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Pfizer Announces Positive Top-Line Results from Phase 4 Study of Crisaborole Ointment, 2%, in Children Aged 3 Months to Less Than 24 Months with Mild to Moderate Atopic Dermatitis

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Data show crisaborole ointment, 2%, a steroid-free topical treatment, was well-tolerated over 4-week treatment period Safety profile consistent with previous clinical trial experience

Pfizer Inc. (NYSE:PFE) today announced top-line results from a Phase 4 study (CrisADe CARE 1) which showed that crisaborole ointment, 2%, was well-tolerated in children aged 3 months to less than 24 months with mild to moderate atopic dermatitis (AD), also known as eczema. The data from the trial are supportive of the primary study objective to examine the safety of crisaborole ointment, 2%, in this patient population, and are consistent with previous clinical trial experience.[1] Crisaborole ointment, 2%, is currently approved in select countries for mild to moderate AD in patients two years of age and older.[2,3,4,5]

“This study reinforces our commitment to young AD patients worldwide who need more options,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “These results add to the growing body of evidence that underscores the strength of data for crisaborole as a steroid-free, topical treatment option for people with mild to moderate atopic dermatitis. We look forward to discussing the data with regulatory authorities in the future.”

The primary endpoints of CrisADe CARE 1 were the number of patients with treatment-emergent adverse events (AEs) and severe adverse events (SAEs) and number of patients with clinically significant changes from baseline in height, weight, vital signs, electrocardiogram (ECG), and clinical laboratory parameters.

Detailed analyses of the study will be submitted for presentation at a future scientific meeting.

Crisaborole ointment, 2%, is a novel, steroid-free, topical phosphodiesterase (PDE4) inhibitor.[6] It is approved in the U.S. and Canada as EUCRISA® (crisaborole ointment, 2%) and Israel and Australia as STAQUIS™ (crisaborole ointment, 2%) for mild to moderate atopic dermatitis (AD) in patients two years of age and older.[2,3,4,5]

About the CrisADe CARE 1 Study

The phase 4 crisaborole study (CrisADe CARE 1) was a 4-week, multicenter, open-label, single-arm study to evaluate the safety, pharmacokinetics (PK), and efficacy of crisaborole ointment, 2%, applied twice daily (BID) in 125 pediatric patients who were 3 months to less than 24 months of age with mild to moderate atopic

dermatitis (AD) involving at least 5% treatable body surface area (%BSA), excluding the scalp. A cohort of 16 of the 125 subjects were included in a subgroup for PK assessment, with clinical diagnoses of moderate AD and a minimum of 35% treatable %BSA, excluding the scalp.[1]

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.[7,8]

AD is one of the most common, chronic, relapsing childhood dermatoses, affecting up to 10% of adults and up to 20% of children worldwide.[9,10] A total of 45% of all AD cases begin within the first 6 months of life, 60% begin during the first year, and 85% begin before 5 years of age.[8,11] Approximately 50% of pediatric AD patients globally have recurrent symptoms into adolescence and adulthood.[11,12]

About Crisaborole

Crisaborole ointment, 2%, is a novel, steroid-free, topical phosphodiesterase (PDE4) inhibitor.[6] It is approved in the U.S. and Canada as EUCRISA® (crisaborole ointment, 2%) and Israel and Australia as STAQUIS™ (crisaborole ointment, 2%) for mild to moderate atopic dermatitis (AD) in patients two years of age and older.[2,3,4,5]

EUCRISA® (crisaborole) ointment, 2%, IMPORTANT SAFETY INFORMATION FROM THE U.S. PRESCRIBING 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 children 2 years of age and older.

Please see full prescribing information for EUCRISA in the U.S. here.

Pfizer Inc: Breakthroughs that change patients' lives

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 health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and 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 July 1, 2019. 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 potential new 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 jurisdictions for any potential indication for crisaborole ointment, 2%; whether and when any such applications 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, 2018 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] Data on file. Pfizer Inc. New York, NY.

[2] EUCRISA® (crisaborole). Full Prescribing Information. December 2018.

[3] EUCRISA™ (crisaborole). Health Canada Product Monograph. June 2018.

[4] STAQUIS. Full Prescribing Information Israel. July 2018.

[5] STAQUIS™ (crisaborole). Australia Product Information. February 2019.

[6] 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.

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