FDA grants Fast Track Designation to Aclaris Therapeutics' Investigational JAK Inhibitor for the treatment of Alopecia Areata

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WAYNE, Pa., July 09, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Aclaris' investigational topical Janus Kinase (JAK) 1/3 inhibitor (ATI-502) for the treatment of alopecia areata, including patchy alopecia areata and the more severe variants of the disease, alopecia totalis and universalis.

The FDA's Fast Track designation is intended to facilitate the development of new therapies for serious conditions and with the potential to address an unmet medical need. A company with an investigational medicine receiving Fast Track designation may be eligible for more frequent communications with the FDA and may receive an expedited review of the new drug application.

"This Fast Track designation represents a positive step for the development of ATI-502. This designation recognizes the unmet need that exists for patients living with this often-devastating autoimmune disease and the impact of sudden or unpredictable hair loss," said Christopher Powala, Chief Regulatory & Development Officer of Aclaris. "We look forward to working closely with the FDA throughout our development program with the hope of ultimately bringing this important treatment option to patients."

About Alopecia Areata

Alopecia areata is an autoimmune disease that results in partial or complete loss of hair on the scalp and body. The scalp is the most commonly affected area, but any hair-bearing site can be affected alone or together with the scalp. Onset of the disease can occur throughout life and affects both women and men. AA can be associated with serious psychological consequences, including anxiety and depression. AA affects up to 2.0% of people globally at some point during their lifetime (i.e. incidence) and up to 0.2% of people are affected at any given time (i.e. prevalence). There are currently no drugs approved by the FDA for the treatment of AA.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan", "potential", "will", and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding Aclaris' clinical development of its JAK inhibitor drug candidates. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2017, Aclaris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "Financial Information" section of the Investors page of Aclaris' website at http://www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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