Trial record **38 of 77** for: Interferon alfa-2b AND interferon alfa-2b AND Intron A | Melanoma

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Phase II Study Incorporating Pegylated Interferon In the Treatment For Children With High-Risk Melanoma

ClinicalTrials.gov Identifier: NCT00539591

Recruitment Status : Completed
First Posted : October 4, 2007
Results First Posted : February 27, 2014
Last Update Posted : March 23, 2017

Sponsor:
St. Jude Children's Research Hospital

Collaborator:
Schering-Plough

Information provided by (Responsible Party):
St. Jude Children's Research Hospital

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Non-Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Malignant **Melanoma**
Interventions	Drug: Peginterferon **alfa-2b** Drug: Temozolomide Drug: Recombinant **interferon alfa-2b**
Enrollment	29

Participant Flow

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Recruitment Details	A total of 29 patients were enrolled between May 9, 2008 and August 22, 2012. Of the 29 participants, 21 were enrolled at St. Jude Children's Research Hospital (SJCRH), 7 at MD Anderson, and 1 at Rady Children's Hospital. Twenty-three participants met stratum A eligibility, 2 met stratum B1 eligibility and 4 met stratum B2 eligibility.
Pre-assignment Details	

Arm/Group Title	Peginterferon α-2b/Non-pegylated Interferon α-2b	Temozolomide/Peginterferon α-2b With Measureable Disease	Temozolomide/Peginterferon α-2b Without Measureable Disease

▼ Arm/Group Description	Stratum A: American Joint Committee on Cancer (AJCC) resected Stages IIC, IIIA, and IIIB Participants received recombinant interferon α-2b 20 million units/m^2/day intravenously 5 consecutive days per week for 4 weeks followed by peginterferon α-2b 1 mcg/kg subcutaneously once a week for 48 weeks.	Stratum B1: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants with measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks.	Stratum B2: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants without measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks. Stratum B2 (no measurable disease) proceeded with 7 courses as outlined.
Period Title: **Overall Study**			
Started	23	2	4
Completed	18	0	1
Not Completed	5	2	3
Reason Not Completed			
Toxicity	3	0	0
Disease progression	2	2	3

Baseline Characteristics Go to

Arm/Group Title	Peginterferon α-2b/Non-pegylated Interferon α-2b	Temozolomide/Peginterferon α-2b With Measureable Disease	Temozolomide/Peginterferon α-2b Without Measureable Disease	Total
▼ Arm/Group Description	Stratum A: American Joint Committee on Cancer (AJCC) resected Stages IIC, IIIA, and IIIB Participants received recombinant interferon α-2b 20 million units/m^2/day intravenously 5 consecutive days per week for 4 weeks followed by peginterferon α-2b 1 mcg/kg subcutaneously once a week for 48 weeks.	Stratum B1: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants with measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks.	Stratum B2: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants without measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks. Stratum B2 (no measurable disease)	Total of all reporting groups

				proceeded with 7 courses as outlined.	
Overall Number of Baseline Participants		23	2	4	29
▼ Baseline Analysis Population Description		[Not Specified]			
Age, Continuous Median (Full Range) Unit of measure: Years					
	Number Analyzed	23 participants	2 participants	4 participants	29 participants
		10.3 (2.4 to 20.0)	11.9 (3.96 to 19.89)	18.4 (3.6 to 22.1)	10.77 (2.4 to 22.1)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants					
	Number Analyzed	23 participants	2 participants	4 participants	29 participants
	Female	15 65.2%	0 0.0%	1 25.0%	16 55.2%
	Male	8 34.8%	2 100.0%	3 75.0%	13 44.8%

Outcome Measures

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1. Primary Outcome

Title	Tumor Response Rate
▼ Description	Tumor response rate of stratum B1 participants was evaluated after 1 treatment course of temozolomide plus peginterferon α-2b. Complete response (CR) and partial response (PR) confirmed with repeated scan at least 4 weeks apart following completion of course 1 therapy. CR defined as disappearance of all target and non-target lesions with no new lesions detected. If available, no disease must be detected by immunocytology or serum tumor markers. PR defined as at least 30% decrease in disease measurement compared to disease measurement at study entry with no new lesions detected. Progressive disease (PD) defined as at least 20% increase in the disease measurement compared to the smallest disease measurement recorded since start of treatment, or appearance of one or more new lesions. Stable disease defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD compared to smallest disease measurement since start of treatment.
Time Frame	8 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

[Not Specified]

Arm/Group Title	Stratum B1
▼ Arm/Group Description:	Stratum B: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants, divided into 2 groups based on presence (B1) or absence (B2) of measurable disease Stratum B1 had presence of measurable disease. Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks. Interventions: Temozolomide, peginterferon α-2b
Overall Number of Participants Analyzed	2
Measure Type: Number Unit of Measure: participants	
Progressive Disease	2
Clinical Remission	0

