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Abstract CT018: A double-blind placebo-controlled randomized phase 2 clinical trial to assess the efficacy of a topical BRAF inhibitor for acneiform rash toxicities from anti-EGFR therapies FREE

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Abstract

Background:

Development of acneiform rash in patients with colon cancer treated with anti-EGFR therapies frequently results in dose attenuation or discontinuation, thereby limiting benefits. BRAF inhibitors block the MAPK pathway in BRAF V600 mutant cells, while they paradoxically activate the MAPK pathway in BRAF wild type cells. We hypothesized that a topical formulation of a BRAF inhibitor (LUT014 gel) applied to the areas of acneiform rash would reverse the upstream inhibition of EGFR in skin, thereby reactivating the MAPK pathway and improving the rash and cancer treatment.

Methods:

Patients with colorectal cancer with grade 2 or non-infected grade 3 acneiform rash while receiving cetuximab or panitumumab were randomized 1:1:1 to: LUT014 gel 0.03%, LUT014 gel 0.1%, or placebo gel. Patients applied the gel to all areas of rash daily for 28 days. Primary endpoint was the proportion of patients who achieved treatment “success” defined as improvement of at least one grade CTCAE score or an improvement of at least 5 for the skin-specific FACT-EGFRI-18 HRQoL. Patients were analyzed via intention to treat (ITT) or as “evaluable pts (EP)” (i.e., those who applied the drug at least once and did not drop out due to reasons besides rash such as disease progression). Sample size calculation was based on an expected treatment success of 20% for the placebo group and 50% for one of the treatment

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groups. A total of 117 patients were required for a two group □2 test with a 0.05 two-sided significance and 80% power.

Results:

The trial enrolled 117 patients from 23 sites. Efficacy is shown in the table. In the ITT as well as the EP, the composite endpoint demonstrated statistically significant rates of success for both LUT014 groups compared to placebo. The table also shows grade 1-5 adverse events (AE) related or suspected to be related to treatment.

Treatment Arm	N	Success Rate (ITT)	P-Value vs Placebo	N	Success Rate (EP)	P-Value vs Placeb
LUT-014 0.1%	39	74%	0.0001	34	85%	0.0001
LUT-014 0.03%	39	56%	0.021	32	69%	0.009
Placebo	39	28%		28	32%	

NB: P-value when comparing all 3 arms = 0.00021 (ITT) and p = 0.00006 (EP)

Conclusion:

This is the first placebo-controlled randomized clinical trial demonstrating the benefit and safety of an agent for treatment of the acneiform rash associated with anti-EGFR.

Citation Format:

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