

# Overview of Crisaborole Topical Ointment, 2%, in Phase 3 Clinical Trials



Anacor has completed enrollment in two pivotal Phase 3 clinical trials of Crisaborole Topical Ointment, 2%, in patients with mild-to-moderate atopic dermatitis. The company expects to announce data from the two trials in 3Q 2015.

<b>Study Design</b>	Double-blind, vehicle-controlled clinical trials
<b>Number of Patients</b>	Study 301: 763 Study 302: 764
<b>Age of Subjects</b>	2+ years with mild-to-moderate atopic dermatitis
<b>Eligibility Criteria</b>	ISGA - <u>Mild</u> <b>2</b> or <u>Moderate</u> <b>3</b> at Baseline/Day 1
<b>Duration of Study</b>	28 Days
<b>Randomization</b>	2:1 ratio (Crisaborole / Vehicle)
<b>Primary Endpoint</b>	<ul style="list-style-type: none"><li>Percentage of patients who achieved an ISGA of <b>0</b> (Clear) or <b>1</b> (Almost Clear) with &gt; 2-grade improvement from baseline at Day 29</li></ul>
<b>Secondary Endpoints</b>	<ul style="list-style-type: none"><li>Percentage of patients who achieved an ISGA of <b>0</b> (Clear) or <b>1</b> (Almost Clear) at Day 29</li><li>Median time to treatment success in ISGA</li></ul>

The Investigator's Static Global Assessment (ISGA) is a clinical endpoint required by the Food and Drug Administration for use as a primary endpoint in clinical trials. **The scores are below:**

**0**

Clear

**1**

Almost Clear

**2**

Mild

**3**

Moderate

**4**

Severe

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