Abbreviated Clinical Study Report
For
Prematurely Terminated Study
AEZS-108-049

A randomized, Phase 2 trial of AEZS-108 in chemotherapy refractory triple negative (ER/PR/HER2-negative) LHRH-R positive metastatic breast cancer

Clinical Phase	**II**
Design	**Open label, randomized, two-arm**
EudraCT No.	**2012-000134-19**
Trial Protocol Version (Date)	**1.2 (16-May-2013)**
Trial Period	**18-Feb-2013 - 10-Jun-2014**
Report Version (Date)	**2.0 (23-Nov-2021)**

This trial was performed in compliance with applicable Good Clinical Practices (GCP) and regulations, including the archiving of essential documents.

Sponsor **Aeterna Zentaris GmbH**
Weismuellerstraße 50
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Germany

Abbreviated Report for Prematurely Terminated Study

Title of Study:
A randomized, Phase 2 trial of AEZS-108 in chemotherapy refractory triple negative (ER/PR/HER2-negative) LHRH-R positive metastatic breast cancer

Sponsor:
Aeterna Zentaris, Weismuellerstr. 50, D- 60314 Frankfurt am Main, Germany

Investigators:
Principal (Site 1): Alberto J. Montero, MD; Department of Medicine, Division of Hematology / Oncology; University of Miami Miller School of Medicine; Miami, FL 33136 USA
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Study centers:
3 sites (1 in USA, 2 in Germany)

Publication (reference):
Stefan Buchholz, Joerg Engel, Andrew V. Schally, Stephan Seitz, Olaf Ortmann, Guenter Emons, Reshma L. Mahtani, Stefan Gluck, Charles L. Vogel, Alberto J. Montero. A randomized, phase II trial of AEZS-108 in chemotherapy refractory triple-negative (ER/PR/HER2-negative) LHRH-R positive metastatic breast cancer. J Clin Oncol 31, 2013 (suppl; abstr TPS11124)

Study period:	**Phase of development:**
First patient enrolled: 18-Feb-2013 Last patient randomized: 19-Dec-2013 Last patient completion/discontinuation: 13-May-2014	II

Objectives:

- **Primary:** To evaluate the efficacy of AEZS-108 compared to standard single agent cytotoxic chemotherapy (SSCC) as measured by the median time of progression-free survival (PFS).
- **Secondary:** To evaluate efficacy of AEZS-108 compared to SSCC as measured by the overall response, clinical benefit, duration of response, time to progression and overall survival. To evaluate toxicity of AEZS-108 in this patient population.

The primary purpose of this synopsis is to summarize AEZS-108 safety results in support of a marketing application.

Methodology:
This was an open label randomized two-arm multicenter Phase II study.
Patients were randomized in a 1:1 ratio to: AEZS-108 (Arm A) or SSCC (Arm B) based upon stratification. A cycle was defined as 21-calendar days.
Stratified randomization was to be used with number of prior lines of therapies (1-2 versus >2).

Analysis of the main study endpoint, PFS, was planned to follow a group sequential design with one interim and one final analysis utilizing the O'Brien-Fleming stopping boundaries procedure. The study would be terminated for futility if the lower bound was crossed and for superiority if the upper bound was crossed. The Sponsor could also terminate the study for futility based on other considerations such as safety.

The study was closed prematurely due to low recruitment.

Due to low recruitment rate, no efficacy analysis was feasible. Thus, abbreviated listings (ICH E3 CSR Section 16) are available, but no tables/figures/listings (ICH E3 CSR Section 14).

Number of patients (planned/analyzed): 74/8; the study was closed prematurely due to low recruitment.

Diagnosis and main criteria for inclusion:

- Women ≥18 years of age
- Histologically documented breast cancer (either primary or metastatic site) that is: (i) ER-negative (0), (ii) PR-negative (0), and (iii) HER2-negative, defined by IHC (immunohistochemistry; IHC 0/1, non-overexpressing) or FISH (fluorescence in situ hybridization; FISH negative) or CISH (chromogen in situ hybridization; CISH negative).
- Expression of LHRH receptor confirmed by IHC on archival (or current biopsy of breast tumor or metastatic site) breast cancer tissue.
- Progressive disease after failure of 1 to 3 lines of prior chemotherapy for recurrent or metastatic (Stage IV) disease (prior adjuvant/neoadjuvant therapy is allowed). A line of therapy was defined as at least one cycle of treatment.
- Measurable disease by RECIST 1.1 criteria; at least one target lesion that has not been previously irradiated.

Test product, dose and mode of administration, batch number:

AEZS-108 (267 mg/m^2, 2-hour IV infusion every Day 1 of a 21-day (3-week) cycle. Dose reduction: to 210 mg/m^2 and 160 mg/m^2 if dose limiting toxicity.
Batch no.: 11C31.

Duration of treatment: Until disease progression.

Reference therapy, dose and mode of administration, batch number:

Commercially available SSCC (doses below the recommended package insert at the discretion of treating oncologist), on a 21-day cycle (although weekly administration was allowed; note: pegylated liposomal doxorubicin would be administered on a 28-day cycle). Drugs considered acceptable as SSCC: paclitaxel, nab-paclitaxel, eribulin, pegylated liposomal doxorubicin (PLD), vinorelbine, gemcitabine, capecitabine.

Criteria for efficacy evaluation:

Progression-free survival (PFS); Overall tumor response per RECIST 1.1 (CR+ PR), overall clinical benefit rate (CR+PR+SD), duration of response, time to progression and overall survival

Criteria for safety evaluation:

Adverse events per NCI Common Terminology Criteria for Adverse Events (version 4.0), (CTCAE v4.0), laboratory variables, LVEF and ECG parameters.

Statistical Methods:

PFS and other time to event variables: Kaplan-Meier procedure, medians of time to events and survival rates at specific times with corresponding 95% confidence intervals, log-rank test or Cox-proportional hazards regression. ORR and CBR rates: exact binomial method with corresponding two-sided 95% confidence intervals. Univariate and multivariate logistic regression models for CBR. Continuous variables: descriptive statistics for all, two-sided 95% confidence intervals for means and proportions.

Categorical analysis of ECG QTc values. Treatment outcome after crossover to AEZS-108: descriptive statistics

Summary:

A total of 8 female patients entered the trial, and one patient withdrew prior to the start of the assigned capecitabine treatment. All patients were white with a median age of 41 years (range 34-75 years) with an ECOG Performance Status of 0/1/2 in 5/1/1 patients, respectively, and more than 2 lines of prior chemotherapy in 4 patients.

Patients assigned to AEZS-108 received 1, 2, 7, and 8 treatment cycles; two of the patients assigned to SSCC received vinorelbine (2 and 3 cycles), one patient received capecitabine (6 cycles). Upon disease progression on SSCC, all three were crossed over to follow-up treatment with AEZS-108 for 2, 3, and 6 cycles, respectively. In all 25 treatment cycles of AEZS-108, the dose of 267 mg/m^2 was used, combined with 8 mg dexamethasone as antiemetic prophylaxis; in 6 cycles additional antiemetics were given post-infusion. Hematopoietic support with Neulasta/Neupogen was used in two patients and 3 cycles of AEZS-108. In one patient (patient # 1/101), the supportive G-CSF therapy started when the patient was treated with vinorelbine and was continued after the cross-over; the same patient also received anti-allergic treatment for an infusion reaction to AEZS-108. Reasons to finally discontinue treatment were as follows: disease progression (4 patients), and completion of maximum allowed number of treatment cycles, withdrawal by patient, and death (after crossover from capecitabine due to progressive disease) in one case each.

Efficacy results:

Overall best response to the randomly allocated treatment included a confirmed partial response (PR) for 2 patients in the AEZS-108 group and an unconfirmed PR in one patient of the SSCC group. No objective response was after cross-over.

Safety results:

No decrease in LVEF has been observed in the 6 patients in whom repeated LVEF measurements have been performed before and after treatment with AEZS-108; this includes the two patients who received 7 or 8 cycles of AEZS-108 after prior therapy including doxorubicin (240 mg/m^2) or expirubicin (360 mg/m^2). No clinically significant ECG changes were noted.

The table below shows the possibly drug-related adverse events by severity and treatment, for AEZS-108 including events reported after the crossover from SSCC. Three of the AEs possibly related to AEZS-108 were classified as serious, one case each of ‘herpes zoster’, ‘reduced general condition’, and ‘white blood cell decreased’ (in the

latter case the hospitalization was due to PD).

Possibly drug-related Adverse Events (including AEs observed after crossover from SSCC to AEZS-108				
***System organ class* / AE, preferred term**	**Grade 1/2**		**Grade 3/4**	
	AEZS-108	**SSCC**	**AEZS-108**	**SSCC**
	(n of 6)	**(n of 3)**	**(n of 6)**	**(n of 3)**
Blood and lymphatic system disorders				
Anemia	0	0	1	0
Leukopenia (WBC decr.)	1	0	2	0
Neutropenia	0	0	2	0
Thrombocytopenia (PLT decr.)	0	0	1	0
Gastrointestinal disorders				
Nausea	2	1	0	0
Vomiting	0	1	0	0
Diarrhea	1	1	0	0
Stomatitis		2	0	0
General disorders and administration site conditions				
Fatigue	4	1	0	0
General physical health deterioration	1	0	0	0
Infections and infestations				
Herpes zoster	0	0	1	0
Injury, poisoning and procedural complications				
Infusion related reaction	1	0	0	0
Muskulosceletal and connective tissue disorders				
Pain in extremity	0	1	0	0
Nervous system disorders				
Polyneuropathy	1	0	0	0
Skin and subcutaneous tissue disorders				
Alopecia	3	0	0	0
Rash	2	1	0	0

Conclusion:
Because of the premature discontinuation due to low recruitment, the available data from 25 treatment cycles with AEZS-108 allow only for preliminary conclusions on

AEZS-108, but no comparison with the comparator standard treatments.
In the patients with triple-negative breast cancer pretreated with multiple lines of chemotherapy, including an anthracycline in 6 of 7 patients, AEZS-108 was well tolerated at the dose of 267 mg/m2. No dose-limiting events or cardiac toxicities or clinically significant ECG changes were observed. Of note, in two out of three patients started on AEZS-108, a confirmed partial remission was observed.