2. Primary Outcome

Title	Number of Patients Who Experience Toxicity at or Above the Target Toxicity for Strata B1 and B2
▼ Description	The objective was to assess the safety of temozolomide administered in combination with peginterferon a-2b in Stratum B participants. Accrual was suspended any time during therapy if 2 or more of 6, 4 or more of 12, 6 or more of 18, 8 or more of 24, 10 or more of 30 participants experienced target toxicity defined as: • Grade 4 non-hematologic (non-hem) toxicity that does not resolve to ≤grade 1 within 2 weeks from the time next dose is due and is determined to be probably or definitely related to protocol therapy • Grade 4 non-hem toxicity that is NOT constitutional symptoms (fever, chills, fatigue and/or pain) • Grade 3 elevations in creatinine or BUN that are determined to be probably or definitely related to protocol therapy • Grade 4 cardiopulmonary toxicity that is determined to be probably or definitely related to protocol therapy • Grade 4 mood alteration (suicidal ideation; danger to self or others)
Time Frame	52 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
This toxicity report was based on intention to treat population (ITT), all patients enrolled were included. The study did not meet its accrual goals within the planned timeframe due to slow accrual.

Arm/Group Title	Temozolomide/Peginterferon α-2b With Measureable Disease	Temozolomide/Peginterferon α-2b Without Measureable Disease

▼ Arm/Group Description:	Stratum B1: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants with measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks.	Stratum B2: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants without measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks. Stratum B2 (no measurable disease) proceeded with 7 courses as outlined.
Overall Number of Participants Analyzed	2	4
Measure Type: Number Unit of Measure: participants		
	0	0

3. Primary Outcome

Title	Number of Patients Who Experience Toxicity at or Above the Target Toxicity for Stratum A Patients
▼ Description	The objective was to study the feasibility and safety of administering peginterferon a-2b weekly for 48 weeks following the initial induction phase to Stratum A participants. Accrual was suspended during the 48-week course if 2 or more of 6, 4 or more of 12, 6 or more of 18, 8 or more of 24, 10 or more of 30 participants experienced target toxicity defined as: • Grade 4 non-hematologic (non-hem) toxicity that does not resolve to ≤grade 1 within 2 weeks from the time next dose is due and is determined to be probably or definitely related to protocol therapy • Grade 4 non-hem toxicity that is NOT constitutional symptoms (fever, chills, fatigue and/or pain) • Grade 3 elevations in creatinine or BUN that are determined to be probably or definitely related to protocol therapy • Grade 4 cardiopulmonary toxicity that is determined to be probably or definitely related to protocol therapy • Grade 4 mood alteration (suicidal ideation; danger to self or others)
Time Frame	52 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Number of participants for the analysis was based on the intent to treat population, all patients enrolled were included. Participants were enrolled on Stratum A until the accrual goals were met on Stratum B.

Arm/Group Title	Peginterferon α-2b/Non-pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A: American Joint Committee on Cancer (AJCC) resected Stages IIC, IIIA, and IIIB Participants received recombinant interferon α-2b 20 million units/m^2/day intravenously 5 consecutive days per week for 4 weeks followed by peginterferon α-2b 1 mcg/kg subcutaneously once a week for 48 weeks.
Overall Number of Participants Analyzed	23

Measure Type: Number Unit of Measure: participants	
Grade 4 non-hem toxicity	2
Grade 4 non-hem/NOT constitutional	0
Grade 3 elevations in creatinine or BUN	0
Grade 4 cardiopulmonary toxicity	0
Grade 4 mood alteration	1

4. Primary Outcome

Title	Probability of Event-free Survival (EFS) of Stratum A Participants
▼ Description	The probability of EFS was estimated as time to first event (relapse, death or second malignancy). As of April 2016, 21 out of 23 participants had no events. The EFS rate was estimated by Kaplan-Meier method.
Time Frame	3 years from diagnosis

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Peginterferon α-2b/Non-pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A: American Joint Committee on Cancer (AJCC) resected Stages IIC, IIIA, and IIIB Participants received recombinant interferon α-2b 20 million units/m^2/day intravenously 5 consecutive days per week for 4 weeks followed by peginterferon α-2b 1 mcg/kg subcutaneously once a week for 48 weeks.
Overall Number of Participants Analyzed	23
Measure Type: Number Number (95% Confidence Interval) Unit of Measure: probability	
	0.913 (0.79 to 1.00)

5. Other Pre-specified Outcome

Title	Median Steady State Trough Concentration of Pegylated **Interferon** α-2B
▼ Description	The pharmacokinetic (PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed.

	Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28

▼ Outcome Measure Data

▼ Analysis Population Description

Only one patient had evaluable data in Stratum B and is not included in the final analysis, because data from more than one patient are required for nonlinear-mixed effects modeling.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	16
Median (Full Range) Unit of Measure: pcg/ml	
	52.8 (13.8 to 152.4)

6. Other Pre-specified Outcome

Title	Area Under the Curve (AUC) of Pegylated **Interferon** α-2B
▼ Description	Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed. Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM. AUC is given as Time 0 through infinity.
Time Frame	Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28

▼ Outcome Measure Data

▼ Analysis Population Description

Only one Stratum B patient had evaluable data and is not included in final analysis, because data from more than one patient are required for nonlinear-mixed effects modeling. Two patients in Week 5 and three in Week 28 were excluded due to inadequate sampling to characterize an AUC value.

