Pfizer Receives FDA Approval for EUCRISA™ (crisaborole)

Wednesday, February 08, 2017 - 10:30am

Pfizer Receives FDA Approval for EUCRISA™ (crisaborole) a Novel Non-Steroidal Topical Ointment for Mild to Moderate Atopic Dermatitis (Eczema) EUCRISA Approved for Patients 2 Years of Age and Older First Prescription Treatment Approved for Eczema in More than a Decade

Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) approved EUCRISATM (crisaborole) ointment 2%, a novel non-steroidal topical phosphodiesterase-4 (PDE-4) inhibitor for the treatment of mild to moderate atopic dermatitis (AD) in patients two years of age and older.1 AD, often called eczema, is a chronic condition impacting nearly 18 million children and adults in the United States.2 Approximately 90 percent of people living with AD have the mild to moderate form of the condition.3

“The approval of EUCRISA is great news for the children and adults suffering from mild to moderate eczema, a community that has not had a new prescription treatment for more than 10 years,” said Albert Bourla, Group President, Pfizer Innovative Health. “This is also an important milestone for Pfizer as we continue to build on our heritage in Inflammation and Immunology by offering innovative treatment options to patients who need them.”

EUCRISA is the first and only non-steroidal topical monotherapy that inhibits the PDE-4 enzyme in the skin. Overactive PDE-4 has been shown to contribute to the signs and symptoms of AD.4 The specific mechanism of action of crisaborole in AD is not well defined.1

“I’m delighted to have a new option for my patients with mild to moderate atopic dermatitis,” said Amy Paller, M.D., Walter J. Hamlin Professor and Chair of Dermatology,

Professor of Pediatrics, Northwestern University Feinberg School of Medicine, a clinical trial investigator. “The results seen in these pivotal Phase 3 studies show the efficacy and safety of EUCRISA as a steroid-free treatment option for people as young as two living with mild to moderate atopic dermatitis.”

SELECTED IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: EUCRISA is contraindicated in patients with known hypersensitivity to crisaborole or any component of the formulation.

EUCRISA TRIAL RESULTS

The approval of EUCRISA is based on a clinical development program including the results of two large, identical, multicenter, randomized, double-blind, parallel-group, vehicle-controlled (non-medicated ointment) trials (Trials 1 and 2) that treated 1,522 patients with mild to moderate AD between the ages of two and 79.1 At baseline, 38.5% of the subjects had an Investigator’s Static Global Assessment (ISGA) score of 2 (mild), and 61.5% had an ISGA score of 3 (moderate). The ISGA score includes erythema (redness), induration (hardening)/papulation (formation of papules), and oozing/crusting on a severity scale of 0 to 4.

In both trials, subjects were randomized 2:1 to receive EUCRISA or vehicle (non-medicated ointment) applied to skin with signs and symptoms of AD twice daily for 28 days.1 The primary efficacy endpoint was success in ISGA at day 29, defined as the proportion of patients achieving an ISGA score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline. These data showed EUCRISA to be an effective treatment that achieved statistically significant results versus vehicle for the primary efficacy endpoint in adults and children two years of age and older [32.8% versus 25.4% ($P=0.038$) for Trial 1 and 31.4% versus 18.0% ($P<0.001$) for Trial 2].1,3 Efficacy results were seen in some patients as early as day eight (first post-baseline assessment), with 13.4% of EUCRISA patients achieving success in ISGA versus 4.5% with vehicle in Trial 1 and 15.9% EUCRISA versus 6.3% vehicle in Trial 2.1,5,6

In these studies, the adverse reaction reported by more than 1% of EUCRISA patients was pain at the application site, such as stinging or burning [4% (N=45)] versus vehicle [1% (N=6)]. The rate of study discontinuation due to adverse reactions was the same in the EUCRISA group versus vehicle (1.2%).3

“After many years without new therapies, this is an exciting day for those living with mild to moderate eczema and their caregivers,” said Julie Block, President and Chief Executive

Officer of the National Eczema Association.

INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION

EUCRISA is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

CONTRAINDICATIONS

EUCRISA is contraindicated in patients with known hypersensitivity to crisaborole or any component of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions, including contact urticaria, have occurred in patients treated with EUCRISA and should be suspected in the event of severe pruritus, swelling and erythema at the application site or at a distant site. Discontinue EUCRISA immediately and initiate appropriate therapy if signs and symptoms of hypersensitivity occur.

ADVERSE REACTIONS

The most common adverse reaction occurring in ≥ 1% in subjects in clinical trials was application site pain, such as burning or stinging.

The full results for these trials were published in July 2016, in the Journal of the American Academy of Dermatology.

For Full Prescribing Information please visit www.pfizer.com.

About Atopic Dermatitis

Atopic dermatitis is a chronic condition characterized by inflammation of the skin.2 Lesions of atopic dermatitis are characterized by erythema (redness), induration (hardening)/papulation (formation of papules), and oozing/crusting.2

About EUCRISATM (crisaborole) ointment 2%

EUCRISA is a prescription ointment used on the skin (topical) to treat mild to moderate atopic dermatitis (commonly referred to as eczema) in adults and children two years of age and older.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com.In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of December 14, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about EUCRISA (crisaborole) ointment 2%, including its potential benefits, and an approval in the U.S. for the topical treatment of mild to moderate atopic dermatitis in patients two years of age and older, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of EUCRISA; the uncertainties inherent in research and development, including the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new Page of 5clinical data and additional analyses of existing clinical data; whether and when any applications for EUCRISA may be filed with regulatory authorities in any jurisdictions (other than the United States); whether and when regulatory authorities in any such other jurisdictions where applications may be filed may approve such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of EUCRISA; and competitive developments. A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its

subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results,” as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

1 EUCRISATM (crisaborole) Prescribing Information. New York. NY: Pfizer Inc: 2016.

2 Hanifin JM, Reed ML. A population-based survey of eczema in the United States. Dermatitis. 2007;18(2):82-91.

3 Paller AS, Tom WL, Lebwohl MG, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. J Am Acad Dermatol. 2016;75(3):494-503.

4 Sawai T, Ikai K, Uehara M. Cyclic adenosine monophosphate phosphodiesterase activity in peripheral blood mononuclear leucocytes from patients with atopic dermatitis: correlation with respiratory atopy. Br J Dermatol.1998;138(5):846-8.

5 Data on file. Final clinical study report for AN2728-AD-301.

6 Data on file. Final clinical study report for AN2728-AD-302.

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