Date of Report Version 1.0: 3-Sep-2015
Date of updated Report Version 2.0: 23-Nov-2021 (update includes the addition of a titlepage, data review and insertion of appendices)

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Listing 16.2.1.1
Randomization by Patient
Enrolled Patients

Site Number	Patient Number	Number of Prior Lines of Treatment	Randomization Date	Treatment Group	Type of SSCC Treatment
001	101	>2	2013-03-07	SSCC	Vinorelbine
	102	>2	2013-03-28	AEZS-108	
	103	>2	2013-04-15	AEZS-108	
	104	>2	2013-12-19	SSCC	Vinorelbine
002	101	1-2	2013-02-18	AEZS-108	
	102	1-2	2013-05-22	SSCC	Capecitabine
003	101	1-2	2013-05-28	AEZS-108	
	201	1-2	2013-07-16	SSCC	Capecitabine

Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.1.2
Patient Disposition by Patient
Enrolled Patients

Site Number	Patient Number	Treatment Group	Date of First Dose/Last Dose-SSCC	Date of First Dose/Last Dose-AEZS-108	Number of Cycles Completed-SSCC/AEZS-108	Completion Status	Date of Completion or Discontiuation
001	101	SSCC	2013-03-08/ 2013-03-29	2013-04-24/ 2013-05-16	2/2	PROGRESSIVE DISEASE	2013-06-05
	102	AEZS-108		2013-03-28/ 2013-03-28		PROGRESSIVE DISEASE	2013-04-17
	103	AEZS-108		2013-04-16/ 2013-09-12		MAXIMUM ALLOWED NUMBER OF TREATMENT CYCLES COMPLETED	2013-09-12
	104	SSCC	2013-12-19/ 2014-01-29	2014-02-18/ 2014-04-23	3/4	PROGRESSIVE DISEASE	2014-05-13
002	101	AEZS-108		2013-02-20/ 2013-07-31		WITHDRAWAL BY SUBJECT	2013-08-21
	102	SSCC	2013-05-28/ 2013-09-09	2013-10-11/ 2013-10-11	6/1	DEATH	2013-10-13
003	101	AEZS-108		2013-05-30/ 2013-06-20		PROGRESSIVE DISEASE	2013-07-09
	201	SSCC				NON-COMPLIANCE WITH STUDY DRUG	2013-08-05

Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.4.1
Demographics by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Date of Birth	Study Participation Informed Consent Date	Age [1]	Sex	Ethnicity	Race
001	101	SSCC	1978-05	2013-02-14	34	Female	Not Hispanic Or Latino	White
	102	AEZS-108	1977-08	2013-03-15	35	Female	Hispanic Or Latino	White
	103	AEZS-108	1956-09	2013-03-25	56	Female	Not Hispanic Or Latino	White
	104	SSCC	1951-07	2013-12-11	62	Female	Not Hispanic Or Latino	White
002	101	AEZS-108	1937-07	2013-02-04	75	Female	Not Hispanic Or Latino	White
	102	SSCC	1963-03	2013-05-08	50	Female	Not Hispanic Or Latino	White
003	101	AEZS-108	1968-08	2013-05-23	44	Female	Not Hispanic Or Latino	White

[1] Age = Integer((Study Participation Informed Consent Date - Date of Birth)/365.25), where the day of the month of birth is assumed to be the day of the month of the informed consent.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_DEMO

Date Produced: 26AUG2015

Listing 16.2.4.2
Concomitant Medications by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Meds Taken	Medication	Type [1]	Indication	S: Start Date E: End Date	Ongoing?	Dose (Units)	F: Dosing Freq. R: Route
001	101	SSCC	Yes	IMMODIUM	1	DIARRHEA	S: 2013-03-08 E:	Yes	20 (MG)	F: PRN R: ORAL
				ZOFRAN	3	ANTIEMETIC	S: 2013-03-08 E: 2013-03-08		16 (MG)	F: ONCE R: IV
				KYTRIL	3	ANTIEMETIC	S: 2013-03-15 E:	Yes	1 (MG)	F: DAY 1 & DAY 8/CYCLE R: IV
				MUGARD	1	STOMATITIS	S: 2013-03-15 E:	Yes	5 (ML)	F: PRN R: SWISH/ SWALLOW
				ATROPINE	3	DIARRHEA	S: 2013-03-15 E: 2013-04-05		0.5 (MG)	F: DAY 1 & DAY 8/CYCLE R: IV
				NEULASTA	3	NEUTROPENIA	S: 2013-03-16 E: 2013-05-17		6 (MG)	F: ONCE R: SQ
				DEXAMETHASONE	1	AEZS-108 INFUSION REACTION	S: 2013-04-24* E: 2013-04-24		4 (MG)	F: ONCE R: IV
				DIPHENHYDRAMINE (BENADRYL)	1	AEZS-108 INFUSION REACTION	S: 2013-04-24* E: 2013-04-24		12.5 (MG)	F: ONCE R: IV
				NORMAL SALINE 0.9%	1	AEZS-108 INFUSION REACTION	S: 2013-04-24* E: 2013-04-24		500 (ML)	F: ONCE R: IV

[1] Type of Indication: 1=Adverse Event, 2=Concomitant Disease, 3=Prophylaxis, 4=Study Indication.
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001	101	SSCC	Yes	PEPCID	1	AEZS-108 INFUSION REACTION	S: 2013-04-24* E: 2013-04-24		20 (MG)	F: ONCE R: IV
				NEUPOGEN	1	NEUTROPENIA	S: 2013-05-15* E: 2013-05-15		300 (MCG)	F: ONCE R: SQ
				DIPHENHYDRAMINE (BEANDRYL)	3	AEZS-108 INFUSION REACTION	S: 2013-05-16* E: 2013-05-16		25 (MG)	F: EVERY 21 DAYS R: IV
				DIPHENHYDRAMINE (BENADRYL)	1	AEZS-108 INFUSION REACTION	S: 2013-05-16* E: 2013-05-16		25 (MG)	F: ONCE R: IV
				FOSAPREPITANT	3	NAUSEA	S: 2013-05-16* E: 2013-05-16		150 (MG)	F: ONCE R: IV
				ZANTAC	1	AEZS-108 INFUSION REACTION	S: 2013-05-16* E: 2013-05-16		50 (MG)	F: ONCE R: IV
	102	AEZS-108	Yes	LEVOTHYROXINE	2	HYPOTHYROIDISM	S: 1993 E:	Yes	100 (MCG)	F: DAILY R: ORAL
				HYDROXYCHLOROQUINE	2	SYSTEMIC LUPUS ERYTHEMATOSUS	S: 2005-12 E:	Yes	200 (MG)	F: DAILY R: ORAL
				PREDNISONE	2	SYSTEMIC LUPUS ERYTHEMATOSUS	S: 2005-12 E:	Yes	10 (MG)	F: DAILY R: ORAL
				DOCUSATE SODIUM	2	CONSTIPATION	S: 2011-10 E:	Yes	100 (MG)	F: DAILY AS NEEDED R: ORAL

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Program: L_CM Date Produced: 26AUG2015

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Concomitant Medications by Patient
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Site Number	Patient Number	Treatment Group	Meds Taken	Medication	Type [1]	Indication	S: Start Date E: End Date	Ongoing?	Dose (Units)	F: Dosing Freq. R: Route
001	102	AEZS-108	Yes	HYDROMORPHONE	2	PAIN	S: 2013-03 E:	Yes	2 (MG)	F: AS NEEDED R: ORAL
				MORPHINE	2	PAIN	S: 2013-03 E:	Yes	30 (MG)	F: EVERY 4 HOURS PRN R: ORAL
				DEXAMETHASONE	3	PRE-MED	S: 2013-03-28 E: 2013-03-28		8 (MG)	F: EVERY 3 WEEKS R: INTRAVENOUS
				ONDANSETRON	3	PRE-MED	S: 2013-03-28 E: 2013-03-28		16 (MG)	F: EVERY 3 WEEKS R: INTRAVENOUS
				COMPAZINE	3	NAUSEA	S: 2013-04-05 E:	Yes	10 (MG)	F: PRN R: ORAL
				IMMODIUM	3	DIARRHEA	S: 2013-04-05 E:	Yes	2 (TABS)	F: PRN R: ORAL
				ZOFRAN	3	NAUSEA	S: 2013-04-05 E:	Yes	8 (MG)	F: PRN R: ORAL
				BLOOD TRANSFUSION	1	ANEMIA	S: 2013-04-12 E: 2013-04-12		2 (PACKS)	F: ONE TIME R: INTRAVENOUS
				NEUPOGEN	1	DECREASED WHITE BLOOD CELLS	S: 2013-04-12 E: 2013-04-12		300 (MCG)	F: ONCE R: INJECTION
				XANAX	2	ANXIETY	S: 2013-04-16 E:	Yes	.5 (MG)	F: PRN R: PO
	103	AEZS-108	Yes	TENORMIN	2	HYPERTENSION	S: 2003 E:		25 (MG)	F: DAILY R: PO

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001	103	AEZS-108	Yes	RESTORIL	2	INSOMNIA	S: 2010 E:	Yes	15 (MG)	F: PRN R: PO
				TOBREX	2	DIPLOPIA	S: 2013-03-13 E: 2013-04-18		0.3 (%)	F: 3 TIMES DAILY R: OPHTHALMIC
				MAXZIDE	2	HYPERTENSION	S: 2013-03-25 E:	Yes	25 (MG)	F: DAILY R: PO
				CALCIUM CITRATE-VITAMIN D	3	BONE METASTASIS	S: 2013-04-16 E:	Yes	1 (TAB)	F: DAILY R: PO
				MULTI-VITAMINS-MINERALS	3	NUTRITIONAL SUPPLEMENT	S: 2013-04-16 E:	Yes	1 (TAB)	F: DAILY R: PO
				ONDANSETRON	4	PRE-MEDICATION	S: 2013-04-16 E:	Yes	16 (MG)	F: EVERY 3 WEEKS R: INTRAVENOUS
				XGEVA	3	BONE METASTASIS	S: 2013-04-16 E:	Yes	120 (MG)	F: EVERY 4 WEEKS R: SUB Q
				DEXAMETASONE	3	PRE-MED	S: 2013-04-16 E: 2013-09-12		8 (MG)	F: EVERY 3 WEEKS R: INTRAVENOUS
				NEULASTA	3	RISK OF INFECTION-NEUTROPENIA	S: 2013-05-09 E:	Yes	6 (MG)	F: EVERY 3 WEEKS R: SUB Q