Arm/Group Title	Week 5 - First Dose	Week 28 - Steady State
▼ Arm/Group Description:	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed are included.	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed.
Overall Number of Participants Analyzed	7	6
Median (Full Range) Unit of Measure: pcg * hr/ml		

	50556 (36166 to 58980)	48480 (34024 to 59857)

7. Other Pre-specified Outcome

Title	α Half Life of Pegylated **Interferon** α-2B
▼ Description	Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed. Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28

▼ Outcome Measure Data

▼ Analysis Population Description

Only one Stratum B patient had evaluable data and is not included in final analysis, because data from more than one patient are required for nonlinear-mixed effects modeling. Two patients in Week 5 and three in Week 28 were excluded due to inadequate sampling to characterize an AUC value.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	9
Median (Full Range) Unit of Measure: hours	
	24.8 (16.6 to 40.6)

8. Other Pre-specified Outcome

Title	Volume of Central Compartment (Vc) of Pegylated **Interferon** α-2B
▼ Description	Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed. Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28

▼ Outcome Measure Data

▼ Analysis Population Description

Only one Stratum B patient had evaluable data and is not included in final analysis, because data from more than one patient are required for nonlinear-mixed effects modeling due to differences in clinical variables. Two patients in Week 5 and three in Week 28 were excluded due to inadequate sampling to characterize an AUC value.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed are included.

Overall Number of Participants Analyzed	9
Median (Full Range) Unit of Measure: ml/kg	
	772 (594 to 1410)

9. Other Pre-specified Outcome

Title	Apparent Clearance (CL) of Pegylated **Interferon** α-2B
Description	Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed. Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28

Outcome Measure Data

Analysis Population Description
Only one Stratum B patient had evaluable data and is not included in final analysis due to differences in clinical variables, because data from more than one patient are required for nonlinear-mixed effects modeling. Two patients in Week 5 and three in Week 28 were excluded due to inadequate sampling to characterize an AUC value.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
Arm/Group Description:	Stratum A participants who received pegylated interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	9
Median (Full Range) Unit of Measure: ml/hr/kg	
	19.8 (16.7 to 31.4)

10. Other Pre-specified Outcome

Title	Area Under the Curve (AUC) of **Interferon** α-2b
Description	Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM. AUC is given as Time 0 to infinity.
Time Frame	Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion

Outcome Measure Data

Analysis Population Description
The pharmacokinetic(PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed. Only one patient had evaluable data in Stratum B and is not included in the final analysis due to differences in clinical variables.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A participants who received interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	16
Median (Full Range) Unit of Measure: pcg * hr/ml	
	5026 (2642 to 10270)

11. Other Pre-specified Outcome

Title	Half-Life of **Interferon** α-2b
▼ Description	Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion

▼ Outcome Measure Data

▼ Analysis Population Description

The pharmacokinetic (PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed. Only one patient had evaluable data in Stratum B and is not included in the final analysis due to differences in clinical variables.

Arm/Group Title	Peginterferon α-2b/Non-Pegylated Interferon α-2b
▼ Arm/Group Description:	Stratum A participants who received interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	16
Median (Full Range) Unit of Measure: hours	
α half-life	0.7 (0.4 to 1.4)
ß half-life	14.7 (12.5 to 28.2)

12. Other Pre-specified Outcome

Title	Volume of Central Compartment (Vc) of **Interferon** α-2b
▼ Description	Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion

▼ Outcome Measure Data

▼ Analysis Population Description

The pharmacokinetic (PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed. Only one patient had evaluable data in Stratum B and is not included in the final analysis due to differences in clinical variables.

Arm/Group Title	Interferon α-2b
▼ Arm/Group Description:	Participants who received interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	16
Median (Full Range) Unit of Measure: l/m^2	
	25.1 (13.9 to 49.2)

13. Other Pre-specified Outcome

Title	Systemic Clearance (CL) of **Interferon** α-2B
▼ Description	Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.
Time Frame	Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion

▼ Outcome Measure Data

▼ Analysis Population Description

The pharmacokinetic (PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed. Only one patient had evaluable data in Stratum B and is not included in the final analysis due to differences in clinical variables.

Arm/Group Title	Interferon α-2b
▼ Arm/Group Description:	Participants who received interferon α-2b and had pharmacokinetic studies performed are included.
Overall Number of Participants Analyzed	16
Median (Full Range) Unit of Measure: l/hr/m^2	
	15.3 (7.5 to 29.1)

14. Other Pre-specified Outcome

Title	Mean Total PedsQL 4.0 Scores for Child Quality of Life (QoL) Assessments (Stratum A)
▼ Description	QoL assessments were completed using Pediatrics Quality of Life Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for child report = 83.0 ± 14.8.
Time Frame	Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

▼ Outcome Measure Data

▼ Analysis Population Description

This QOL analysis included patients only within Stratum A.

