

# Pfizer Announces the Publication of Final Results from Two Pivotal Phase 3 Studies of Crisaborole Topical Ointment in Patients with Mild to Moderate Atopic Dermatitis

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Phase 3 Data Published in the Journal of the American Academy of Dermatology

## **“Forward-Looking Information and Factors That May Affect Future Results”**

Pfizer Inc. (NYSE:PFE) announced today the publication of findings from two pivotal Phase 3 studies of investigational crisaborole topical ointment 2% (formerly AN2728) in the online issue of the *Journal of the American Academy of Dermatology*.

“Atopic dermatitis, or eczema, is a chronic, inflammatory skin disease that affects millions of children and adults. There have been no new therapies approved in the United States for people with atopic dermatitis in the past 15 years,” said Amy Paller, M.D., Walter J. Hamlin Professor and Chair of Dermatology, Professor of Pediatrics, Northwestern University Feinberg School of Medicine. “The results seen in these pivotal Phase 3 studies demonstrate that crisaborole, if approved, could be a meaningful treatment option for patients with mild to moderate atopic dermatitis.”

The detailed results from the Pivotal Phase 3 studies (AD-301 and AD-302) showed that crisaborole achieved statistically significant results on primary and secondary endpoints for the treatment of atopic dermatitis (AD) in children two years of age and up and adults versus vehicle ointment alone. Crisaborole treatment-related adverse events were infrequent, mild to moderate in severity, and similar to vehicle ointment.

“The addition of crisaborole to the Pfizer inflammation and immunology portfolio as a potential treatment option for patients with mild to moderate atopic dermatitis underscores our commitment to deliver innovative medicines for patients with high unmet needs in medical dermatology,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development, “This publication highlights the quality of the Phase 3 clinical data with crisaborole, and we are excited to continue to work with our Anacor colleagues and regulatory authorities in our effort to bring this important medicine to patients.” Pfizer recently completed the acquisition of Anacor Pharmaceuticals. If approved, crisaborole would represent the first commercialized product as a result of the combination with Anacor.

## **About Atopic Dermatitis**

Atopic dermatitis (AD) is a chronic condition characterized by inflammation and itching.<sup>1,2,3</sup> Lesions of AD are commonly red, elevated patches and are often accompanied by pruritus (itching).<sup>1,2,3</sup> Based on available

sources, approximately 18 to 25 million people in the United States suffer from AD,<sup>4</sup> and 80% to 90% have mild or moderate disease.<sup>5</sup> AD most commonly appears in childhood, with estimates that between 8% and 18% of all infants and children in the United States are affected by the disease.<sup>6</sup>

### **About Crisaborole Topical Ointment, 2%**

Crisaborole topical ointment, 2%, is an investigational non-steroidal topical anti-inflammatory PDE4 inhibitor in development for the potential treatment of mild to moderate AD. Crisaborole is a boron-containing small molecule that inhibits PDE4 in target cells, which may reduce the production of pro-inflammatory cytokines thought to cause the signs and symptoms of AD.

### **Pfizer Inc.: Working together for a healthier world®**

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](http://www.pfizer.com). In addition, to learn more, follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer\\_News](https://twitter.com/Pfizer_News), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/user/Pfizer) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**DISCLOSURE NOTICE:** The information contained in this release is as of July 13, 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 a product candidate, crisaborole topical ointment 2%, including its 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, 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 clinical data and additional analyses of existing clinical data; whether and when any applications for crisaborole may be filed with regulatory authorities in any jurisdictions (other than the United States); whether and when the U.S. Food and Drug Administration will approve the pending application for crisaborole and whether and when regulatory authorities in any 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 crisaborole; 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com)

<sup>1</sup> Bieber T. Atopic dermatitis. *Ann Dermatol* 2010;22:125-37.

<sup>2</sup> Bieber T. Atopic dermatitis. *N Engl J Med*. 2008;358:1483-94.

<sup>3</sup> Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71:116-32.

<sup>4</sup> Hanifin JM, Reed ML. A population-based survey of eczema in the United States. *Dermatitis*. 2007;18(2):82-91.

<sup>5</sup> Arkwright PD, Motala C, Subramanian H, Spergel J, Schneider LC, Wollenberg A. Management of difficult-to-treat atopic dermatitis. *Journal of Allergy Clin Immunol Pract*. 2013;1:142-51.

<sup>6</sup> 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.

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