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001	103	AEZS-108	Yes	CLARITIN	3	ALLERGY SYMPTOMS	S: 2013-09-09 E:	Yes	I (TAB)	F: PRN R: PO
	104	SSCC	Yes	CALCIUM/VITAMIN D	3	NITRICIONAL SUPPLEMENT	S: 1999 E:	Yes	1 (TAB)	F: ONCE DAILY R: ORAL
				MULTIVITAMIS	3	NUTRICIONAL SUPPLEMENT	S: 1999 E:	Yes	1 (TAB)	F: ONCE DAILY R: ORAL
				VITAMIN D	2	OSTEOPENIA	S: 1999 E:	Yes	1000 (UNITS)	F: ONCE DAILY R: ORAL
				SINGULAIR	2	ASTHMA	S: 2004 E:	Yes	10 (MG)	F: ONCE DAILY R: ORAL
				ZOCOR	2	HYPERCHOLESTEROLEMIA	S: 2004 E:	Yes	20 (MG)	F: EVERY BED TIMES R: ORAL
				ATIVAN	2	ANXIETY	S: 2008 E:	Yes	1 (MG)	F: PRN R: ORAL
				ZOLOFT	2	DEPRESSION	S: 2010 E:	Yes	50 (MG)	F: ONCE DAILY R: ORAL
				ADVAIR	2	ASTHMA	S: 2012 E:	Yes	1 (PUFF)	F: PRN R: INHALED
				FLONASE NA	2	ASTHMA	S: 2012 E: 2014-04-01		1 (PUFF)	F: PRN R: INHALED
				OXYCOTIN HCI	2	PAIN IN STERNUM AREA	S: 2013 E: 2014-02-18		30 (MG)	F: PRN R: ORAL
				OXY-IR (OXYXOTIN)	2	PAIN IN STERNUM AREA BREAST	S: 2013-03 E: 2014-05-13		5 (MG)	F: PRN R: ORAL

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001	104	SSCC	Yes	ZOFRAN	3	NAUSEA	S: 2013-12-16 E:	Yes	8 (MG)	F: PRN R: ORAL
				EMLA CREAM	3	ANESTETIC PORT	S: 2013-12-16 E: 2013-12-20		30 (GR)	F: PRN R: SUBCUTANEOUS
				FENTANYL PATCH	2	PAIN STERNUM AREA BREAST	S: 2013-12-16 E: 2013-12-20		50 (MCG/HR)	F: EVERY 72 HRS R: SUBCUTANEOUS
				XGEVA	2	OSTEOPENIA	S: 2013-12-19 E: 2014-02-18		120 (MG)	F: EVERY 4 WEEKS R: INTRAVENOUS
				BENADRYL	3	ANIETY PRIOR TO TREATMENT	S: 2014-01-29 E:	Yes	25 (MG)	F: PRN R: INTRAVENOUS
				OXYCONTIN HCI	2	PAIN IN STERNUM AREA BREAST	S: 2014-01-29 E: 2014-05-13		40 (MG)	F: EVERY 4 HRS PRN R: ORAL
				ZOMETA	2	BONE METASTASIS	S: 2014-02-18* E:	Yes	4 (MG)	F: EVERY 4 WEEKS R: INTRAVENOUS
				FENTANYL PATCH	2	PAIN IN STERNUM	S: 2014-02-18* E: 2014-02-19		25 (MCG/HR)	F: EVERY 72 HRS R: SUBCUTANEOUS
				KEFLEX	1	FOLLICULITIS	S: 2014-02-18* E: 2014-02-27		500 (MG)	F: THREE X DAILY R: ORAL
				PREDNISONE	1	ASTHMA ATTACK	S: 2014-02-25* E: 2014-03-02		60 (MG)	F: X SIX DAYS R: ORAL

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001	104	SSCC	Yes	ANUSOL HC	1	HEMORRHOIDS	S: 2014-03-18* E: 2014-03-25		1 (SUPPOSITORY)	F: PRN R: RECTAL
002	101	AEZS-108	Yes	AMLODIPIN	2	HYPERTENSION	S: 2010 E:	Yes	5 (MG)	F: 1/2-0-1/2 R: PO
				LOSARTAN	2	HYPERTENSION	S: 2010 E: 2013-08-12		100 (MG)	F: 1/2-0-1/2 R: PO
				METOHEXAL	2	HYPERTENSION	S: 2010 E: 2013-08-22		95 (MG)	F: 1/2-0-1/2 R: PO
				METFORMIN	2	DIABETES	S: 2011 E:	Yes	500 (MG)	F: 0-0-1 R: PO
				PLASTULEN	1	FATIGUE	S: 2013-02 E:	Yes	150 (MG)	F: 1-0-0 R: PO
				ONDANSETRON	1	NAUSEA	S: 2013-06-17 E: 2013-08-22		8 (MG)	F: 1-0-1 R: PO
	102	SSCC	Yes	IDEOS	3	BONES	S: 2012-03 E: 2013-10		500 (MG)	F: 1-0-1 R: PO
				MCP TROPFEN	1	NAUSEA	S: 2013-05-30 E: 2013-09-11		10 (MG)	F: 1-1-1 R: PO
				IBU	1	HEAD AND HEADACHE PAIN	S: 2013-06-01 E: 2013-06-01		400 (MG)	F: 1-0-0 R: PO
				IBU	1	HEAD AND HEADACHE PAIN	S: 2013-06-04 E: 2013-06-04		400 (MG)	F: 1-0-0 R: PO

[1] Type of Indication: 1=Adverse Event, 2=Concomitant Disease, 3=Prophylaxis, 4=Study Indication.
*Start date on or after the date a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.4.2
Concomitant Medications by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Meds Taken	Medication	Type [1]	Indication	S: Start Date E: End Date	Ongoing?	Dose (Units)	F: Dosing Freq. R: Route
002	102	SSCC	Yes	IBU	1	PAIN FEET	S: 2013-07-02 E: 2013-07-04		400 (MG)	F: 1-0-0 R: PO
003	101	AEZS-108	Yes	AMINEURIN	2	DEPRESSION	S: 2012-07 E:	Yes	1 (25 MG)	F: 0-0-1 R: P.O.
				PREDNISOLON	2	PROPHYLACTIC NAUSEA	S: 2013-04-27 E:	Yes	2 (2,5 MG)	F: 1-0-1 R: P.O.
				PANTOZOL	3	NAUSEA, GASTRIC PROTECTION	S: 2013-04-27 E: 2013-07		1 (40 MG)	F: 0-0-1, DAY 1-3 OF CT R: P.O.
				DEXAMETHSON	3	NAUSEA	S: 2013-05-30 E:	Yes	1 (8 MG)	F: DAY 0 (I.V.),1-3 P.O R: I.V., P.O.
				PASPERTIN	3	NAUSEA, VOMITING	S: 2013-05-30 E: 2013-07		3 (30 DROPS)	F: AS NEEDED R: P.O.
				EMEND (APREPITANT)	3	NAUSEA, VOMITING	S: 2013-05-31 E: 2013-07			F: R:

[1] Type of Indication: 1=Adverse Event, 2=Concomitant Disease, 3=Prophylaxis, 4=Study Indication.
*Start date on or after the date a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.4.3
Use of Prophylactic Treatment or Post-Infusion Anti-Emetics by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Cycle Number	Dose Given	Admin. Date	Prophylactic Treatment [1]	Post-Infusion Antiemetics
001	101	SSCC	1	Yes	2013-03-08	3	No
			2	Yes	2013-03-29	3	No
			3	Yes	2013-04-24*	1	Yes
			4	Yes	2013-05-16*	1	Yes
	102	AEZS-108	1	Yes	2013-03-28	1	No
	103	AEZS-108	1	Yes	2013-04-16	1	No
			2	Yes	2013-05-07	1	No
			3	Yes	2013-05-28	1	No
			4	Yes	2013-06-18	1	No
			5	Yes	2013-07-09	1	No
			6	Yes	2013-07-30	1	No
			7	Yes	2013-08-22	1	No
			8	Yes	2013-09-12	1	Yes
	104	SSCC	1	Yes	2013-12-19	3	No
			2	Yes	2014-01-08	3	No
			3	Yes	2014-01-29	3	No
			4	Yes	2014-02-18*	1	Yes
			5	Yes	2014-03-11*	1	No
			6	Yes	2014-04-02*	1	No
			7	Yes	2014-04-23*	1	No
002	101	AEZS-108	1	Yes	2013-02-20	1	No

[1] Phophylactic Treatment: 0=No; 1=Yes, 8 mg Dexamethasone; 2=Yes, Other; 3 = Yes.
*Administration date on or after the date a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.4.3
Use of Prophylactic Treatment or Post-Infusion Anti-Emetics by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Cycle Number	Dose Given	Admin. Date	Prophylactic Treatment [1]	Post-Infusion Antiemetics
002	101	AEZS-108	2	Yes	2013-03-13	1	No
			3	Yes	2013-04-10	1	No
			4	Yes	2013-05-03	1	No
			5	Yes	2013-05-29	1	No
			6	Yes	2013-06-26	1	No
			7	Yes	2013-07-31	1	No
	102	SSCC	1	Yes	2013-05-28	0	No
			2	Yes	2013-06-17	0	No
			3	Yes	2013-07-09	0	No
			4	Yes	2013-07-29	0	Yes
			5	Yes	2013-08-19	0	Yes
			6	Yes	2013-09-09	0	Yes
			7	Yes	2013-10-11*	1	No
003	101	AEZS-108	1	Yes	2013-05-30	1	Yes
			2	Yes	2013-06-20	1	Yes

[1] Phophylactic Treatment: 0=No; 1=Yes, 8 mg Dexamethasone; 2=Yes, Other; 3 = Yes.
*Administration date on or after the date a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_PROPTRT Date Produced: 26AUG2015

Listing 16.2.4.4
Concomitant Treatments by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Treatments Given	Treatment	Type [1]	Indication	Start Date	End Date	Ongoing?
001	101	SSCC	No						
	102	AEZS-108	No						
	103	AEZS-108	No						
	104	SSCC	No						
002	101	AEZS-108	No						
	102	SSCC	No						
003	101	AEZS-108	No						

[1] Type of Indication: 1=Adverse Event, 2=Concomitant Disease, 3=Prophylaxis, 4=Study Indication.
*Start date on or after the date a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_CT Date Produced: 26AUG2015

Listing 16.2.5.1
Total Exposure by Patient – AEZS-108
Safety Population

Site Number	Patient Number	Cumulative Dose Amount [1] (mg)	Number of Cycles
001	101	841.05	2
	102	419	1
	103	3761	8
	104	2112	4
002	101	3531.916	7
	102	478	1
003	101	986	2

[1] Cumulative Dose Amount = Sum of Starting Dose * Body surface area at each cycle.

