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U.S. FDA Approves Supplemental New Drug Application (sNDA) for Expanded Indication of EUCRISA® (Crisaborole) Ointment, 2%, in Children as Young as 3 Months of Age With Mild-to-Moderate Atopic Dermatitis

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EUCRISA is the first and only 100% steroid-free, topical prescription medication approved for patients as young as 3 months of age in the United States

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved its supplemental New Drug Application (sNDA) for EUCRISA® (crisaborole) ointment, 2%, extending the lower age limit from 24 months down to 3 months in children with mild-to-moderate atopic dermatitis (AD), also known as eczema.[1] EUCRISA was previously approved for use in adults and children 2 years of age and older.[2] This supplemental approval makes EUCRISA the first and only steroid-free, topical prescription medication for mild-to-moderate AD patients as young as 3 months of age.

"Families often spend hours each day attempting to ease their child's eczema symptoms, affecting both infants and caregivers. This is a struggle I see in my daily practice, and it can take a toll on the entire family," said Lawrence Eichenfield, M.D., chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, vice chair of the Department of Dermatology, and a professor of Dermatology and Pediatrics at UC San Diego School of Medicine. "The approval of a steroid-free treatment option for this age group offers potential relief for these very young patients."

AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects that affects nearly 18 million people and approximately 11% of children in the U.S.[3,4,5] Early onset AD is the most common form of the condition and begins within the first two years of life.[6] A total of 45% of all AD cases begin within the first six months of life, and 60% begin during the first year.[4,7]

“Despite atopic dermatitis often manifesting during infancy, there are few approved treatment options for this population available today,” said Richard Blackburn, Global President, Inflammation & Immunology, Pfizer. “We are committed to making a meaningful difference to patients’ lives, and with this indication extension, we look forward to now helping many of the youngest children suffering with eczema.”

The approval for the expanded indication of EUCRISA was supported by data from a Phase 4, open-label, clinical study designed to assess the safety of crisaborole ointment in infants aged 3 months to less than 24 months with mild-to-moderate AD, with effectiveness as an exploratory endpoint. In this study, crisaborole ointment, 2%, was well-tolerated and demonstrated effectiveness in patients with mild-to-moderate AD with no

new safety signals identified.[8]

About the CrisADe CARE 1 Study

The sNDA submission was based on data from the Phase 4 CrisADe CARE 1 trial. The four-week, multicenter, open-label, single-arm study evaluated the safety of crisaborole ointment, 2%, applied twice daily in 137 pediatric patients who were 3 months to less than 24 months of age, with effectiveness as an exploratory endpoint. All patients had mild-to-moderate AD involving at least 5% treatable body surface area (%BSA), excluding the scalp. A cohort of 21 of the 137 subjects was included in a subgroup for pharmacokinetic (PK) assessment, with clinical diagnoses of moderate AD and a minimum of 35% treatable %BSA, excluding the scalp.[8]

Additional information about the study can be found at www.clinicaltrials.gov.

About Atopic Dermatitis

AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects. Lesions of AD are characterized by erythema (redness), induration (hardening)/papulation (formulation of papules), and oozing/crusting.[3,4]

In addition to causing physical discomfort, AD can also have a significant impact on emotional and social aspects of an individual's life.[9,10] AD can also have a negative effect on patients' families, and childhood AD may have a greater impact on health-related quality of life than diabetes.[9,11]

Approximately 50% of pediatric AD patients globally have recurrent symptoms into adolescence and adulthood.[7,11]

About EUCRISA® (crisaborole) ointment, 2%

Crisaborole ointment, 2%, is a novel, steroid-free, topical phosphodiesterase (PDE4) inhibitor.[12] It is approved in the U.S. as EUCRISA® (crisaborole ointment, 2%) for topical treatment of mild-to-moderate AD in adults and pediatric patients 3 months of age and older. Crisaborole is also approved in Canada as EUCRISA® (crisaborole ointment, 2%) and Israel and Australia as STAQUIS™ (crisaborole ointment, 2%) for mild-to-moderate atopic dermatitis (AD) in patients 2 years of age and older.[1,13,14,15]

EUCRISA® (crisaborole) ointment, 2%, IMPORTANT SAFETY INFORMATION

Do not use EUCRISA if you are allergic to crisaborole or any of the ingredients in EUCRISA.