Arm/Group Title	Pretherapy	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Month After End Therapy
▼ Arm/Group Description:	QoL assessment completed before start of therapy.	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessme completed 12 months after end therapy.
Overall Number of Participants Analyzed	15	15	17	14	14	17	15	13	15
Mean (Standard Deviation) Unit of Measure: units on a scale									
	75.5 (18.4)	71.6 (18.7)	77.2 (16.3)	79.3 (17.4)	77.8 (20.6)	80.6 (15.6)	80.4 (16.1)	87.5 (12.5)	91.0 (7.1

15. Other Pre-specified Outcome

Title	Mean Total PedsQL 4.0 Scores for Child Quality of Life (QoL) Assessments (Stratum B)
▼ Description	QoL assessments were completed using Pediatrics Quality of Life Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for child report = 83.0 ± 14.8.
Time Frame	Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

▼ Outcome Measure Data

▼ Analysis Population Description

Only one patient had evaluable data in Stratum B. The raw score, rather than the mean +/- SD, is presented. Data was not collected at Week 24, and the patient was taken off study prior to 6 months after end of therapy.

Arm/Group Title	Pretherapy	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Mo After E Thera
▼ Arm/Group Description:	QoL assessment completed before start of therapy.	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessr complet 12 mon after en therapy
Overall Number of Participants Analyzed	1	1	1	1	1	0	1	0	0

Measure Type: Number Unit of Measure: units on a scale									
	90.3	93.1	72.8	79.2	68.1		65.6		

16. Other Pre-specified Outcome

Title	Mean Total PedsQL 4.0 Scores for Parent Quality of Life Assessments (Stratum A)
▼ Description	QoL assessments were completed using Pediatrics Quality of Live Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for parent report = 87.6 ± 12.3.
Time Frame	Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

▼ Outcome Measure Data

▼ Analysis Population Description
This QOL analysis included patients only within Stratum A.

Arm/Group Title	Pretherapy	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Month After End Therapy
▼ Arm/Group Description:	QoL assessment completed before start of therapy.	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessme completed 12 months after end therapy.
Overall Number of Participants Analyzed	16	15	17	13	16	17	15	15	15
Mean (Standard Deviation) Unit of Measure: units on a scale									
	70.3 (19.1)	71.8 (16.4)	74.4 (17.9)	79.1 (16.6)	79.0 (19.0)	82.2 (14.5)	87.5 (15.3)	86.0 (17.6)	87.3 (17.

17. Other Pre-specified Outcome

Title	Mean Total PedsQL 4.0 Scores for Parent Quality of Life Assessments (Stratum B)
▼ Description	QoL assessments were completed using Pediatrics Quality of Live Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for parent report = 87.6 ± 12.3.
Time Frame	Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

▼ Outcome Measure Data

▼ Analysis Population Description

Only one patient had evaluable data in Stratum B. The raw score, rather than the mean +/- SD, is presented. Data was not collected after Week 4.

Arm/Group Title	Pretherapy	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Mo After E Thera
▼ Arm/Group Description:	QoL assessment completed before start of therapy.	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessr comple 12 mon after en therapy
Overall Number of Participants Analyzed	1	1	1	0	0	0	0	0	0
Measure Type: Number Unit of Measure: units on a scale									
	77.6	72.2	89.1						

18. Other Pre-specified Outcome

Title	Mean Total PedsQL 3.0 Scores for Child Cancer Quality of Life (QoL) Assessments (Stratum A)
▼ Description	QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.
Time Frame	Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

▼ Outcome Measure Data

▼ Analysis Population Description

PedsQL v3.0 was not completed pretherapy. This QOL analysis included patients only within Stratum A.

Arm/Group Title	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Months After End of Therapy
▼ Arm/Group Description:	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessment completed 12 months after end of therapy.
Overall Number of Participants Analyzed	17	19	17	17	16	17	15	15

Mean (Standard Deviation) Unit of Measure: units on a scale								
	71.1 (17.2)	76.1 (15.4)	79.2 (19.2)	78.5 (14.7)	77.1 (16.0)	77.0 (16.5)	83.7 (18.0)	85.4 (8.9)

19. Other Pre-specified Outcome

Title	Mean Total PedsQL 3.0 Scores for Child Cancer Quality of Life (QoL) Assessments (Stratum B)
Description	QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.
Time Frame	Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

Outcome Measure Data

Analysis Population Description

PedsQL v3.0 was not completed pretherapy. Only one patient had evaluable data in Stratum B. The raw score, rather than the mean +/- SD, is presented. Data was not collected at Week 24, and the patient was taken off study prior to 6 months after end of therapy.

Arm/Group Title	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Months After End of Therapy
Arm/Group Description:	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessment completed 12 months after end of therapy.
Overall Number of Participants Analyzed	1	1	1	1	0	1	0	0
Measure Type: Number Unit of Measure: units on a scale								
	92.8	90.1	93.2	79.6		67.4		

20. Other Pre-specified Outcome

Title	Mean Total PedsQL 3.0 Scores for Parent Cancer Quality of Life (QoL) Assessments (Stratum A)
Description	QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.
Time Frame	Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

Outcome Measure Data

Analysis Population Description

PedsQL v3.0 was not completed pretherapy. This QOL analysis included patients only within Stratum A.

