



Aclaris Therapeutics Announces the Allowance of a U.S. Patent Application and Issuance of a Japanese Patent Covering Tofacitinib for Treating Hair Loss Disorders

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MALVERN, Pa., Oct. 24, 2017 (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, today announced that Columbia University has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent application covering methods of treating a hair loss disorder, such as alopecia areata and androgenetic alopecia, or inducing hair growth, by administering tofacitinib topically or by administering tofacitinib as the sole active ingredient, and treating androgenetic alopecia or inducing hair growth in a subject having androgenetic alopecia by administering tofacitinib. The application was allowed with 66 claims.

This U.S. application will become the latest patent to issue in Aclaris' JAK inhibitor drug development program for hair loss disorders. Columbia University has previously issued U.S. patents covering the use of ruxolitinib, baricitinib, and decernotinib (VX-509) for the treatment of hair loss disorders, for inducing hair growth, as well as the use of these JAK inhibitors to treat androgenetic alopecia. The allowed U.S. application is part of an intellectual property portfolio which includes other issued patents and numerous patent applications in the U.S. and major international markets directed to various JAK inhibitors for the treatment of hair loss disorders, such as alopecia areata, androgenetic alopecia, and other hair loss conditions.

The allowance of this U.S. application follows closely on the heels of the issuance of Japanese Letters Patent No. 6212107, which is directed to topical compositions of tofacitinib, as well as pharmaceutical compositions of tofacitinib as the sole therapeutic active agent, for treating hair loss disorders and for inducing hair growth. Japanese Letters Patent No. 6212107 was issued on September 22, 2017 with 25 claims and expires in March 2033. The claims cover tofacitinib in a topical composition or as the sole active therapeutic agent in a pharmaceutical composition for inducing hair growth and for treating hair loss disorders, such as alopecia areata and androgenetic alopecia. This newly issued patent is owned by The Trustees of Columbia University in the City of New York and exclusively licensed to Aclaris.

Another patent has already been issued in Japan for the pharmaceutical compositions of ruxolitinib or baricitinib for the treatment of hair loss disorders, such as androgenetic alopecia and alopecia areata. This previously issued patent, Japanese Letters Patent No. 5948337, was granted on June 10, 2016 and will expire in November 2031. These Japanese patents further bolster the steadily growing worldwide protection Aclaris has acquired for its JAK drug development program for hair loss disorders.

"We are delighted with the steady expansion of the patent portfolio we exclusively licensed from Columbia University. The U.S. allowance and the new Japanese patent augment our already strong worldwide intellectual property portfolio related to the use of JAK inhibitors for the treatment of hair loss disorders," said Stu Shanler, M.D., Chief Scientific Officer of Aclaris.

Through exclusive licenses, Aclaris has built an extensive intellectual property estate consisting of selective JAK 1/3 compounds, highly selective JAK 3 compounds, and methods of using JAK inhibitors to treat AA, AGA, and various other hair loss disorders. Aclaris has exclusively licensed a patent portfolio from Columbia University directed to methods of using JAK inhibitors for the treatment of AA, AGA, and other hair loss disorders. This portfolio includes four issued U.S. patents and a recently allowed U.S. application directed to methods of treating AA, AGA and other hair loss disorders by administering baricitinib, decernotinib, ruxolitinib, or tofacitinib, and two recently issued patents in Japan directed to pharmaceutical compositions comprising baricitinib, ruxolitinib, or tofacitinib for use in treating AA, AGA and other hair loss disorders. Aclaris will continue to prosecute additional intellectual property to protect our interests.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is 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. Aclaris is focused on large, underserved market segments with no FDA-approved medications or where treatment gaps exist. Aclaris is based in Malvern, Pennsylvania and more information can be found by visiting the Aclaris website at www.aclaristx.com.

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 the development of Aclaris' product candidates focused on JAK inhibition for the treatment of hair loss disorders, including Aclaris' intellectual property strategy. 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, risks associated with maintaining its intellectual property portfolio and other risks and uncertainties that are described in Aclaris' Annual Report on Form 10-K for the year ended December 31, 2016, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, and other filings Aclaris makes with the SEC 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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