Listing 16.2.5.2
Total Exposure by Patient – SSCC
Safety Population

Site Number	Patient Number	Cumulative Dose Amount [1] (mg)	Number of Cycles
001	101	78.5	2
	104	151.75	3
002	102	27000	6

[1] Cumulative Dose Amount = Sum of Starting Dose * Body surface area at each cycle.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
See Listing 16.2.1.1 for description of SSCC treatment received.
Program: L_TOTEX

Date Produced: 26AUG2015

Listing 16.2.6.1
Response Evaluations by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit [1]	Evaluation Date	Target Lesion Response [2]	Non-Target Lesion Response [3]	New Lesions	New Lesion Location	New Lesion Date Documented	Overall Response [4]
001	101	SSCC	Cycle 2	2013-04-19	SD	PD	Yes	SUBCARINAL ADENOPATHY 15MM, NEW MEDIASTINAL NODES	2013-04-19	PD
			Cycle 4	2013-06-03*	PR	PD	Yes	RIGHT HILAR NODE IN MEDIASTINUM THAT WAS NON-MEASURABLE, NOW MEASURABLE PER RECIST	2013-06-03	PD
			EOT	2013-06-03*	PD	PD	Yes	RIGHT HILAR NODE PREVIOUSLY NOT MEASURABLE NOW MEASURABLE PER RECIST CRITERIA	2013-06-03	PD

[1] Visit: EOT=End of Therapy
[2] Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
[3] Non-Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, Non-CR/PD=Non-CR/Non-PD, PD=Progressive Disease.
[4] Overall Response: CR=Complete response, NE=Not Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
*Evaluation on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_RESP Date Produced: 26AUG2015

Listing 16.2.6.1
Response Evaluations by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit [1]	Evaluation Date	Target Lesion Response [2]	Non-Target Lesion Response [3]	New Lesions	New Lesion Location	New Lesion Date Documented	Overall Response [4]
001	102	AEZS-108	EOT	2013-04-16	NE	PD	No			PD
	103	AEZS-108	Cycle 2	2013-05-21	SD	NA	No			SD
			Cycle 4	2013-07-09	SD	NON CR/PD	No			SD
			Cycle 6	2013-07-15	PR	NA	No			PR
			Cycle 8	2013-09-09	PR	NA	No			PR
			EOT							
	104	SSCC	Cycle 2	2014-02-04	PD	NA	Yes	PLEURAL BASED SOFT TISSUE MAS WITHIN LEFT CHEST	2014-02-04	PD
			EOT	2014-05-01*	PD	NA	No			PD
002	101	AEZS-108	Cycle 2	2013-04-08	PR	NA	No			PR
			Cycle 4	2013-05-29	PR	NA	No			PR
			Cycle 6	2013-07-16	PR	NA	No			PR
			EOT	2013-09-03	SD	NA	No			SD

[1] Visit: EOT=End of Therapy
[2] Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
[3] Non-Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, Non-CR/PD=Non-CR/Non-PD, PD=Progressive Disease.
[4] Overall Response: CR=Complete response, NE=Not Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
*Evaluation on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.6.1
Response Evaluations by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit [1]	Evaluation Date	Target Lesion Response [2]	Non-Target Lesion Response [3]	New Lesions	New Lesion Location	New Lesion Date Documented	Overall Response [4]
002	102	SSCC	Cycle 2	2013-07-15	SD	NA	No			SD
			Cycle 4	2013-08-19	PR	NA	No			PR
			Cycle 6	2013-10-01	SD	NA	Yes	PULMONARY THREE NEW LESIONS - SEE ENTRIES TARGET LESION CYCLE 6	2013-10-01	PD
003	101	AEZS-108	Cycle 2	2013-07-09	PD	PD	Yes	LUNG (THORAX) INTRAPULMONARY, 20MM	2013-06-09	PD

[1] Visit: EOT=End of Therapy
[2] Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
[3] Non-Target Lesion Response: CR=Complete response, NA=Not Applicable, NE=Not Evaluated/Not All Lesions Evaluated, Non-CR/PD=Non-CR/Non-PD, PD=Progressive Disease.
[4] Overall Response: CR=Complete response, NE=Not Evaluated, PD=Progressive Disease, PR=Partial response, SD=Stable disease.
*Evaluation on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_RESP Date Produced: 26AUG2015