Arm/Group Title	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Months After End of Therapy

Arm/Group Description:	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessment completed 12 months after end of therapy.
Overall Number of Participants Analyzed	19	19	17	18	16	16	15	15
Mean (Standard Deviation) Unit of Measure: units on a scale								
	73.2 (13.9)	75.1 (15.2)	81.4 (11.6)	78.7 (17.7)	81.6 (17.1)	85.6 (13.8)	85.0 (11.5)	89.1 (11.6)

21. Other Pre-specified Outcome

Title	Mean Total PedsQL 3.0 Scores for Parent Cancer Quality of Life (QoL) Assessments (Stratum B)
Description	QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.
Time Frame	Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post

Outcome Measure Data

Analysis Population Description
PedsQL v3.0 was not completed pretherapy. Only one patient had evaluable data in Stratum B. The raw score, rather than the mean +/- SD, is presented. Data was not collected after Week 4.

Arm/Group Title	Week 2	Week 4	Week 8	Week 12	Week 24	End of Therapy	6 Months After End of Therapy	12 Months After End of Therapy
Arm/Group Description:	QoL assessment completed at Week 2.	QoL assessment completed at Week 4.	QoL assessment completed at Week 8.	QoL assessment completed at Week 12.	QoL assessment completed at Week 24.	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.	QoL assessment completed 12 months after end of therapy.
Overall Number of Participants Analyzed	1	1	0	0	0	0	0	0
Measure Type: Number Unit of Measure: units on a scale								
	67.7	71.4						

22. Other Pre-specified Outcome

Title	BASC-2 Psychological Assessment (Stratum A)
Description	The Behavioral Assessment System for Children, 2nd Edition (BASC-2) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The behavior system index (BSI) T-score (range 0-100) is reported for the BASC-2 assessment. Higher scores reflect greater behavioral problems.
Time Frame	Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy

Outcome Measure Data

Analysis Population Description

This QOL analysis included patients only within Stratum A.

Arm/Group Title	Pretherapy	Week 4	Week 24	End of Therapy	6 Months After End of Therapy
Arm/Group Description:	Psychological assessment completed before start of therapy.	Psychological assessment completed at Week 4	Psychological assessment completed at Week 24	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.
Overall Number of Participants Analyzed	21	21	19	18	16
Mean (Standard Deviation) Unit of Measure: T score					
	44.9 (8.1)	45.9 (8.3)	44.2 (6.9)	47.2 (11.1)	42.3 (7.2)

23. Other Pre-specified Outcome

Title	BASC-2 Psychological Assessment (Stratum B)
Description	The Behavioral Assessment System for Children, 2nd Edition (BASC-2) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The behavior system index (BSI) T-score (range 0-100) is reported for the BASC-2 assessment. Higher scores reflect greater behavioral problems.
Time Frame	Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy

Outcome Measure Data

Analysis Population Description

Only one patient had evaluable data in Stratum B, but scores were not available for this instrument due to the age of the patient.

Arm/Group Title	Pretherapy	Week 4	Week 24	End of Therapy	6 Months After End of Therapy
Arm/Group Description:	Psychological assessment completed before start of therapy.	Psychological assessment completed at Week 4	Psychological assessment completed at Week 24	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.
Overall Number of Participants Analyzed	0	0	0	0	0

No data displayed because Outcome Measure has zero total analyzed.

24. Other Pre-specified Outcome

Title	BRIEF Psychological Assessment (Stratum A)
Description	The Behavioral Rating Inventory of Executive Function (BRIEF) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The global executive composite (GEC) T-score (range 0-100) is reported for the BRIEF assessment. Higher scores reflect poorer executive function.
Time Frame	Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy

Outcome Measure Data

▼ Analysis Population Description

This QOL analysis included patients only within Stratum A.

Arm/Group Title	Pretherapy	Week 4	Week 24	End of Therapy	6 Months After End of Therapy
▼ Arm/Group Description:	Psychological assessment completed before start of therapy.	Psychological assessment completed at Week 4	Psychological assessment completed at Week 24	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.
Overall Number of Participants Analyzed	17	17	13	14	11
Mean (Standard Deviation) Unit of Measure: T score					
	47.9 (12.8)	50.8 (11.9)	48.6 (12.4)	47.6 (12.6)	42.6 (8.1)

25. Other Pre-specified Outcome

Title	BRIEF Psychological Assessment (Stratum B)
▼ Description	The Behavioral Rating Inventory of Executive Function (BRIEF) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The global executive composite (GEC) T-score (range 0-100) is reported for the BRIEF assessment. Higher scores reflect poorer executive function.
Time Frame	Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy

▼ Outcome Measure Data

▼ Analysis Population Description

Only one patient had evaluable data in Stratum B, but scores were not available for this instrument due to the age of the patient.

