https://clinicaltrials.gov/ct2/show/NCT00521053.

For a complete history of Provectus' research into PV-10 as a treatment for melanoma, visit https://www.pvct.com/pv10melanoma.html

About Provectus Biopharmaceuticals, Inc.

Provectus Biopharmaceuticals, Inc., specializes in developing oncology and dermatology therapies. PV-10, its novel investigational drug for cancer, is designed for injection into solid tumors (intralesional administration), thereby 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. PH-10, its topical investigational drug for dermatology, is undergoing clinical testing for psoriasis and atopic dermatitis. Provectus has 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.

FORWARD-LOOKING STATEMENTS: This release contains "forward-looking statements" as defined under U.S. federal securities laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current views of future performance, results, and trends and may be identified by their use of terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date hereof, and we undertake no obligation to update such statements after this date.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014) and the following:

- our determination, based on guidance from the FDA, whether to proceed with or without a partner with the fully enrolled phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma and the costs associated with such a trial if it is necessary to complete (versus interim data alone);
- our determination whether to license PV-10, our melanoma drug product candidate, and other solid tumors such as liver cancer, if such licensure is appropriate considering the timing and structure of such a license, or to commercialize PV-10 on our own to treat melanoma and other solid tumors such as liver cancer;
- our ability to license our dermatology drug product candidate, PH-10, on the basis of our phase 2 atopic dermatitis and psoriasis results, which are in the process of being further developed in conjunction with mechanism of action studies; and
- our ability to raise additional capital if we determine to commercialize PV-10 and/or PH-10 on our own, although our expectation is to be acquired by a prospective pharmaceutical or biotech concern prior to commercialization.

Contact:

Provectus Biopharmaceuticals, Inc.
Peter R. Culpepper, 866-594-5999 #30
CFO, COO
or
Porter, LeVay & Rose, Inc.
Investor Relations
Marlon Nurse, DM, SVP, 212-564-4700
or
Media Relations
Bill Gordon, 212-724-6312