Carbylan Therapeutics Completes Enrollment of Phase 3 Pivotal Trial for Hydros-TA

Jun 08, 2015

COR1.1 is the First of Two Phase 3 Pivotal Trials for Carbylan's Novel Osteoarthritis Therapy

PALO ALTO, Calif., June 8, 2015 (GLOBE NEWSWIRE) -- Carbylan Therapeutics (Nasdaq:CBYL), a specialty pharmaceutical company focused on the development of novel and proprietary combination therapies, today announced that it has completed enrollment of its 510 subject COR1.1 Phase 3 pivotal trial of Hydros-TA for the treatment of pain associated with osteoarthritis. Subjects were enrolled at 30 clinical sites in Canada, Australia, New Zealand, The Netherlands, Hungary and Curacao.

COR1.1 is the first of two pivotal trials of Hydros-TA as part of Carbylan's Phase 3 program design. The trial is comprised of subjects with Kellgren-Lawrence Grade 2 and 3 osteoarthritis (OA) of the knee. Subjects were randomized equally between three treatment arms: Hydros-TA, Hydros and TA (Triamcinolone Acetonide). The objective of the trial is to demonstrate the safety and efficacy of Hydros-TA and the contribution of each of the two components in this therapy. The primary endpoints are the change from baseline in WOMAC A (pain) subscale scores for Hydros-TA versus Hydros at two weeks and Hydros-TA versus TA at 26 weeks. Secondary endpoints include WOMAC C (function) changes, subject and physician global assessment changes and OMERACT_OARSI responder analysis. The Company expects top-line data from this trial in early 2016.

David Renzi, President and CEO of Carbylan Therapeutics, commented, "The completion of COR1.1 subject enrollment is a significant milestone for Carbylan and an important step toward our goal of bringing Hydros-TA to market. We believe this product can provide a potentially best in class alternative to the treatment options currently available for patients suffering from the pain of osteoarthritis by utilizing our proprietary crosslinking technology to combine a low dose steroid with our novel hyaluronan in order to offer both rapid and sustained pain relief."

About Carbylan Therapeutics

Carbylan is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel and proprietary combination therapies that address significant unmet clinical needs. The Company's lead product candidate, Hydros-TA, is a proprietary, cross-linked combination of low dose corticosteroid and novel hyaluronic acid viscosupplement, designed to provide both rapid and sustained osteoarthritis pain relief via a single intra-articular injection.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Carbylan Therapeutics, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including statements regarding the timing of receipt of top-line data from the COR1.1 trial, Carbylan's ability to successfully bring Hydros-TA to market, and statements regarding the potential for Hydros-TA to offer a best in class alternative to the treatment options currently available for patients suffering from the pain of osteoarthritis. Such forward-looking statements involve substantial risks and uncertainties that could cause Carbylan's future results to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing and success of regulatory filings and other matters that could affect the availability or commercial potential of Carbylan's drug candidates. Carbylan Therapeutics undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see Carbylan's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 21, 2015, and its subsequent periodic reports to be filed with the Securities and Exchange Commission.

CONTACT: The Ruth Group
David Burke/Lee Roth
646-536-7009/7012
dburke@theruthgroup.com/lroth@theruthgroup.com

Carbylan Therapeutics