Arm/Group Title	Pretherapy	Week 4	Week 24	End of Therapy	6 Months After End of Therapy
▼ Arm/Group Description:	Psychological assessment completed before start of therapy.	Psychological assessment completed at Week 4	Psychological assessment completed at Week 24	QoL assessment completed at end of therapy.	QoL assessment completed 6 months after end of therapy.
Overall Number of Participants Analyzed	0	0	0	0	0

No data displayed because Outcome Measure has zero total analyzed.

Adverse Events

Go to

Time Frame	Adverse events are reported from the start of treatment for the first patient in May 2008 through April 2016.
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Peginterferon α-2b/Non-pegylated Interferon α-2b	Temozolomide/Peginterferon α-2b With Measureable Disease	Temozolomide/Peginterferon α-2b Without Measureable

			Disease
▼ Arm/Group Description	Stratum A: American Joint Committee on Cancer (AJCC) resected Stages IIC, IIIA, and IIIB Participants received recombinant interferon α-2b 20 million units/m^2/day intravenously 5 consecutive days per week for 4 weeks followed by peginterferon α-2b 1 mcg/kg subcutaneously once a week for 48 weeks.	Stratum B1: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants with measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks.	Stratum B2: American Joint Committee on Cancer (AJCC) resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent participants without measurable disease Participants received 8 weekly doses of peginterferon α-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75 mg/m^2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course was 8 weeks. Stratum B2 (no measurable disease) proceeded with 7 courses as outlined.

All-Cause Mortality

	Peginterferon α-2b/Non-pegylated Interferon α-2b		Temozolomide/Peginterferon α-2b With Measureable Disease		Temozolomide/Peginterferon α-2b Without Measureable Disease	
	Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--		--/--	

▼ Serious Adverse Events

	Peginterferon α-2b/Non-pegylated Interferon α-2b		Temozolomide/Peginterferon α-2b With Measureable Disease		Temozolomide/Peginterferon α-2b Without Measureable Disease	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	3/23 (13.04%)		0/2 (0.00%)		0/4 (0.00%)	
Musculoskeletal and connective tissue disorders						
Joint effusion * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Joint function * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Nervous system disorders						
Confusion * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Extrapyramidal/involuntary movement/restlessness * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Mood alteration, agitation * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Psychosis (hallucinations/delusions) * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0
Seizure * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	0/4 (0.00%)	0

* Indicates events were collected by non-systematic assessment

1 Term from vocabulary, CTC version 3

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Peginterferon α-2b/Non-pegylated Interferon α-2b		Temozolomide/Peginterferon α-2b With Measureable Disease		Temozolomide/Peginterferon α-2b Without Measureable Disease	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	23/23 (100.00%)		2/2 (100.00%)		4/4 (100.00%)	
Blood and lymphatic system disorders						
Hemoglobin [*1]	13/23 (56.52%)	29	2/2 (100.00%)	2	2/4 (50.00%)	11
Leukocytes) total WBC) [*1]	22/23 (95.65%)	116	2/2 (100.00%)	4	4/4 (100.00%)	16
Neutrophils/granulocytes (ANC/AGC) [*1]	23/23 (100.00%)	142	0/2 (0.00%)	0	4/4 (100.00%)	16
Platelets [*1]	15/23 (65.22%)	28	0/2 (0.00%)	0	3/4 (75.00%)	18
Edema: head and neck [*1]	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	1
Edema: limb [*1]	2/23 (8.70%)	5	0/2 (0.00%)	0	1/4 (25.00%)	1
Edema: trunk/genital [*1]	3/23 (13.04%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Lymphatics - other [*1]	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	2
Cardiac disorders						
Supraventricular and nodal arrhythmia, sinus bradycardia [*1]	8/23 (34.78%)	20	0/2 (0.00%)	0	1/4 (25.00%)	3
Supraventricular and nodal arrhythmia, sinus tachycardia [*1]	9/23 (39.13%)	22	2/2 (100.00%)	4	1/4 (25.00%)	3
Hypertension [*1]	6/23 (26.09%)	21	0/2 (0.00%)	0	2/4 (50.00%)	2
Endocrine disorders						
Hot flashes/flushes [*1]	3/23 (13.04%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Thyroid function, low (hypothyroidism) [*1]	3/23 (13.04%)	5	0/2 (0.00%)	0	0/4 (0.00%)	0
Eye disorders						
Ocular surface disease [*1]	2/23 (8.70%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Ocular/visual - other [*1]	2/23 (8.70%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Vision-blurred vision [*1]	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	1
Gastrointestinal disorders						
Anorexia [*1]	18/23 (78.26%)	42	2/2 (100.00%)	2	2/4 (50.00%)	3
Constipation [*1]	9/23 (39.13%)	18	0/2 (0.00%)	0	0/4 (0.00%)	0
Dehydration [*1]	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Diarrhea [*1]	13/23 (56.52%)	32	1/2 (50.00%)	1	4/4 (100.00%)	9
Flatulence [*1]	1/23 (4.35%)	1	1/2 (50.00%)	1	0/4 (0.00%)	0
Heartburn/dyspepsia [*1]	2/23 (8.70%)	3	0/2 (0.00%)	0	1/4 (25.00%)	1
Mucositis/stomatitis (clinical exam), oral cavity [*1]	3/23 (13.04%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Nausea [*1]	17/23 (73.91%)	38	0/2 (0.00%)	0	4/4 (100.00%)	9
Taste alteration (dysgeusia) [*1]	2/23 (8.70%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Vomiting [*1]	12/23 (52.17%)	30	0/2 (0.00%)	0	3/4 (75.00%)	17
General disorders						