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	101	SSCC/ SSCC	S: Nervous system disorders P: Headache V: HEADACHE	2013-03-08	2013-03-08	Yes	1/2	2	Other, CHANGED ZOFRAN TO KYTRIL	Yes	1/1	No
		SSCC/ SSCC	S: Gastrointestinal disorders P: Diarrhoea V: DIARRHEA	2013-03-08	2013-03-09	Yes	1/2	2	Other, ADDITION OF ATROPINE TO PRE-MEDICATIONS PRIOR TO EACH DOSE OF VINORELBINE	Yes	3/1	No
		SSCC/ SSCC	S: Gastrointestinal disorders P: Stomatitis V: STOMATITIS	2013-03-10	2013-03-12	Yes	1/3	2	Other, ADDITION OF MUGARD TO CON MEDS	Yes	3/1	No
		SSCC/ SSCC	S: Gastrointestinal disorders P: Flatulence V: FLATULENCE	2013-03-29		Yes	2/1	1	None	No	1/3	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	101	SSCC/ SSCC	S: Vascular disorders P: Hot flush V: HOT FLASHES	2013-03-29		Yes	2/1	1	None	No	1/3	No
		SSCC/ SSCC	S: General disorders and administration site conditions P: Chest pain V: LEFT-SIDED CHEST PAIN	2013-04-19	2013-04-24	Yes	2/2	1	None	No	1/1	No
		SSCC/ AEZS-108	S: Injury, poisoning and procedural complications P: Infusion related reaction V: INFUSION REACTION	2013-04-24* 14:21	2014-04-24	Yes	1/1	2	Delay	Yes	3/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	101	SSCC/ AEZS-108	S: Skin and subcutaneous tissue disorders P: Rash V: PATCHY RASH ON BILATERAL FOREARMS	2013-05-16* 13:35	2013-05-16	Yes	1/1	1	Delay	Yes	3/1	No
		SSCC/ AEZS-108	S: Skin and subcutaneous tissue disorders P: Alopecia V: ALOPECIA	2013-06-05*		Yes	1/3	2	None	No	4/3	No
		SSCC/ AEZS-108	S: Blood and lymphatic system disorders P: Neutropenia V: NEUTROPENIA	2014-05-15* 10:19	2014-05-16	Yes	2/3	3	Delay	Yes	3/1	No
	102	AEZS-108/ AEZS-108	S: Gastrointestinal disorders P: Constipation V: CONSTIPATION	2013-04-05		Yes	2/3	1	None	Yes	1/6	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	102	AEZS-108/ AEZS-108	S: General disorders and administration site conditions P: Fatigue V: WORSENING OF (FATIGUE)	2013-04-05		Yes	2/3	3	None	No	2/6	No
		AEZS-108/ AEZS-108	S: Investigations P: White blood cell count decreased V: WHITE BLOOD CELL DECREASED	2013-04-05	2013-04-25	Yes	1/3	4	None	No	3/4	Yes
		AEZS-108/ AEZS-108	S: Investigations P: Platelet count decreased V: PLATELET COUNT DECREASED	2013-04-05 09:27	2013-04-12	Yes	2/3	3	None	No	3/4	No
		AEZS-108/ AEZS-108	S: Blood and lymphatic system disorders P: Anaemia V: ANEMIA	2013-04-05 09:27	2013-04-16	Yes	2/3	3	None	Yes	3/4	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	102	AEZS-108/ AEZS-108	S: Investigations P: White blood cell count decreased V: DECREASED WHITE BLOOD CELLS	2013-04-12	2013-04-19	Yes	1/3	3	None	No	3/1	No
		AEZS-108/ AEZS-108	S: Respiratory, thoracic and mediastinal disorders P: Pleural effusion V: WORSENING OF PLERAL EFFUSION	2013-04-16		Yes	1/3	2	Discon	No	2/3	No
	103	AEZS-108/ AEZS-108	S: Blood and lymphatic system disorders P: Leukopenia V: LEUKOPENIA	2013-04-23	2013-04-29	Yes	2/3	1	None	No	3/4	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	103	AEZS-108/ AEZS-108	S: Blood and lymphatic system disorders P: Leukopenia V: LEUKOPENIA	2013-04-30 12:50	2013-05-07	Yes	1/3	2	None	Yes	3/1	No
		AEZS-108/ AEZS-108	S: Blood and lymphatic system disorders P: Neutropenia V: NEUTROPENIA	2013-04-30 12:50	2013-05-07	Yes	1/3	4	None	Yes	3/1	No
		AEZS-108/ AEZS-108	S: Gastrointestinal disorders P: Nausea V: NUSEA	2013-05-07	2013-05-11	Yes	2/3	1	None	Yes	3/1	No
		AEZS-108/ AEZS-108	S: Skin and subcutaneous tissue disorders P: Alopecia V: ALOPECIA	2013-06-18		Yes	2/3	1	None	No	3/3	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	103	AEZS-108/ AEZS-108	S: General disorders and administration site conditions P: Fatigue V: FATIGUE	2013-06-18	2013-08-22	Yes	2/3	1	None	No	3/1	No
		AEZS-108/ AEZS-108	S: Eye disorders P: Eye allergy V: IRRITATED EYES (ALLERGIES)	2013-07-09		Yes	2/3	1	None	No	1/3	No
		AEZS-108/ AEZS-108	S: Infections and infestations P: Rhinitis V: RHINITIS	2013-07-09		Yes	2/3	1	None	No	1/2	No
		AEZS-108/ AEZS-108	S: Respiratory, thoracic and mediastinal disorders P: Cough V: COUGH	2013-10-29		Yes	2/3	1	None	No	1/3	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	104	SSCC/ SSCC	S: General disorders and administration site conditions P: Fatigue V: FATIGUE	2013-12-20	2013-12-22	Yes	1/3	1	None	No	2/1	No
		SSCC/ SSCC	S: Infections and infestations P: Folliculitis V: FOLLICULITIS (HEAD ARM CHEST)	2014-01-29	2014-02-27	Yes	1/3	1	None	Yes	1/1	No
		SSCC/ AEZS-108	S: Skin and subcutaneous tissue disorders P: Alopecia V: ALOPECIA	2014-02-25*		Yes	2/3	2	None	No	3/3	No
		SSCC/ AEZS-108	S: Respiratory, thoracic and mediastinal disorders P: Asthma V: ASTHMA ATTACK	2014-02-25*	2014-02-25	Yes	2/3	2	None	Yes	1/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	104	SSCC/ AEZS-108	S: General disorders and administration site conditions P: Fatigue V: FATIGUE	2014-03-18*		Yes	2/3	1	None	No	3/3	No
		SSCC/ AEZS-108	S: Gastrointestinal disorders P: Haemorrhoids V: HEMORRHOIDS	2014-03-18*	2014-03-25	Yes	1/3	1	None	Yes	1/1	No
002	101	AEZS-108/ AEZS-108	S: Nervous system disorders P: Polyneuropathy V: POLYNEUROPATY FEET	2013-02-21		Yes	2/3	2	None	No	4/3	No
		AEZS-108/ AEZS-108	S: Gastrointestinal disorders P: Diarrhoea V: DIARRHEA	2013-02-21	2013-08-22	Yes	2/1	2	None	Yes	3/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
002	101	AEZS-108/ AEZS-108	S: Skin and subcutaneous tissue disorders P: Rash V: RASH FOOT SKIN REACTION	2013-03-13		Yes	2/3	2	None	No	4/3	No
		AEZS-108/ AEZS-108	S: General disorders and administration site conditions P: Fatigue V: FATGUE	2013-05-22		Yes	2/2	2	None	Yes	3/3	No
		AEZS-108/ AEZS-108	S: Gastrointestinal disorders P: Nausea V: NAUSEA	2013-05-22	2013-08-22	Yes	2/3	2	None	Yes	4/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
002	101	AEZS-108/ AEZS-108	S: General disorders and administration site conditions P: General physical health deterioration V: REDUCED GENERAL CONDITION	2013-08-16	2013-08-22	Yes	2/1	2	None	Yes	3/1	Yes
		AEZS-108/ AEZS-108	S: Infections and infestations P: Herpes zoster V: HERPES ZOSTER REDUCED	2013-08-16	2013-08-22	Yes	1/3	3	None	No	3/1	Yes
	102	SSCC/ SSCC	S: Gastrointestinal disorders P: Nausea V: NAUSEA	2013-05-30		Yes	2/2	2	None	Yes	4/3	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
002	102	SSCC/ SSCC	S: General disorders and administration site conditions P: Fatigue V: FATIGUE	2013-05-30		Yes	2/3	2	None	No	3/3	No
		SSCC/ SSCC	S: Nervous system disorders P: Headache V: HEAD AND HEADACHE PAIN	2013-06-01	2013-06-01	Yes	1/2	2	None	Yes	2/1	No
		SSCC/ SSCC	S: Gastrointestinal disorders P: Vomiting V: VOMITING	2013-06-02	2013-06-02	Yes	1/1	2	None	No	4/1	No
		SSCC/ SSCC	S: Nervous system disorders P: Headache V: HEAD AND HEADACHE PAIN	2013-06-04	2013-06-04	Yes	1/2	2	None	Yes	2/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
002	102	SSCC/ SSCC	S: Skin and subcutaneous tissue disorders P: Rash V: RASH FOOT SKIN REACTION	2013-06-29	2013-07-07	Yes	1/3	2	None	No	4/1	No
		SSCC/ SSCC	S: Musculoskeletal and connective tissue disorders P: Pain in extremity V: PAIN FEET	2013-07-02	2013-07-04	Yes	2/3	2	None	Yes	3/1	No
		SSCC/ SSCC	S: Gastrointestinal disorders P: Stomatitis V: STOMATITIS	2013-08-25		Yes	1/3	2	None	No	3/3	No
		SSCC/ SSCC	S: Respiratory, thoracic and mediastinal disorders P: Dyspnoea V: DYSPNEA	2013-09-15	2013-10	Yes	1/3	2	None	No	1/1	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.1
Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
002	102	SSCC/ SSCC	S: Respiratory, thoracic and mediastinal disorders P: Dyspnoea V: DYSPNEA	2013-10-07	2013-10	Yes	1/3	3	None	No	1/5	No

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.7.2
Serious Adverse Events by Patient
Safety Population

Site Number	Patient Number	Treatment Group/ Treatment at Start Date	S: SOC P: PT V: Verbatim	Start Date/ Start Time	End Date	Treatment Emergent	Pattern [1]/ Duration [2]	CTCAE v4.0 Grade [3]	Action Taken	Change in Concom Trmt	Causality [4]/ Outcome [5]	SAE
001	102	AEZS-108/ AEZS-108	S: Investigations P: White blood cell count decreased V: WHITE BLOOD CELL DECREASED	2013-04-05	2013-04-25	Yes	1/3	4	None	No	3/4	Yes
002	101	AEZS-108/ AEZS-108	S: General disorders and administration site conditions P: General physical health deterioration V: REDUCED GENERAL CONDITION	2013-08-16	2013-08-22	Yes	2/1	2	None	Yes	3/1	Yes
		AEZS-108/ AEZS-108	S: Infections and infestations P: Herpes zoster V: HERPES ZOSTER REDUCED	2013-08-16	2013-08-22	Yes	1/3	3	None	No	3/1	Yes

[1] Pattern: 1=Once, 2=Intermittent, 3=After Each Administration.
[2] Duration: 1=Minutes, 2=Hours, 3= >12 Hours.
[3] CTCAE v4.0 Grade: 1=Grade 1 (Mild), 2=Grade 2 (Moderate), 3=Grade 3 (Severe), 4=Grade 4 (Life Threatening), 5=Grade 5 (Outcome Death).
[4] Causality: 1=Unrelated, 2=Unlikely, 3=Possible, 4=Likely.
[5] Outcome: 1=Recovered/Resolved, 2=Recovering/Resolving, 3=Not Recovered/Resolved, 4=Recovered/Resolved with Sequelae, 5=Fatal, 6=Unknown.
* Adverse event that started on or after the date that a patient crossed over to AEZS-108.
Note: Adverse Events were coded using MedDRA version 15.0. Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Basophils (%)	6	Baseline		2013-03-04	0.5		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	0.3		
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	0.6		
				6	Cycle 3	1	2013-04-24*	0.6		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	0.3		
				6	End of Therapy		2013-06-05*	0.5		
			Eosinophils (%)	6	Baseline		2013-03-04	7.9		HIGH
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	8.4	NCS	HIGH
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	1.0		
				6	Cycle 3	1	2013-04-24*	0.8		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	0.4		
				6	End of Therapy		2013-06-05*	0.5		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Erythrocytes (X10^12/L)	6	Baseline		2013-03-04	3.95		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	3.60		
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	3.67		
				6	Cycle 3	1	2013-04-24*	3.41	NCS	LOW
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	3.20	NCS	LOW
				6	End of Therapy		2013-06-05*	3.28	NCS	LOW
			Hematocrit (%)	6	Baseline		2013-03-04	38.4		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	34.4	NCS	LOW
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	35.3	NCS	LOW
				6	Cycle 3	1	2013-04-24*	32.7	NCS	LOW
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	31.8	NCS	LOW
				6	End of Therapy		2013-06-05*	32.4	NCS	LOW

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Hemoglobin (G/DL)	6	Baseline		2013-03-04	13.1		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	11.6	NCS	LOW
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	11.6	NCS	LOW
				6	Cycle 3	1	2013-04-24*	10.5	NCS	LOW
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	10.1	NCS	LOW
				6	End of Therapy		2013-06-05*	10.7	NCS	LOW
			Lymphocytes (%)	6	Baseline		2013-03-04	26.0		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	39.2		
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	20.6		LOW
				6	Cycle 3	1	2013-04-24*	20.1		LOW
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	9.1	NCS	LOW
				6	End of Therapy		2013-06-05*	19.6		LOW
			Monocytes (%)	6	Baseline		2013-03-04	3.5	NCS	LOW

