Aclaris Therapeutics Announces Positive Results from Phase 2b Clinical Trial of A-101 for the Removal of Seborrheic Keratosis, a Common Type of Benign Skin Tumor

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Malvern, PA – January 27, 2015 – Aclaris Therapeutics, Inc. today announced positive results from a Phase 2b clinical trial of the Company's lead drug, A-101. In the trial, A-101 demonstrated clinically and statistically significant improvements in clearing multiple seborrheic keratoses (SK), one of the most common types of skin tumors. Though the lesions are benign, many patients elect to have SK treated, either because the lesions are irritated or are cosmetically concerning.

The double-blind, vehicle-controlled Phase 2b clinical trial was designed to evaluate the safety, tolerability and efficacy of A-101 in removing multiple SK lesions on the trunk and extremities. The trial used a parallel-group design to compare two concentrations of A-101 and vehicle (placebo) in 172 subjects with SK lesions. Results from the study showed A-101 achieved statistical significance in clearing SK lesions in a dose-related fashion. A-101 was well tolerated at both concentrations studied.

"This positive outcome represents an important milestone for A-101 and further demonstrates its potential as a non-invasive treatment for SK, a condition for which there are currently no FDA-approved therapies," said Dr. Neal Walker, President and CEO of Aclaris. "These findings, along with results from a second, ongoing Phase 2b study to evaluate A-101 in treating SK lesions on the face, will be used to support the progression of A-101 into Phase 3 trials. Results from the second Phase 2b study are expected later this quarter."

SK are among the most common skin tumors seen in middle-aged and older adults, affecting approximately 83 million people in the U.S.* SK lesions have a waxy, scaly, slightly elevated appearance and often multiple growths are present. Currently, SK lesions are treated using modalities such as cryosurgery, electrosurgery, curettage, or surgical removal which may be painful and may often result in pigmentary changes and/or scarring at the treatment site.

"These study results are promising and suggest that A-101 may have the potential to address an unmet medical need," said Janet DuBois, MD, a dermatologist in Austin, TX and an investigator on multiple A-101 clinical trials. "While cryotherapy is the most commonly used treatment for the removal of SK lesions, it is painful for patients and sometimes results in permanent hypopigmentation. A well-tolerated, FDA-approved, non-invasive treatment option for SK would be a welcome advance for patients and physicians."

About Seborrheic Keratosis

Seborrheic keratoses are one of the most common skin tumors, affecting a majority of middle-aged to older adults. While benign, these lesions are often cosmetically disturbing, may become symptomatic (irritated, pruritic (itchy), painful) or may be confused with more serious skin lesions. Numerous surgical/destructive treatment options for SK exist, however they are typically painful and are often complicated by significant adverse cosmetic outcomes including pigmentary changes, and/or scarring. There are currently no therapies approved by the United States Food and Drug Administration (FDA) for the treatment of seborrheic keratosis.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a privately-held specialty pharmaceutical company focused on the development of the first topically applied therapy directed toward the removal of seborrheic keratosis (SK) and other verrucoid lesions of the skin. The Company is based in Malvern, Pennsylvania and more information can be found by visiting the Company's website at www.aclaristx.com.

* Reference: Lewin Group, Burden of Skin Diseases Report, 2004.