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Trial record **1 of 1** for: CLDE225B2204

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To Evaluate the Safety, Local Tolerability, PK and PD of LDE225 on Sporadic Superficial and Nodular Skin Basal Cell Carcinomas (sBCC)

This study has been terminated.

(The data from participants with sBCCs showed insufficient efficacy with current formulation and treatment conditions.)

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01033019

First received: December 15, 2009
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

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Results First Received: August 18, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Sporadic Superficial and Nodular Skin Basal Cell Carcinomas
Interventions:	Drug: LDE225 0.75% Drug: Vehicle

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Twenty-five participants were enrolled into the trial. However, one participant was excluded from the efficacy analysis. Therefore, the enrollment number differs from the number started below.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
LDE225 0.75%	Participants topically applied 0.75% LDE225 cream twice daily for 6 weeks.
Vehicle	Participants topically applied matching placebo cream twice daily for 6 weeks.

Participant Flow: Overall Study

	LDE225 0.75%	**Vehicle**
STARTED	**16**	**8**

COMPLETED	**15**	**8**
NOT COMPLETED	**1**	**0**
Withdrawal by Subject	**1**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
LDE225 0.75%	Participants topically applied 0.75% LDE225 cream twice daily for 6 weeks.
Vehicle	Participants topically applied matching placebo cream twice daily for 6 weeks.
Total	Total of all reporting groups

Baseline Measures

	LDE225 0.75%	**Vehicle**	**Total**
Number of Participants [units: participants]	**16**	**8**	**24**
Age [units: Years] Mean (Standard Deviation)	**63 (7.3)**	**63 (7.5)**	**63 (7.4)**
Gender [units: Participants]			
Female	**4**	**4**	**8**
Male	**12**	**4**	**16**

Outcome Measures

1. Primary: Clinical Evaluation of sBCCs Tumors [Time Frame: Day 43]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Clinical Evaluation of sBCCs Tumors
Measure Description	The clinical response parameters were defined as (i) complete response (i.e., there is no longer any visible evidence of a lesion consistent with BCC at this site), (ii) partial response (i.e., although a BCC still remains at this site, it has demonstrated a visible decrease in size compared with baseline), and (iii) no response / worsening (i.e., the BCC has not demonstrated any visible decrease in size compared with baseline).
Time Frame	Day 43
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Efficacy analysis set: the efficacy analysis set included all randomized participants with evaluable data.

Reporting Groups

	Description
LDE225 0.75%	Participants topically applied 0.75% LDE225 cream twice daily for 6 weeks.
Vehicle	Participants topically applied matching placebo cream twice daily for 6 weeks.

Measured Values

	LDE225 0.75%	Vehicle
Number of Participants Analyzed [units: participants]	**16**	**8**
Clinical Evaluation of sBCCs Tumors [units: Participants]		
Complete response	**3**	**1**
Partial response	**9**	**4**
No response	**4**	**3**

No statistical analysis provided for Clinical Evaluation of sBCCs Tumors

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The nBCC participant from the LDE225 75% group was analyzed for safety as a separate arm.

Reporting Groups

	Description
LDE225 0.75% - sBCC	Participants topically applied 0.75% LDE225 cream twice daily for 6 weeks.
Vehicle - sBCC	Participants topically applied matching placebo cream twice daily for 6 weeks.
LDE225 0.75% - nBCC	No text entered.

Serious Adverse Events

	LDE225 0.75% - sBCC	Vehicle - sBCC	LDE225 0.75% - nBCC
Total, serious adverse events			
# participants affected / at risk	**0/16 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	The nBCC participant from the LDE225 75% group was analyzed for safety as a separate arm.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
LDE225 0.75% - sBCC	Participants topically applied 0.75% LDE225 cream twice daily for 6 weeks.
Vehicle - sBCC	Participants topically applied matching placebo cream twice daily for 6 weeks.
LDE225 0.75% - nBCC	No text entered.

Other Adverse Events

	LDE225 0.75% - sBCC	Vehicle - sBCC	LDE225 0.75% - nBCC
Total, other (not including serious) adverse events			
# participants affected / at risk	**8/16 (50.00%)**	**5/8 (62.50%)**	**1/1 (100.00%)**
Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**0/16 (0.00%)**	**0/8 (0.00%)**	**1/1 (100.00%)**
Gingival cyst † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Gingivitis † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
General disorders			
Application site dermatitis † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Application site pruritus † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Local swelling † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Infections and infestations			
Acute tonsillitis † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Application site folliculitis † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Gastrointestinal infection † 1			
# participants affected / at risk	**2/16 (12.50%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Oral herpes † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Injury, poisoning and procedural complications			
Arthropod bite † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Incision site pain † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Post procedural haematoma † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Investigations			
Blood creatinine increased † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**

Blood glucose increased † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Blood pressure increased † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Body temperature increased † 1			
# participants affected / at risk	**0/16 (0.00%)**	**0/8 (0.00%)**	**1/1 (100.00%)**
Glomerular filtration rate increased † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Glucose urine present † 1			
# participants affected / at risk	**1/16 (6.25%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Polyarthritis † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**0/16 (0.00%)**	**1/8 (12.50%)**	**1/1 (100.00%)**
Renal and urinary disorders			
Dysuria † 1			
# participants affected / at risk	**1/16 (6.25%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Skin and subcutaneous tissue disorders			
Skin irritation † 1			
# participants affected / at risk	**2/16 (12.50%)**	**0/8 (0.00%)**	**0/1 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01033019 History of Changes
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