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Monocytes (%)		Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	1.0	NCS	LOW
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	3.8	NCS	LOW
				6	Cycle 3	1	2013-04-24*	5.6		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	5.9		
				6	End of Therapy		2013-06-05*	6.0		
			Neutrophils (%)	6	Baseline		2013-03-04	62.1		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	51.1		
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	74.0		HIGH
				6	Cycle 3	1	2013-04-24*	72.9		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	84.3	NCS	HIGH
				6	End of Therapy		2013-06-05*	73.4		HIGH
			Platelets (X10^9/L)	6	Baseline		2013-03-04	263		
					Cycle 1	1		ND		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Platelets (X10^9/L)	6	Cycle 1	8	2013-03-15	205		
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	234		
				6	Cycle 3	1	2013-04-24*	287		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	320		
				6	End of Therapy		2013-06-05*	377		
			WBC (X10^9/L)	6	Baseline		2013-03-04	5.1		
					Cycle 1	1		ND		
				6	Cycle 1	8	2013-03-15	2.6	NCS	LOW
					Cycle 1	15		ND		
				6	Cycle 2	1	2013-03-29	7.2		
				6	Cycle 3	1	2013-04-24*	4.3		
				6	Unscheduled		2013-05-15*	ND		
				6	Cycle 4	1	2013-05-16*	14.3	NCS	HIGH
				6	End of Therapy		2013-06-05*	5.3		
	102	AEZS-108	Basophils (%)	5	Baseline		2013-03-22	0.5		
				5	Cycle 1	1	2013-03-27	0.1		
				5	Cycle 1	8	2013-04-05	ND		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	Basophils (%)	5	Cycle 1	15	2013-04-12	ND		
				5	End of Therapy		2013-04-19	0.0		
				5	Unscheduled		2014-04-25	0.0		
			Eosinophils (%)	5	Baseline		2013-03-22	0.2		
				5	Cycle 1	1	2013-03-27	0.1		
				5	Cycle 1	8	2013-04-05	ND		
				5	Cycle 1	15	2013-04-12	1.0		
				5	End of Therapy		2013-04-19	0.2		
				5	Unscheduled		2014-04-25	0.3		
			Erythrocytes (X10^12/L)	5	Baseline		2013-03-22	3.45	NCS	LOW
				5	Cycle 1	1	2013-03-27	3.52	NCS	LOW
				5	Cycle 1	8	2013-04-05	2.47	NCS	LOW
				5	Cycle 1	15	2013-04-12	2.49	NCS	LOW
				5	End of Therapy		2013-04-19	2.96	NCS	LOW
				5	Unscheduled		2014-04-25	3.87		
			Hematocrit (%)	5	Baseline		2013-03-22	32.1	NCS	LOW
				5	Cycle 1	1	2013-03-27	32.7	NCS	LOW

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	Hematocrit (%)	5	Cycle 1	8	2013-04-05	22.3	NCS	LOW
				5	Cycle 1	15	2013-04-12	23.0	NCS	LOW
				5	End of Therapy		2013-04-19	26.3	NCS	LOW
				5	Unscheduled		2014-04-25	34.5	NCS	LOW
			Hemoglobin (G/DL)	5	Baseline		2013-03-22	10.4	NCS	LOW
				5	Cycle 1	1	2013-03-27	10.3	NCS	LOW
				5	Cycle 1	8	2013-04-05	7.4	CS	LOW
				5	Cycle 1	15	2013-04-12	7.4	CS	LOW
				5	End of Therapy		2013-04-19	8.8	CS	LOW
				5	Unscheduled		2014-04-25	11.5	NCS	LOW
			Lymphocytes (%)	5	Baseline		2013-03-22	6.8	NCS	LOW
				5	Cycle 1	1	2013-03-27	6.2	NCS	LOW
				5	Cycle 1	8	2013-04-05	24.0	NCS	
				5	Cycle 1	15	2013-04-12	43.0	NCS	
				5	End of Therapy		2013-04-19	4.7	NCS	LOW
				5	Unscheduled		2014-04-25	8.1	NCS	LOW
			Monocytes (%)	5	Baseline		2013-03-22	4.8	NCS	LOW
				5	Cycle 1	1	2013-03-27	3.9	NCS	LOW

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	Monocytes (%)	5	Cycle 1	8	2013-04-05	4.0	NCS	LOW
				5	Cycle 1	15	2013-04-12	9.0	NCS	
				5	End of Therapy		2013-04-19	1.1		LOW
				5	Unscheduled		2014-04-25	7.1		
			Neutrophils (%)	5	Baseline		2013-03-22	87.7	NCS	HIGH
				5	Cycle 1	1	2013-03-27	89.7	NCS	HIGH
				5	Cycle 1	8	2013-04-05	64.0	NCS	
				5	Cycle 1	15	2013-04-12	40.0	NCS	
				5	End of Therapy		2013-04-19	94	NCS	HIGH
				5	Unscheduled		2014-04-25	84.5	NCS	HIGH
			Platelets (X10^9/L)	5	Baseline		2013-03-22	124	NCS	LOW
				5	Cycle 1	1	2013-03-27	163		
				5	Cycle 1	8	2013-04-05	27	NCS	LOW
				5	Cycle 1	15	2013-04-12	101	NCS	LOW
				5	End of Therapy		2013-04-19	25	CS	LOW
				5	Unscheduled		2014-04-25	58	NCS	LOW
			WBC (X10^9/L)	5	Baseline		2013-03-22	12.1	NCS	HIGH
				5	Cycle 1	1	2013-03-27	14.7	NCS	HIGH

