Aclaris Therapeutics' Lead Drug Candidate A-101 Achieves Statistically Significant Results in Third Phase 2 Clinical Trial for Seborrheic Keratosis, a Common Type of Benign Skin Tumor

March 17, 2015 5:07 PM ET

Malvern, PA – March 17, 2015 – Aclaris Therapeutics, Inc. today announced statistically significant results from a Phase 2 clinical trial of its lead drug candidate, A-101. In the trial, A-101 demonstrated clinically and statistically significant improvements in removing seborrheic keratosis (SK) lesions on the face. SK is one of the most common types of skin tumors. Although the lesions are benign, many patients elect to have SK treated, either because the lesions have become irritated or because the patient feels they are cosmetically concerning.

The double-blind, vehicle-controlled Phase 2 clinical trial was designed to evaluate the safety, tolerability and effectiveness of A-101 in removing targeted SK lesions on the face. The trial used a parallel-group design to compare two concentrations of A-101 and vehicle (placebo) in 120 subjects with SK lesions on the face. Results from the trial 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 outcome represents another important milestone for A-101 and, along with results from prior Phase 2 studies, lays the groundwork for discussions with the FDA about next steps," said Stuart D. Shanler, M.D., Chief Scientific Officer of Aclaris Therapeutics. "We look forward to moving A-101 into Phase 3 development and are encouraged about its potential as a non-invasive treatment for SK, a condition for which there are currently no FDA-approved drug therapies."

SK are among the most common skin tumors seen in middle-aged and older adults, affecting over 83 million people in the United States. 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.

"Results from the three Phase 2 clinical trials suggest that A-101 has the potential to be an effective option to treat SK lesions," said Jonathan S. Weiss, M.D., Assistant Clinical Professor of Dermatology at Emory University School of Medicine and private practitioner in Snellville, GA. "A well-tolerated, FDA-approved, non-invasive treatment for SK would be a welcome advance for patients and physicians."

About Seborrheic Keratosis

Seborrheic keratoses (SK) are one of the most common skin tumors, affecting over 83 million people in the United States*. SK lesions have a waxy, scaly, slightly elevated appearance and often multiple growths are present. While benign, these lesions are often cosmetically disturbing, may become symptomatic (irritated, pruritic (itchy), painful) or may be confused with more serious skin lesions. Currently, SK lesions are treated by cryotherapy, electrosurgery, curettage, or surgical removal. Each of these methods may be painful or can result in pigmentary changes or scarring at the treatment site. There are currently no drugs approved by the FDA for the treatment of SK.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage specialty pharmaceutical company focused on identifying, developing, and commercializing novel topical drugs to address unmet needs in dermatology. Aclaris Therapeutics, Inc. is based in Malvern, Pennsylvania.

* Bickers et al. Burden of Skin Diseases Report: 2004. *J Am Acad Dermatol:* September 2006;55(3):490-500.