Fatigue (asthenia, lethargy, malaise) * 1	20/23 (86.96%)	100	0/2 (0.00%)	0	3/4 (75.00%)	4
Fever (in the absence of neutropenia, where neutropenia is defined as ANC<1.0 x 10e9/L) * 1	16/23 (69.57%)	39	1/2 (50.00%)	1	2/4 (50.00%)	3
Rigors/chills * 1	10/23 (43.48%)	19	0/2 (0.00%)	0	0/4 (0.00%)	0
Sweating (diaphoresis) * 1	2/23 (8.70%)	5	0/2 (0.00%)	0	0/4 (0.00%)	0
Weight gain * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Weight loss * 1	4/23 (17.39%)	9	1/2 (50.00%)	2	1/4 (25.00%)	1
Pain, abdomen NOS * 1	8/23 (34.78%)	16	1/2 (50.00%)	2	2/4 (50.00%)	5
Pain, back * 1	3/23 (13.04%)	22	1/2 (50.00%)	1	2/4 (50.00%)	2
Pain, chest wall * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	1/4 (25.00%)	4
Pain, chest/thorax NOS * 1	3/23 (13.04%)	5	0/2 (0.00%)	0	2/4 (50.00%)	3
Pain, dental/teeth/peridontal * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, external ear * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, extremity-limb * 1	12/23 (52.17%)	27	1/2 (50.00%)	1	0/4 (0.00%)	0
Pain, head/headache * 1	18/23 (78.26%)	257	1/2 (50.00%)	2	2/4 (50.00%)	6
Pain, joint * 1	3/23 (13.04%)	4	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, muscle * 1	6/23 (26.09%)	12	0/2 (0.00%)	0	1/4 (25.00%)	1
Pain, neck * 1	3/23 (13.04%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, pain NOS * 1	8/23 (34.78%)	43	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, stomach * 1	3/23 (13.04%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Pain, throat/pharynx/larynx * 1	7/23 (30.43%)	9	0/2 (0.00%)	0	0/4 (0.00%)	0
Immune system disorders						
Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip) * 1	11/23 (47.83%)	19	0/2 (0.00%)	0	2/4 (50.00%)	2
Infections and infestations						
Infection with normal ANC or Grade 1 or 2 neutrophils, lip/perioral * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	2
Infection with normal ANC or Grade 1 or 2 neutrophils, middle ear (otitis media) * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Infection with normal ANC or Grade 1 or 2 neutrophils, nerve-peripheral * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	1
Infection with normal ANC or Grade 1 or 2 neutrophils, sinus * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Infection with normal ANC or Grade 1 or 2 neutrophils, upper airway NOS * 1	3/23 (13.04%)	4	0/2 (0.00%)	0	1/4 (25.00%)	1
Infection with unknown ANC, sinus * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Infection with normal ANC or Grade 1 or 2 neutrophils, Lung (pnemonia) * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	1

