Trial record **1 of 1** for: NCT00930644

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Open-Label Study of Teduglutide for Subjects With PN-Dependent Short Bowel Syndrome (SBS)

ClinicalTrials.gov Identifier: NCT00930644

Recruitment Status : Completed
First Posted : June 30, 2009
Results First Posted : December 24, 2014
Last Update Posted : June 11, 2021

Sponsor:
Shire

Collaborator:
Nycomed Germany GmbH

Information provided by (Responsible Party):
Takeda (Shire)

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

Study Type	Interventional
Study Design	Allocation: N/A; Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Short Bowel Syndrome
Intervention	Drug: teduglutide
Enrollment	88

Participant Flow

Go to

Recruitment Details	Subjects who met any of the following could be enrolled: Completed 24 weeks of treatment in Study CL0600-020; based on PI and sponsor decision, subjects who were required to stop treatment prematurely due to a non drug related AE; or successfully completed Stage I (optimization/stabilization) in Study CL0600-020 after ~86 subjects were randomized
Pre-assignment Details	

Arm/Group Title	Teduglutide 0.05 mg/kg/Day
Arm/Group Description	teduglutide: 0.05 mg/kg/day subcutaneously taken once per day for 24 months
Period Title: **Overall Study**	
Started	88
Completed	65
Not Completed	23

Reason Not Completed	
Withdrawal by Subject	4
Physician Decision	2
Death	1
Adverse Event	16

Baseline Characteristics Go to

	Arm/Group Title	Teduglutide 0.05 mg/kg/Day	
	▼ Arm/Group Description	teduglutide: 0.05 mg/kg/day subcutaneously taken once per day for 24 months	
	Overall Number of Baseline Participants	88	
	▼ Baseline Analysis Population Description	[Not Specified]	
Age, Categorical Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	88 participants	
	<=18 years	0	0.0%
	Between 18 and 65 years	73	83.0%
	>=65 years	15	17.0%
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	88 participants	
	Female	47	53.4%
	Male	41	46.6%
Years since start of PN/IV dependecy Mean (Standard Deviation) Unit of measure: Years			
	Number Analyzed	88 participants	
		6.41 (6.272)	
Prescribed weekly PN/IV volume Mean (Standard Deviation) Unit of measure: Liters			
	Number Analyzed	88 participants	
		12.07 (7.56)	
Prescribed weekly number of days on PN/IV Mean (Standard Deviation) Unit of measure: Days			
	Number Analyzed	88 participants	
		5.6 (1.68)	

Outcome Measures Go to

1. Primary Outcome

Title	Percent Change in PN/IV Volume by Visit
▼ Description	The mean change from baseline in weekly PN.IV volume in percent change is shown by visit.
Time Frame	24 months

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	NT/TED	PBO/TED	TED/TED
▼ Arm/Group Description:	No treatment in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	Placebo in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	0.05 mg/kg/day subcutaneously taken once per day for 6 months CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial
Overall Number of Participants Analyzed	12	39	37
Mean (Standard Deviation) Unit of Measure: percent change			
Month 1	-5.35 (11.287)	-6.44 (11.241)	-40.65 (21.546)
Month 2	-12.88 (22.789)	-10.27 (14.027)	-44.24 (21.823)
Month 3	-10.83 (47.396)	-14.18 (16.440)	-45.80 (22.681)
Month 6	-24.13 (17.496)	-16.48 (20.979)	-34.70 (55.319)
Month 9	-25.35 (17.855)	-20.95 (27.500)	-37.91 (57.460)
Month 12	-23.33 (20.296)	-22.00 (33.858)	-51.33 (28.299)
Month 15	-31.62 (25.901)	-18.89 (33.165)	-54.24 (27.871)
Month 18	-35.11 (35.545)	-24.18 (32.183)	-63.01 (26.587)
Month 21	-39.40 (36.504)	-27.67 (33.064)	-64.99 (27.920)
Month 24	-39.40 (36.504)	-28.33 (35.169)	-65.61 (33.606)

2. Primary Outcome

Title	Absolute Change in PN/IV Volume by Visit
▼ Description	The mean change from baseline in weekly PN.IV volume in Liters is shown by visit.
Time Frame	24 months

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	NT/TED	PBO/TED	TED/TED
▼ Arm/Group Description:	No treatment in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	Placebo in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	0.05 mg/kg/day subcutaneously taken once per day for 6 months CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial
Overall Number of Participants Analyzed	12	39	37
Mean (Standard Deviation) Unit of Measure: Liters			
Month 1	-1.05 (1.315)	-0.95 (1.938)	-5.28 (3.819)
Month 2	-1.88 (2.057)	-1.38 (2.228)	-5.62 (3.873)
Month 3	-2.55 (3.123)	-1.65 (2.456)	-5.72 (3.771)
Month 6	-3.85 (2.761)	-1.90 (3.309)	-5.20 (4.650)
Month 9	-3.69 (2.916)	-2.61 (4.071)	-5.59 (4.899)
Month 12	-2.90 (2.762)	-2.72 (4.310)	-6.36 (4.633)
Month 15	-3.58 (2.811)	-2.48 (4.398)	-6.37 (4.261)
Month 18	-3.63 (2.834)	-2.90 (4.394)	-6.99 (4.048)
Month 21	-4.01 (2.910)	-3.00 (3.571)	-7.34 (4.412)
Month 24	-4.01 (2.910)	-3.11 (3.880)	-7.55 (4.930)

