



# Provectus Biopharmaceuticals Updates Market on Business Developments

## Amended Phase 3 Protocol Submitted to FDA Enrollment Begun in PH-10 Mechanism of Action Study Enrollment Completed in PV-10 Immunology Mechanism of Action Trial

**Thursday March 12, 2015**

KNOXVILLE, Tenn.--(BUSINESS WIRE)--Provectus Biopharmaceuticals, Inc. (NYSE MKT: PVCT, [www.pvct.com](http://www.pvct.com)), a development-stage oncology and dermatology biopharmaceutical company ("Provectus"), today provides the market with a business update that addresses several matters.

The Company noted that an amended phase 3 protocol for the testing of PV-10, its novel investigational drug for cancer, for the treatment of melanoma has been submitted to the U.S. Food and Drug Administration (the "FDA"). There were a number of minor changes made to the protocol that the Company discussed in its press release of February 9, 2015, which addressed the FDA review. The Company does not require additional FDA review to start the phase 3 study, and has begun the process of gaining IRB approval for the amended protocol (<https://clinicaltrials.gov/show/NCT02288897>).

In addition, the Company's study of PV-10 for liver tumors is continuing to accrue patients, in particular those with tumors metastatic to the liver (<https://clinicaltrials.gov/show/NCT00986661>). The Company expects to report initial data at one or more international cancer conferences this summer.

Also with regard to study enrollments, the Company announced that enrollment has begun in its mechanism of action [MOA] study for PH-10, its topical investigational drug for dermatology (<https://clinicaltrials.gov/show/NCT02322086>). The Company expects to recruit up to 30 patients at three study centers in the U.S. At the same time, Provectus announced the completion of enrollment in the PV-10 MOA study, meeting the target of enrolling 15 patients in the study (<https://clinicaltrials.gov/show/NCT01760499>). Enrollment and data collection for the PH-10 study are expected to be completed in December 2015. The Company expects further data from the PV-10 MOA study to be reported later this year or early in 2016.

The Company also noted that enrollment is continuing under its expanded access protocol for PV-10, with well over 100 melanoma patients having received PV-10 in the U.S. and Australia (<https://clinicaltrials.gov/show/NCT01260779>).

The Company noted that the January 2015 allowance of its novel synthesis patent application by the Chinese Patent Office, following on the issuance of the parent case in the U.S. in September 2013, represents a continued expansion of its global patent strategy, in particular protecting the key component of both PV-10 and PH-10 in major markets. Such process patents serve to strengthen its product-specific patents, such as U.S. Patent No. 8,974,363 issued earlier this week covering PH-10.

Provectus will also hold its year-end quarterly business update conference call at 4 p.m. (EDT) today to provide a detailed business update on PV-10 and PH-10 to the investment community and answer questions

from investors.

Those who wish to participate in the conference call may telephone 877-407-4019 from the U.S. International callers may telephone 201-689-8337, approximately 15 minutes before the call. A webcast will also be available at Provectus's website, [www.pvct.com](http://www.pvct.com). A digital replay will be available by telephone approximately two hours after the completion of the call until March 31, 2015, and may be accessed by dialing 877-660-6853 from the U.S. or 201-612-7415 for international callers, and using the Conference ID# 13601930.

#### About Provectus Biopharmaceuticals, Inc.

Provectus Biopharmaceuticals 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 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](http://www.clinicaltrials.gov). For additional information about Provectus please visit the Company's website at [www.pvct.com](http://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 a phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma and the costs associated with such a trial if it is necessary;
- 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.

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