EUCRISA may cause side effects including allergic reactions at or near the application site. These can be serious and may include hives, itching, swelling and redness. If you have any of these symptoms, stop using EUCRISA and get medical help right away.

The most common side effect of EUCRISA is application site pain, such as burning or stinging.

EUCRISA is for use on skin (topical use) only. Do not use EUCRISA in your eyes, mouth or vagina.

INDICATION

EUCRISA is a prescription ointment used on the skin (topical) to treat mild-to-moderate eczema (atopic dermatitis) in adults and pediatric patients 3 months of age and older.

Please see full prescribing information for EUCRISA here.

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DISCLOSURE NOTICE: *The information contained in this release is as of March 24, 2020. 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 crisaborole ointment, 2%, and a new, expanded indication for the treatment of children aged 3 months to less than 24 months with mild to moderate atopic dermatitis, including their potential benefits, 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 crisaborole ointment, 2%; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any other jurisdictions for any potential indication for crisaborole ointment, 2%; whether and when any such applications that may be pending or filed for crisaborole ointment, 2% may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether crisaborole ointment, 2%, will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of crisaborole ointment, 2%; 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, 2019 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.

References

[1]EUCRISA® (crisaborole). Full Prescribing Information. March 2020.
[2]Pfizer Inc. Pfizer Receives FDA Approval for EUCRISA™ (crisaborole), a Novel Non-Steroidal Topical Ointment for Mild to Moderate Atopic Dermatitis (Eczema). https://www.pfizer.com/news/press-release/press-

release-detail/pfizer_receives_fda_approval_for_eucrisa_crisaborole_a_novel_non_steroidal_topical_ointment_for_mild_to_mo
. Accessed August 14, 2018.
[3]Hanifin JM, Reed ML. A population-based survey of eczema in the United States. *Dermatitis*. 2007;18(2):82-91.
[4]Bieber T. Atopic dermatitis. *Dermatology*. 2012;1(3):203-217.
[5]Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health. *J Invest Dermatol*. 2011;131(1):67-73.
[6] McAleer MA, O'Regan GM, Irvine AD. Atopic dermatitis. In: Bolognia JL, Schaffer JV, Cerroni L, eds. *Dermatology*. 4th ed: Elsevier; 2018:208-227.
[7] Williams HC. Clinical practice. Atopic dermatitis. *N Engl J Med*. 2005;352(22):2314-2324.
[8] Data on file. Pfizer Inc. New York, NY.
[9] Lifschitz C. The impact of atopic dermatitis on quality of life. *Ann Nutr Metab*. 2015;66(suppl 1):24-40.
[10]Anderson RT, Rajagopalan R. Effects of allergic dermatosis on health-related quality of life. *Curr Allergy Asthma Rep*. 2001;1:309-315.
[11]Leung DYM. New insights into atopic dermatitis: role of skin barrier and immune dysregulation. *Allergol Intl*. 2013;62(2):151-161.
[12]Jarnagin K, Chanda S, Coronado D, et al. Crisaborole topical ointment, 2%: a nonsteroidal, topical, anti-inflammatory phosphodiesterase 4 inhibitor in clinical development for the treatment of atopic dermatitis. *J Drugs Dermatol*. 2016;15(4):390-396.
[13]EUCRISA™ (crisaborole). Health Canada Product Monograph. June 2018.
[14]STAQUIS. Full Prescribing Information Israel. July 2018.
[15]STAQUIS™ (crisaborole). Australia Product Information. February 2019.

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