3. Secondary Outcome

Title	Number of Subjects Achieving PN/IV Reduction
▼ Description	The number of subjects who achieve at least 1-, 2-, and 3-day reductions in PN/IV per Week.
Time Frame	24 Months or Last Dosing Visit

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	NT/TED	PBO/TED	TED/TED
▼ Arm/Group Description:	No treatment in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	Placebo in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	0.05 mg/kg/day subcutaneously taken once per day for 6 months CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial
Overall Number of Participants Analyzed	12	39	37
Measure Type: Number Unit of Measure: participants			
Achieving >= 1 Day of PN/IV Reduction	3	14	21
Achieving >= 2 Day of PN/IV Reduction	2	7	18
Achieving >= 3 Day of PN/IV Reduction	2	5	18

Adverse Events Go to

Time Frame	Adverse event data were collected for each subject from the time informed consent was signed to the end of the study. The most commonly reported treatment emergent adverse events (>= 3% grouped at PT level) are listed.
Adverse Event Reporting Description	Adverse events monitoring was performed through investigator assessment and safety laboratory testing at each visit.

Arm/Group Title	NT,PBO/TED	TED/TED
▼ Arm/Group Description	No treatment or placebo in CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial	0.05 mg/kg/day subcutaneously taken once per day for 6 months CL0600-020 trial and teduglutide 0.05 mg/kg/day subcutaneously taken once per day for 24 months in CL0600-021 trial

All-Cause Mortality

	NT,PBO/TED		TED/TED	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

▼ Serious Adverse Events

	NT,PBO/TED		TED/TED	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	32/51 (62.75%)		24/37 (64.86%)	
Blood and lymphatic system disorders				
Anaemia †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Lymphadenitis †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Cardiac disorders				
Cardiac failure congestive †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Tachycardia †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Gastrointestinal disorders				
Crohns disease †1	1/51 (1.96%)	2	1/37 (2.70%)	1
Abdominal pain †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Abdominal pain upper †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Fecal volume increased †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Intestinal obstruction †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Melena †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Pancreatitis acute †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Papilla of Vater stenosis †1	0/51 (0.00%)	0	1/37 (2.70%)	1
General disorders				
Pyrexia †1	4/51 (7.84%)	7	1/37 (2.70%)	1
Face oedema †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Injection site haematoma †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Soft tissue inflammation †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Hepatobiliary disorders				
Cholecystitis †1	1/51 (1.96%)	1	0/37 (0.00%)	0

Cholecystitis acute [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Cholelithiasis [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Cholestasis [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Portal hypertension [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Infections and infestations				
Central line infection [†1]	3/51 (5.88%)	5	5/37 (13.51%)	7
Catheter bacteraemia [†1]	4/51 (7.84%)	7	0/37 (0.00%)	0
Catheter sepsis [†1]	3/51 (5.88%)	3	1/37 (2.70%)	1
Sepsis [†1]	3/51 (5.88%)	3	1/37 (2.70%)	1
Catheter related infection [†1]	1/51 (1.96%)	1	2/37 (5.41%)	2
Pneumonia [†1]	1/51 (1.96%)	1	2/37 (5.41%)	2
Urinary tract infection [†1]	0/51 (0.00%)	0	3/37 (8.11%)	4
Catheter site infection [†1]	0/51 (0.00%)	0	2/37 (5.41%)	3
Gastroenteritis [†1]	0/51 (0.00%)	0	2/37 (5.41%)	2
Bacteraemia [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Brain abscess [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Catheter site cellulitis [†1]	1/51 (1.96%)	2	0/37 (0.00%)	0
Clostridial infection [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Diverticulitis [†1]	0/51 (0.00%)	0	1/37 (2.70%)	2
Hepatic cyst infection [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Herpes Zoster [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Infection [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Intervertebral discitis [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Sepsis syndrome [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Tuberculosis [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Injury, poisoning and procedural complications				
Gastrointestinal stoma complication [†1]	2/51 (3.92%)	3	0/37 (0.00%)	0
Chemical burn of the eye [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Clavicle fracture [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Device breakage [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Incisional hernia [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Intestinal anastomosis complication [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Lumbar vertebral fracture [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Rib fracture [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Investigations				
Blood bilirubin increased [†1]	1/51 (1.96%)	1	1/37 (2.70%)	1
Alanine aminotransferase increased [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Aspartate aminotransferase increased [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Blood alkaline phosphatase increased [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Gamma glutamyltransferase increased [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Metabolism and nutrition disorders				
Hypokalemia [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Lactic acidosis [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Musculoskeletal and connective tissue disorders				
Arthritis [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung squamous cell carcinoma stage unspecified [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Metastatic neoplasm [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Non-small cell lung cancer [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0
Nervous system disorders				
Cerebrovascular accident [†1]	0/51 (0.00%)	0	1/37 (2.70%)	2
Syncope [†1]	0/51 (0.00%)	0	1/37 (2.70%)	1
Suicide attempt [†1]	1/51 (1.96%)	1	0/37 (0.00%)	0