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	WBC (X10^9/L)	5	Cycle 1	8	2013-04-05	0.6	CS	LOW
				5	Cycle 1	15	2013-04-12	1.0	CS	LOW
				5	End of Therapy		2013-04-19	7.5		
				5	Unscheduled		2014-04-25	2.4	NCS	LOW
	103	AEZS-108	Basophils (%)	5	Baseline		2013-04-04	0.8		
				5	Cycle 1	1	2013-04-16	0.6		
				5	Cycle 1	8	2013-04-23	0.6		
				5	Cycle 1	15	2013-04-30	1.0		
				5	Cycle 2	1	2013-05-07	0.8		
				5	Cycle 3	1	2013-05-28	0.6		
				5	Cycle 4	1	2013-06-18	0.9		
				5	Cycle 5	1	2013-07-09	0.6		
				5	Cycle 6	1	2013-07-26	0.5		
				5	Cycle 7	1	2013-08-22	0.8		
				5	Cycle 8	1	2013-09-12	0.9		
				5	End of Therapy		2013-10-03	0.7		
			Eosinophils (%)	5	Baseline		2013-04-04	1.5		
				5	Cycle 1	1	2013-04-16	1.9		
				5	Cycle 1	8	2013-04-23	2.0		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Eosinophils (%)	5	Cycle 1	15	2013-04-30	1.0		
				5	Cycle 2	1	2013-05-07	0.3		
				5	Cycle 3	1	2013-05-28	1.5		
				5	Cycle 4	1	2013-06-18	1.7		
				5	Cycle 5	1	2013-07-09	1.9		
				5	Cycle 6	1	2013-07-26	1.3		
				5	Cycle 7	1	2013-08-22	1.8		
				5	Cycle 8	1	2013-09-12	0.9		
				5	End of Therapy		2013-10-03	1.1		
			Erythrocytes (X10^12/L)	5	Baseline		2013-04-04	3.74		
				5	Cycle 1	1	2013-04-16	3.89		
				5	Cycle 1	8	2013-04-23	3.66		
				5	Cycle 1	15	2013-04-30	3.45	NCS	LOW
				5	Cycle 2	1	2013-05-07	3.49	NCS	LOW
				5	Cycle 3	1	2013-05-28	3.25	NCS	LOW
				5	Cycle 4	1	2013-06-18	3.60		
				5	Cycle 5	1	2013-07-09	3.50	NCS	LOW
				5	Cycle 6	1	2013-07-26	3.48	NCS	LOW
				5	Cycle 7	1	2013-08-22	3.59	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Erythrocytes (X10^12/L)	5	Cycle 8	1	2013-09-12	3.51	NCS	LOW
				5	End of Therapy		2013-10-03	3.53	NCS	LOW
			Hematocrit (%)	5	Baseline		2013-04-04	37.6		
				5	Cycle 1	1	2013-04-16	38.8		
				5	Cycle 1	8	2013-04-23	35.6	NCS	LOW
				5	Cycle 1	15	2013-04-30	34.1	NCS	LOW
				5	Cycle 2	1	2013-05-07	34.6	NCS	LOW
				5	Cycle 3	1	2013-05-28	31.7	NCS	LOW
				5	Cycle 4	1	2013-06-18	34.7	NCS	LOW
				5	Cycle 5	1	2013-07-09	34.3	NCS	LOW
				5	Cycle 6	1	2013-07-26	34.5	NCS	LOW
				5	Cycle 7	1	2013-08-22	35.9	NCS	LOW
				5	Cycle 8	1	2013-09-12	35.6	NCS	LOW
				5	End of Therapy		2013-10-03	34.7	NCS	LOW
			Hemoglobin (G/DL)	5	Baseline		2013-04-04	12.7		
				5	Cycle 1	1	2013-04-16	13.1		
				5	Cycle 1	8	2013-04-23	12.0		
				5	Cycle 1	15	2013-04-30	11.5	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Hemoglobin (G/DL)	5	Cycle 2	1	2013-05-07	11.7	NCS	LOW
				5	Cycle 3	1	2013-05-28	10.7	NCS	LOW
				5	Cycle 4	1	2013-06-18	11.7	NCS	LOW
				5	Cycle 5	1	2013-07-09	11.4	NCS	LOW
				5	Cycle 6	1	2013-07-26	11.4	NCS	LOW
				5	Cycle 7	1	2013-08-22	11.8	NCS	LOW
				5	Cycle 8	1	2013-09-12	11.2	NCS	LOW
				5	End of Therapy		2013-10-03	11.9	NCS	LOW
			Lymphocytes (%)	5	Baseline		2013-04-04	18.7		
				5	Cycle 1	1	2013-04-16	18.2		
				5	Cycle 1	8	2013-04-23	26.8		
				5	Cycle 1	15	2013-04-30	53.0	NCS	HIGH
				5	Cycle 2	1	2013-05-07	34.6		
				5	Cycle 3	1	2013-05-28	20.9		
				5	Cycle 4	1	2013-06-18	20.8		
				5	Cycle 5	1	2013-07-09	20.5		
				5	Cycle 6	1	2013-07-26	27.9		
				5	Cycle 7	1	2013-08-22	17.5		
				5	Cycle 8	1	2013-09-12	18.9		
				5	End of Therapy		2013-10-03	14.4	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Monocytes (%)	5	Baseline		2013-04-04	6.1		
				5	Cycle 1	1	2013-04-16	5.7		
				5	Cycle 1	8	2013-04-23	0.8	NCS	LOW
				5	Cycle 1	15	2013-04-30	29.0	NCS	HIGH
				5	Cycle 2	1	2013-05-07	10.4		
				5	Cycle 3	1	2013-05-28	8.7		
				5	Cycle 4	1	2013-06-18	9.3		
				5	Cycle 5	1	2013-07-09	8.4		
				5	Cycle 6	1	2013-07-26	8.6		
				5	Cycle 7	1	2013-08-22	9.5		
				5	Cycle 8	1	2013-09-12	9.8		
				5	End of Therapy		2013-10-03	8.2		
			Neutrophils (%)	5	Baseline		2013-04-04	72.9		
				5	Cycle 1	1	2013-04-16	73.6		
				5	Cycle 1	8	2013-04-23	69.8		
				5	Cycle 1	15	2013-04-30	16.0	NCS	LOW
				5	Cycle 2	1	2013-05-07	53.9		
				5	Cycle 3	1	2013-05-28	68.3		
				5	Cycle 4	1	2013-06-18	67.3		
				5	Cycle 5	1	2013-07-09	68.6		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Neutrophils (%)	5	Cycle 6	1	2013-07-26	61.7		
				5	Cycle 7	1	2013-08-22	70.4		
				5	Cycle 8	1	2013-09-12	69.5		
				5	End of Therapy		2013-10-03	75.6		
			Platelets (X10^9/L)	5	Baseline		2013-04-04	344		
				5	Cycle 1	1	2013-04-16	310		
				5	Cycle 1	8	2013-04-23	227		
				5	Cycle 1	15	2013-04-30	429		
				5	Cycle 2	1	2013-05-07	543	NCS	HIGH
				5	Cycle 3	1	2013-05-28	428		
				5	Cycle 4	1	2013-06-18	396		
				5	Cycle 5	1	2013-07-09	399		
				5	Cycle 6	1	2013-07-26	404		
				5	Cycle 7	1	2013-08-22	326		
				5	Cycle 8	1	2013-09-12	402		
				5	End of Therapy		2013-10-03	350		
			WBC (X10^9/L)	5	Baseline		2013-04-04	5.7		
				5	Cycle 1	1	2013-04-16	7.0		
				5	Cycle 1	8	2013-04-23	3.9	CS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	WBC (X10^9/L)	5	Cycle 1	15	2013-04-30	2.3	CS	LOW
				5	Cycle 2	1	2013-05-07	4.6		
				5	Cycle 3	1	2013-05-28	4.6		
				5	Cycle 4	1	2013-06-18	4.1	NCS	LOW
				5	Cycle 5	1	2013-07-09	4.2	NCS	LOW
				5	Cycle 6	1	2013-07-26	3.8	NCS	LOW
				5	Cycle 7	1	2013-08-22	4.9		
				5	Cycle 8	1	2013-09-12	4.6		
				5	End of Therapy		2013-10-03	4.4		
	104	SSCC	Basophils (%)	5	Baseline		2013-12-16	0.3		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	0.4		
				5	Cycle 3	1	2014-01-29	1.1		
				5	Cycle 4	1	2014-02-18*	1.0		
				5	Cycle 5	1	2014-03-11*	0.3		
				5	Cycle 6	1	2014-04-02*	0.3		
				5	Cycle 7	1	2014-04-23*	0.4		
				5	End of Therapy		2014-05-13*	ND		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Eosinophils (%)	5	Baseline		2013-12-16	2.4		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	0.9		
				5	Cycle 3	1	2014-01-29	3.3		
				5	Cycle 4	1	2014-02-18*	3.0		
				5	Cycle 5	1	2014-03-11*	0.7		
				5	Cycle 6	1	2014-04-02*	0.3		
				5	Cycle 7	1	2014-04-23*	1.1		
				5	End of Therapy		2014-05-13*	ND		
			Erythrocytes (X10^12/L)	5	Baseline		2013-12-16	4.16		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	4.34		
				5	Cycle 3	1	2014-01-29	3.81		
				5	Cycle 4	1	2014-02-18*	3.69		
				5	Cycle 5	1	2014-03-11*	3.81		
				5	Cycle 6	1	2014-04-02*	3.37	NCS	LOW
				5	Cycle 7	1	2014-04-23*	3.30	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Erythrocytes (X10^12/L)	5	End of Therapy		2014-05-13*	3.11	NCS	LOW
			Hematocrit (%)	5	Baseline		2013-12-16	37.5		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	38.8		
				5	Cycle 3	1	2014-01-29	34.1	NCS	LOW
				5	Cycle 4	1	2014-02-18*	32.4	NCS	LOW
				5	Cycle 5	1	2014-03-11*	33.9	NCS	LOW
				5	Cycle 6	1	2014-04-02*	30.7	NCS	LOW
				5	Cycle 7	1	2014-04-23*	30.2	NCS	LOW
				5	End of Therapy		2014-05-13*	29.3	NCS	LOW
			Hemoglobin (G/DL)	5	Baseline		2013-12-16	12.2		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	12.8		
				5	Cycle 3	1	2014-01-29	11.4	NCS	LOW
				5	Cycle 4	1	2014-02-18*	10.3	NCS	LOW
				5	Cycle 5	1	2014-03-11*	10.4	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Hemoglobin (G/DL)	5	Cycle 6	1	2014-04-02*	9.7	NCS	LOW
				5	Cycle 7	1	2014-04-23*	9.5	NCS	LOW
				5	End of Therapy		2014-05-13*	9.3	NCS	LOW
			Lymphocytes (%)	5	Baseline		2013-12-16	9.6	NCS	LOW
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	13.2	NCS	LOW
				5	Cycle 3	1	2014-01-29	35.2		
				5	Cycle 4	1	2014-02-18*	23.0		
				5	Cycle 5	1	2014-03-11*	12.3	NCS	LOW
				5	Cycle 6	1	2014-04-02*	10.5	NCS	LOW
				5	Cycle 7	1	2014-04-23*	12.9	NCS	LOW
				5	End of Therapy		2014-05-13*	7.0	NCS	LOW
			Monocytes (%)	5	Baseline		2013-12-16	5.2		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	4.9	NCS	LOW
				5	Cycle 3	1	2014-01-29	14.9	NCS	HIGH
				5	Cycle 4	1	2014-02-18*	18.0	NCS	HIGH

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Monocytes (%)	5	Cycle 5	1	2014-03-11*	7.8		
				5	Cycle 6	1	2014-04-02*	5.9	NCS	
				5	Cycle 7	1	2014-04-23*	10.2		
				5	End of Therapy		2014-05-13*	6.0		
			Neutrophils (%)	5	Baseline		2013-12-16	82.5	NCS	HIGH
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	80.6	NCS	HIGH
				5	Cycle 3	1	2014-01-29	45.5		
				5	Cycle 4	1	2014-02-18*	43.0		
				5	Cycle 5	1	2014-03-11*	78.9	NCS	HIGH
				5	Cycle 6	1	2014-04-02*	83.0	NCS	HIGH
				5	Cycle 7	1	2014-04-23*	75.4	NCS	
				5	End of Therapy		2014-05-13*	79.0	NCS	HIGH
			Platelets (X10^9/L)	5	Baseline		2013-12-16	351		
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	325		
				5	Cycle 3	1	2014-01-29	374		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Platelets (X10^9/L)	5	Cycle 4	1	2014-02-18*	477	NCS	HIGH
				5	Cycle 5	1	2014-03-11*	380		
				5	Cycle 6	1	2014-04-02*	512	NCS	HIGH
				5	Cycle 7	1	2014-04-23*	515	NCS	HIGH
				5	End of Therapy		2014-05-13*	410	NCS	
			WBC (X10^9/L)	5	Baseline		2013-12-16	11.6	NCS	HIGH
					Cycle 1	8		ND		
					Cycle 1	15		ND		
				5	Cycle 2	1	2014-01-08	12.2	NCS	HIGH
				5	Cycle 3	1	2014-01-29	4.9		
				5	Cycle 4	1	2014-02-18*	5.9		
				5	Cycle 5	1	2014-03-11*	9.3		
				5	Cycle 6	1	2014-04-02*	9.7		
				5	Cycle 7	1	2014-04-23*	9.5		
				5	End of Therapy		2014-05-13*	36.6	NCS	HIGH
002	101	AEZS-108	Basophils (%)	7	Baseline		2013-01-02	1		HIGH
				7	Unscheduled		2013-02-11	1		HIGH
				7	Cycle 1	1	2013-02-18	1		HIGH
				7	Cycle 1	8	2013-02-27	1		HIGH

