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Trial record **1 of 1** for: 26866138LYM2033

Previous Study | Return to List | Next Study

Phase 2 Study of VELCADE With Fludarabine in Comparison to Rituximab With Fludarabine in Follicular Lymphoma Patients Previously Treated With Rituximab

This study has been terminated.

Sponsor:
Millennium Pharmaceuticals, Inc.

Collaborator:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Information provided by (Responsible Party):
Millennium Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT00850499

First received: February 24, 2009
Last updated: December 10, 2012
Last verified: December 2012
History of Changes

Results First Received: October 3, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Follicular Lymphoma
Interventions:	Drug: fludarabine Drug: rituximab Drug: VELCADE

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
No text entered.

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
Velcade + Fludarabine	No text entered.
Rituximab + Fludarabine	No text entered.

Participant Flow: Overall Study

	Velcade + Fludarabine	**Rituximab + Fludarabine**

STARTED	**4**	**8**
COMPLETED	**1**	**6**
NOT COMPLETED	**3**	**2**
Adverse Event	**3**	**1**
Lack of Efficacy	**0**	**1**

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
Velcade + Fludarabine	No text entered.
Rituximab + Fludarabine	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Velcade + Fludarabine	**Rituximab + Fludarabine**	**Total**
Number of Participants [units: participants]	**4**	**8**	**12**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**3**	**6**	**9**
>=65 years	**1**	**2**	**3**
Age [units: years] Mean (Standard Deviation)	**61.3 (12.84)**	**60.0 (10.06)**	**60.4 (10.47)**
Gender [units: participants]			
Female	**2**	**3**	**5**
Male	**2**	**5**	**7**
Region of Enrollment [units: participants]			
France	**0**	**3**	**3**
Greece	**0**	**1**	**1**
Spain	**1**	**0**	**1**
Israel	**1**	**0**	**1**
Germany	**0**	**1**	**1**
Switzerland	**1**	**0**	**1**
Italy	**1**	**3**	**4**

Outcome Measures

Hide All Outcome Measures

1. Primary: Complete Response Rate [Time Frame: Up to 8 cycles (1 cycle is 35 days: 280 days)]

Measure Type	Primary
Measure Title	Complete Response Rate
Measure Description	The proportion of response-evaluable subjects who achieved a confirmed complete response (CR) or complete response unconfirmed (CRu). Disease response and progression were evaluated according to modified International Workshop Response Criteria (IWRC) criteria by radiographic imaging and other procedures as necessary.
Time Frame	Up to 8 cycles (1 cycle is 35 days: 280 days)
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.
Received at least one dose of study drug

Reporting Groups

	Description
Velcade + Fludarabine	Velcade + Fludarabine
Rituximab + Fludarabine	Rituximab + Fludarabine

Measured Values

	Velcade + Fludarabine	**Rituximab + Fludarabine**
Number of Participants Analyzed [units: participants]	**4**	**8**
Complete Response Rate [units: participants]	**2**	**3**

No statistical analysis provided for Complete Response Rate

2. Secondary: Overall Response Rate [Time Frame: Up to 8 cycles (1 cycle is 35 days: 280 days)]

Measure Type	Secondary
Measure Title	Overall Response Rate
Measure Description	The proportion of subjects who achieve CR, CRu, or partial response (PR) relative to the response evaluable population. Disease response and progression were evaluated according to the modified IWRC criteria by radiographic imaging and other procedures as necessary.
Time Frame	Up to 8 cycles (1 cycle is 35 days: 280 days)
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.
Received at least one dose of study drug

Reporting Groups

	Description
Velcade + Fludarabine	Velcade + Fludarabine
Rituximab + Fludarabine	Rituximab + Fludarabine

Measured Values

	Velcade + Fludarabine	Rituximab + Fludarabine
Number of Participants Analyzed [units: participants]	**4**	**8**
Overall Response Rate [units: participants]	**3**	**6**

No statistical analysis provided for Overall Response Rate

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Velcade + Fludarabine	No text entered.
Rituximab + Fludarabine	No text entered.

Serious Adverse Events

	Velcade + Fludarabine	Rituximab + Fludarabine
Total, serious adverse events		
# participants affected / at risk	**2/4 (50.00%)**	**2/8 (25.00%)**
Blood and lymphatic system disorders		
Anaemia †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**
Febrile neutropenia †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**
Gastrointestinal disorders		
Abdominal pain †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**
Small Intestinal Obstruction †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**
General disorders		
General physical health deterioration †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**
Pyrexia †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**

Respiratory, thoracic and mediastinal disorders		
Dypnoea †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**
Respiratory gas exchange disorder †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**

† Events were collected by systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Velcade + Fludarabine	No text entered.
Rituximab + Fludarabine	No text entered.

Other Adverse Events

	Velcade + Fludarabine	**Rituximab + Fludarabine**
Total, other (not including serious) adverse events		
# participants affected / at risk	**4/4 (100.00%)**	**8/8 (100.00%)**
Blood and lymphatic system disorders		
Leukopenia †		
# participants affected / at risk	**1/4 (25.00%)**	**2/8 (25.00%)**
Lymphopenia †		
# participants affected / at risk	**0/4 (0.00%)**	**2/8 (25.00%)**
Neutropenia †		
# participants affected / at risk	**1/4 (25.00%)**	**4/8 (50.00%)**
Thrombocytopenia †		
# participants affected / at risk	**1/4 (25.00%)**	**3/8 (37.50%)**
Eye disorders		
Blepharitis †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**
Gastrointestinal disorders		
Constipation †		
# participants affected / at risk	**2/4 (50.00%)**	**0/8 (0.00%)**
Diarrhoea †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**
Gastrointestinal pain †		
# participants affected / at risk	**1/4 (25.00%)**	**0/8 (0.00%)**

Nausea †		
# participants affected / at risk	1/4 (25.00%)	1/8 (12.50%)
General disorders		
Asthenia †		
# participants affected / at risk	1/4 (25.00%)	3/8 (37.50%)
Fatigue †		
# participants affected / at risk	0/4 (0.00%)	2/8 (25.00%)
Oedema peripheral †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Performance status decreased †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Infections and infestations		
Nasopharyngitis †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Pharyngitis †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Tinea infection †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Metabolism and nutrition disorders		
Decreased appetite †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Musculoskeletal and connective tissue disorders		
Back pain †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Bone pain †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Osteoarthritis †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Nervous system disorders		
Peripheral sensory neuropathy †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Psychiatric disorders		
Conversion disorder †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Depression †		
# participants affected / at risk	1/4 (25.00%)	0/8 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease †		
# participants affected / at risk	0/4 (0.00%)	1/8 (12.50%)
Cough †		
# participants affected / at risk	1/4 (25.00%)	1/8 (12.50%)
Skin and subcutaneous tissue disorders		
Rash †		

# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**
Skin reaction †		
# participants affected / at risk	**0/4 (0.00%)**	**1/8 (12.50%)**

† Events were collected by systematic assessment

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
Early termination leading to small numbers of subjects analyzed

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There is **NOT** 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.

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Responsible Party: Millennium Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier: NCT00850499 History of Changes
Other Study ID Numbers: **26866138-LYM-2033**
Study First Received: February 24, 2009
Results First Received: October 3, 2012
Last Updated: December 10, 2012
Health Authority: United States: Food and Drug Administration

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