

PIVOTAL DATA

SUBJECT CASE REPORT FORM

Cancer Z4B Protocol

Study Number: PCR-798

Clinical Phase: III

CONFIDENTIAL

_____ Investigator Number	_____ Subject Initials	_____ Subject Number
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I affirm by my signature below that the information reflected on all pages of the case report form for this subject have been fully reviewed and deemed accurate.

Principal Investigator Signature

□□ / □□ / □□
Date (MM/DD/YY)

Pivotal Research Associates

2087 South Grant Street
Denver, CO 80210

ENTERprise PRODUCTS

_____ Investigator Number	_____ Subject Initials	_____ Subject Number
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Demographics/Inclusion/Exclusion Criteria Screening

/ /
 Screening Date

/ /
 Date of Birth

Height (cm)

Weight (kg)

Ethnicity

White
 Black
 Asian
 Indian
 Hispanic
 Other

Inclusion Criteria:

To be eligible for this study, all inclusion items must be checked "YES".

- Is the subject a healthy non-smoking male between 18 and 50 years of age? Yes No
- Is the subject's body weight within ten percent of ideal body weight based on height and body frame? Yes No
- Is the subject's urine drug screen negative? Yes No

Exclusion Criteria:

To be eligible for this study, all exclusion items must be checked "NO".

- Does the subject have any clinically relevant abnormality identified during the screening physical examination? Yes No
- Does the subject have a history of alcohol or drug abuse within one year of the start date of the study session? Yes No
- Has the subject been treated with any investigation drugs in the past six months? Yes No



_____ Investigator Number	_____ Subject Initials	_____ Subject Number
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Medical History Screening

Please check the appropriate box for each BODY SYSTEM examined. Indicate if the subject has a medical condition and describe the condition under the COMMENTS section.

BODY SYSTEM	YES	NO	COMMENTS
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	

CONDITIONS	ONSET DATE MM/DD/YY	COMMENTS
	<input type="text"/> / <input type="text"/> / <input type="text"/>	
	<input type="text"/> / <input type="text"/> / <input type="text"/>	
	<input type="text"/> / <input type="text"/> / <input type="text"/>	
	<input type="text"/> / <input type="text"/> / <input type="text"/>	