Metabolism and nutrition disorders						
ALT, SGPT (serum gluatmic pyruvic transaminase) * 1	22/23 (95.65%)	90	0/2 (0.00%)	0	2/4 (50.00%)	10
AST, SGOT (serum glutamic oxaloacetic transaminase) * 1	23/23 (100.00%)	73	1/2 (50.00%)	1	1/4 (25.00%)	3
Albumin, serum-low (hypoalbuminemia) * 1	6/23 (26.09%)	6	1/2 (50.00%)	1	1/4 (25.00%)	1
Alkaline phosphatase * 1	4/23 (17.39%)	6	0/2 (0.00%)	0	0/4 (0.00%)	0
Amylase * 1	8/23 (34.78%)	14	0/2 (0.00%)	0	1/4 (25.00%)	4
Calcium, serum-high (hypercalcemia) * 1	0/23 (0.00%)	0	1/2 (50.00%)	2	0/4 (0.00%)	0
Calcium, serum-low (hypocalcemia * 1	3/23 (13.04%)	5	0/2 (0.00%)	0	0/4 (0.00%)	0
Glucose, serum-high (hyperglycemia) * 1	12/23 (52.17%)	23	1/2 (50.00%)	1	2/4 (50.00%)	5
Glucose, serum-low (hypoglycemia) * 1	10/23 (43.48%)	14	0/2 (0.00%)	0	1/4 (25.00%)	3
Lipase * 1	3/23 (13.04%)	4	0/2 (0.00%)	0	2/4 (50.00%)	5
Magnesium, serum-high (hypermagnesemia) * 1	6/23 (26.09%)	9	0/2 (0.00%)	0	0/4 (0.00%)	0
Magnesium, serum-low (hypomagnesemia) * 1	3/23 (13.04%)	8	0/2 (0.00%)	0	0/4 (0.00%)	0
Metabolic/laboratory - other * 1	7/23 (30.43%)	23	0/2 (0.00%)	0	0/4 (0.00%)	0
Potassium, serum-high (hyperkalemia * 1	5/23 (21.74%)	9	0/2 (0.00%)	0	2/4 (50.00%)	8
Potassium, serum-low (hypokalemia) * 1	4/23 (17.39%)	4	0/2 (0.00%)	0	2/4 (50.00%)	2
Proteinuria * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	1
Sodium, serum-high (hypernatremia) * 1	9/23 (39.13%)	17	0/2 (0.00%)	0	2/4 (50.00%)	2
Triglyceride, serum-high (hypertriglyceridemia) * 1	11/23 (47.83%)	17	0/2 (0.00%)	0	1/4 (25.00%)	1
Uric acid, serum-high (hyperuricemia) * 1	7/23 (30.43%)	7	0/2 (0.00%)	0	3/4 (75.00%)	9
Bilirubin (hyperbilirubinemia) * 1	2/23 (8.70%)	6	0/2 (0.00%)	0	0/4 (0.00%)	0
Nervous system disorders						
Dizziness * 1	3/23 (13.04%)	5	0/2 (0.00%)	0	0/4 (0.00%)	0
Mood alteration, agitation * 1	9/23 (39.13%)	23	0/2 (0.00%)	0	0/4 (0.00%)	0
Mood alteration, anxiety * 1	3/23 (13.04%)	3	0/2 (0.00%)	0	1/4 (25.00%)	1
Mood alteration, depression * 1	3/23 (13.04%)	4	0/2 (0.00%)	0	0/4 (0.00%)	0
Neuropathy: sensory * 1	5/23 (21.74%)	8	0/2 (0.00%)	0	0/4 (0.00%)	0
Personality/behavioral * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Renal and urinary disorders						
Incontinence, urinary * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	2
Urinary frequency/urgency * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	2
Reproductive system and breast disorders						

Irregular menses (change from baseline) * 1	2/23 (8.70%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0
Respiratory, thoracic and mediastinal disorders						
Bronchospasm, wheezing * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	6
Cough * 1	6/23 (26.09%)	8	0/2 (0.00%)	0	1/4 (25.00%)	1
Dyspnea (shortness of breath) * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	1
Skin and subcutaneous tissue disorders						
Bruising (in absence of Grade 3 or 4 thrombocytopenia) * 1	4/23 (17.39%)	9	0/2 (0.00%)	0	0/4 (0.00%)	0
Dermatology/skin - other * 1	4/23 (17.39%)	7	0/2 (0.00%)	0	0/4 (0.00%)	0
Dry skin * 1	6/23 (26.09%)	6	0/2 (0.00%)	0	0/4 (0.00%)	0
Flushing * 1	3/23 (13.04%)	7	0/2 (0.00%)	0	1/4 (25.00%)	1
Hair loss/alopecia (scalp or body) * 1	7/23 (30.43%)	8	0/2 (0.00%)	0	1/4 (25.00%)	1
Photosensitivity * 1	1/23 (4.35%)	1	0/2 (0.00%)	0	1/4 (25.00%)	1
Pruritus/itching * 1	5/23 (21.74%)	5	1/2 (50.00%)	1	1/4 (25.00%)	1
Rash/desquamation * 1	20/23 (86.96%)	83	1/2 (50.00%)	2	3/4 (75.00%)	5
Urticaria (hives, welts, wheals) * 1	0/23 (0.00%)	0	1/2 (50.00%)	1	0/4 (0.00%)	0
Vascular disorders						
Hemorrhage, GI, lower GI NOS * 1	3/23 (13.04%)	4	0/2 (0.00%)	0	0/4 (0.00%)	0
Hemorrhage, GI, oral cavity * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Hemorrhage, GI, rectum * 1	2/23 (8.70%)	2	0/2 (0.00%)	0	0/4 (0.00%)	0
Hemorrhage, GI, upper GI NOS * 1	0/23 (0.00%)	0	0/2 (0.00%)	0	1/4 (25.00%)	2
Hemorrhage, pulmonary/upper respiratory, nose * 1	3/23 (13.04%)	7	0/2 (0.00%)	0	0/4 (0.00%)	0
Hemorrhage/bleeding - other * 1	2/23 (8.70%)	3	0/2 (0.00%)	0	0/4 (0.00%)	0

* Indicates events were collected by non-systematic assessment

1 Term from vocabulary, CTC version 3

Limitations and Caveats

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The study closed early due to poor accrual to stratum B1.

More Information

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Certain Agreements

All Principal Investigators ARE employed by the organization sponsoring the study.

Results Point of Contact

Name/Title: Alberto Pappo, MD
Organization: St. Jude Children's Research Hospital
Phone: 901-595-2322
EMail: info@stjude.org

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