Psychiatric disorders				
Delusional disorder, unspecified type †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Renal and urinary disorders				
Hydronephrosis †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Nephrolithiasis †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Renal colic †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Renal failure acute †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Renal failure chronic †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Dyspnoea †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Hydrothorax †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Pulmonary hypertension †1	1/51 (1.96%)	2	0/37 (0.00%)	0
Pulmonary oedema †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Skin and subcutaneous tissue disorders				
Rash †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Vascular disorders				
Subclavian vein thrombosis †1	1/51 (1.96%)	1	1/37 (2.70%)	1
Deep vein thrombosis †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Haematoma †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Hypertension †1	0/51 (0.00%)	0	1/37 (2.70%)	1
Jugular vein thrombosis †1	1/51 (1.96%)	1	0/37 (0.00%)	0
Superior vena caval stenosis †1	0/51 (0.00%)	0	1/37 (2.70%)	1

† Indicates events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	3%			
	NT,PBO/TED		TED/TED	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	49/51 (96.08%)		35/37 (94.59%)	
Blood and lymphatic system disorders				
Blood and Lymphatic System Disorders †1	5/51 (9.80%)	10	3/37 (8.11%)	5
Gastrointestinal disorders				
Gastrointestinal Disorders †1 [1]	34/51 (66.67%)	148	20/37 (54.05%)	68
General disorders				
General Disorders, and Administration Site Conditions †1	27/51 (52.94%)	100	15/37 (40.54%)	40
Hepatobiliary disorders				
Hepatobiliary Disorders †1	8/51 (15.69%)	10	2/37 (5.41%)	2
Infections and infestations				
Infections and Infestations †1	31/51 (60.78%)	97	26/37 (70.27%)	62
Injury, poisoning and procedural complications				
Injury, Poisoning, and Procedural Complications †1	19/51 (37.25%)	39	13/37 (35.14%)	39
Investigations				
Investigations †1	22/51 (43.14%)	62	19/37 (51.35%)	31
Metabolism and nutrition disorders				
Metabolism and Nutrition Disorder †1	14/51 (27.45%)	44	14/37 (37.84%)	33
Musculoskeletal and connective tissue disorders				
Musculoskeletal and Connective Tissue Disorders †1	11/51 (21.57%)	37	13/37 (35.14%)	23
Nervous system disorders				
Nervous System Disorders †1	10/51 (19.61%)	60	10/37 (27.03%)	18
Psychiatric disorders				
Psychiatric Disorders †1	8/51 (15.69%)	11	2/37 (5.41%)	2

Renal and urinary disorders				
Renal and Urinary Disorders †1	6/51 (11.76%)	17	4/37 (10.81%)	17
Respiratory, thoracic and mediastinal disorders				
Respiratory, Thoracic, and Mediastinal Disorders †1	10/51 (19.61%)	20	7/37 (18.92%)	9
Vascular disorders				
Vascular Disorder †1	14/51 (27.45%)	18	6/37 (16.22%)	16

† Indicates events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)
[1] Includes abdominal pain, nausea, abdominal distension, diarrhea, flatulence, vomiting, abdominal pain upper, dyspepsia, abdominal discomfort, constipation, faecal volume increased, intestinal obstruction, abdominal pain lower, and others.

Limitations and Caveats

Go to

[Not Specified]

More Information

Go to

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 terms and conditions of NPS Pharmaceuticals agreements with its investigators may vary. However, NPS 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.

Results Point of Contact

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Publications:

Jeppesen PB, Sanguinetti EL, Buchman A, Howard L, Scolapio JS, Ziegler TR, Gregory J, Tappenden KA, Holst J, Mortensen PB. Teduglutide (ALX-0600), a dipeptidyl peptidase IV resistant glucagon-like peptide 2 analogue, improves intestinal function in short bowel syndrome patients. Gut. 2005 Sep;54(9):1224-31.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Pape UF, Iyer KR, Jeppesen PB, Kunecki M, Pironi L, Schneider SM, Seidner DL, Lee HM, Caminis J. Teduglutide for the treatment of adults with intestinal failure associated with short bowel syndrome: pooled safety data from four clinical trials. Therap Adv Gastroenterol. 2020 Apr 20;13:1756284820905766. doi: 10.1177/1756284820905766. eCollection 2020.

Responsible Party:	Takeda (Shire)
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