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Basophils (%)	7	Cycle 1	15	2013-03-06	5	NCS	HIGH
				7	Cycle 2	1	2013-03-11	2	NCS	HIGH
				7	Cycle 3	1	2013-04-08	3	NCS	HIGH
				7	Cycle 4	1	2013-05-02	1		HIGH
				7	Cycle 5	1	2013-05-28	2		HIGH
				7	Cycle 6	1	2013-06-24	2	NCS	HIGH
				7	Cycle 7	1	2013-07-29	1		HIGH
				7	End of Therapy		2013-09-02	1		HIGH
			Eosinophils (%)	7	Baseline		2013-01-02	2		
				7	Unscheduled		2013-02-11	3		
				7	Cycle 1	1	2013-02-18	3		
				7	Cycle 1	8	2013-02-27	2		
				7	Cycle 1	15	2013-03-06	1	NCS	LOW
				7	Cycle 2	1	2013-03-11	0	NCS	LOW
				7	Cycle 3	1	2013-04-08	1	NCS	LOW
				7	Cycle 4	1	2013-05-02	0	NCS	LOW
				7	Cycle 5	1	2013-05-28	1	NCS	LOW
				7	Cycle 6	1	2013-06-24	2		
				7	Cycle 7	1	2013-07-29	4		
				7	End of Therapy		2013-09-02	3		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Erythrocytes (X10^12/L)	7	Baseline		2013-01-02	2.91	NCS	LOW
				7	Unscheduled		2013-02-11	2.81	NCS	LOW
				7	Cycle 1	1	2013-02-18	3.29	NCS	LOW
				7	Cycle 1	8	2013-02-27	3.51	NCS	LOW
				7	Cycle 1	15	2013-03-06	3.30	NCS	LOW
				7	Cycle 2	1	2013-03-11	3.61	NCS	LOW
				7	Cycle 3	1	2013-04-08	4		
				7	Cycle 4	1	2013-05-02	4.05		
				7	Cycle 5	1	2013-05-28	4		
				7	Cycle 6	1	2013-06-24	3.71	NCS	LOW
				7	Cycle 7	1	2013-07-29	3.54	NCS	LOW
				7	End of Therapy		2013-09-02	3.71		LOW
			Hematocrit (%)	7	Baseline		2013-01-02	30	NCS	LOW
				7	Unscheduled		2013-02-11	27	NCS	LOW
				7	Cycle 1	1	2013-02-18	31	NCS	LOW
				7	Cycle 1	8	2013-02-27	31	NCS	LOW
				7	Cycle 1	15	2013-03-06	28	NCS	LOW
				7	Cycle 2	1	2013-03-11	31	NCS	LOW
				7	Cycle 3	1	2013-04-08	34	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Hematocrit (%)	7	Cycle 4	1	2013-05-02	33	NCS	LOW
				7	Cycle 5	1	2013-05-28	33	NCS	LOW
				7	Cycle 6	1	2013-06-24	32	NCS	LOW
				7	Cycle 7	1	2013-07-29	31	NCS	LOW
				7	End of Therapy		2013-09-02	33	NCS	LOW
			Hemoglobin (G/DL)	7	Baseline		2013-01-02	10.8	NCS	LOW
				7	Unscheduled		2013-02-11	8.50	NCS	LOW
				7	Cycle 1	1	2013-02-18	9.5	NCS	LOW
				7	Cycle 1	8	2013-02-27	10.0	NCS	LOW
				7	Cycle 1	15	2013-03-06	9.40	NCS	LOW
				7	Cycle 2	1	2013-03-11	9.8	NCS	LOW
				7	Cycle 3	1	2013-04-08	10.5	NCS	LOW
				7	Cycle 4	1	2013-05-02	10.8	NCS	LOW
				7	Cycle 5	1	2013-05-28	10.7	NCS	LOW
				7	Cycle 6	1	2013-06-24	10.5	NCS	LOW
				7	Cycle 7	1	2013-07-29	10.3	NCS	LOW
				7	End of Therapy		2013-09-02	11.2	NCS	LOW
			Lymphocytes (%)	7	Baseline		2013-01-02	28		
				7	Unscheduled		2013-02-11	18	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Lymphocytes (%)	7	Cycle 1	1	2013-02-18	16	NCS	LOW
				7	Cycle 1	8	2013-02-27	19	NCS	LOW
				7	Cycle 1	15	2013-03-06	52	NCS	HIGH
				7	Cycle 2	1	2013-03-11	28		
				7	Cycle 3	1	2013-04-08	21	NCS	LOW
				7	Cycle 4	1	2013-05-02	24		LOW
				7	Cycle 5	1	2013-05-28	25		
				7	Cycle 6	1	2013-06-24	25		
				7	Cycle 7	1	2013-07-29	27		
				7	End of Therapy		2013-09-02	20	NCS	LOW
			Monocytes (%)	7	Baseline		2013-01-02	13		
				7	Unscheduled		2013-02-11	14		
				7	Cycle 1	1	2013-02-18	15	NCS	HIGH
				7	Cycle 1	8	2013-02-27	1		LOW
				7	Cycle 1	15	2013-03-06	38	NCS	HIGH
				7	Cycle 2	1	2013-03-11	30	NCS	HIGH
				7	Cycle 3	1	2013-04-08	18	NCS	HIGH
				7	Cycle 4	1	2013-05-02	21	NCS	HIGH
				7	Cycle 5	1	2013-05-28	18	NCS	HIGH
				7	Cycle 6	1	2013-06-24	22	NCS	HIGH

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Monocytes (%)	7	Cycle 7	1	2013-07-29	21	NCS	HIGH
				7	End of Therapy		2013-09-02	17	NCS	HIGH
			Neutrophils (%)	7	Baseline		2013-01-02	57		
				7	Unscheduled		2013-02-11	64		
				7	Cycle 1	1	2013-02-18	65		
				7	Cycle 1	8	2013-02-27	77		HIGH
				7	Cycle 1	15	2013-03-06	5	NCS	LOW
				7	Cycle 2	1	2013-03-11	40	NCS	LOW
				7	Cycle 3	1	2013-04-08	58		
				7	Cycle 4	1	2013-05-02	54		
				7	Cycle 5	1	2013-05-28	53		
				7	Cycle 6	1	2013-06-24	49		
				7	Cycle 7	1	2013-07-29	47		
				7	End of Therapy		2013-09-02	58		
			Platelets (X10^9/L)	7	Baseline		2013-01-02	230		
				7	Unscheduled		2013-02-11	480	NCS	HIGH
				7	Cycle 1	1	2013-02-18	387		
				7	Cycle 1	8	2013-02-27	184		
				7	Cycle 1	15	2013-03-06	426		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Platelets (X10^9/L)	7	Cycle 2	1	2013-03-11	545	NCS	HIGH
				7	Cycle 3	1	2013-04-08	306		
				7	Cycle 4	1	2013-05-02	314		
				7	Cycle 5	1	2013-05-28	262		
				7	Cycle 6	1	2013-06-24	264		
				7	Cycle 7	1	2013-07-29	240		
				7	End of Therapy		2013-09-02	253		
			WBC (X10^9/L)	7	Baseline		2013-01-02	4.40		
				7	Unscheduled		2013-02-11	5.65		
				7	Cycle 1	1	2013-02-18	4.51		
				7	Cycle 1	8	2013-02-27	3.19	NCS	LOW
				7	Cycle 1	15	2013-03-06	1.33	NCS	LOW
				7	Cycle 2	1	2013-03-11	3.20	NCS	LOW
				7	Cycle 3	1	2013-04-08	4.43		
				7	Cycle 4	1	2013-05-02	4.24		
				7	Cycle 5	1	2013-05-28	4.18		
				7	Cycle 6	1	2013-06-24	4.01		
				7	Cycle 7	1	2013-07-29	3.68	NCS	LOW
				7	End of Therapy		2013-09-02	3.68	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Basophils (%)	7	Baseline		2013-05-13	0		
				7	Cycle 1	1	2013-05-27	0		
				7	Cycle 1	8	2013-06-04	0		
				7	Cycle 1	15	2013-06-11	0		
				7	Cycle 2	1	2013-06-17	0		
				7	Cycle 3	1	2013-07-08	0		
				7	Cycle 4	1	2013-07-29	0		
				7	Cycle 5	1	2013-08-19	0		
				7	Cycle 6	1	2013-09-09	0		
				7	Cycle 7	1	2013-10-10	0		
			Eosinophils (%)	7	Baseline		2013-05-13	2		
				7	Cycle 1	1	2013-05-27	1	NCS	LOW
				7	Cycle 1	8	2013-06-04	1	NCS	LOW
				7	Cycle 1	15	2013-06-11	1	NCS	LOW
				7	Cycle 2	1	2013-06-17	1	NCS	LOW
				7	Cycle 3	1	2013-07-08	2		
				7	Cycle 4	1	2013-07-29	1	NCS	LOW
				7	Cycle 5	1	2013-08-19	1	NCS	LOW
				7	Cycle 6	1	2013-09-09	2		
				7	Cycle 7	1	2013-10-10	1	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Erythrocytes (X10^12/L)	7	Baseline		2013-05-13	4.58		
				7	Cycle 1	1	2013-05-27	4.67		
				7	Cycle 1	8	2013-06-04	4.75		
				7	Cycle 1	15	2013-06-11	4.40		
				7	Cycle 2	1	2013-06-17	4.26		
				7	Cycle 3	1	2013-07-08	3.93		
				7	Cycle 4	1	2013-07-29	3.5	NCS	LOW
				7	Cycle 5	1	2013-08-19	3.18	NCS	LOW
				7	Cycle 6	1	2013-09-09	3	NCS	LOW
				7	Cycle 7	1	2013-10-10	3.94		
			Hematocrit (%)	7	Baseline		2013-05-13	41		
				7	Cycle 1	1	2013-05-27	41		
				7	Cycle 1	8	2013-06-04	40		
				7	Cycle 1	15	2013-06-11	37		
				7	Cycle 2	1	2013-06-17	37		
				7	Cycle 3	1	2013-07-08	35	NCS	LOW
				7	Cycle 4	1	2013-07-29	33	NCS	LOW
				7	Cycle 5	1	2013-08-19	31	NCS	LOW
				7	Cycle 6	1	2013-09-09	31	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Hematocrit (%)	7	Cycle 7	1	2013-10-10	39		
			Hemoglobin (G/DL)	7	Baseline		2013-05-13	13.1		
				7	Cycle 1	1	2013-05-27	13.4		
				7	Cycle 1	8	2013-06-04	13.9		
				7	Cycle 1	15	2013-06-11	12.6		
				7	Cycle 2	1	2013-06-17	12.5		
				7	Cycle 3	1	2013-07-08	11.8	NCS	LOW
				7	Cycle 4	1	2013-07-29	11.0		LOW
				7	Cycle 5	1	2013-08-19	10.4	NCS	LOW
				7	Cycle 6	1	2013-09-09	10.5	NCS	LOW
				7	Cycle 7	1	2013-10-10	13.2		
			Lymphocytes (%)	7	Baseline		2013-05-13	19	NCS	LOW
				7	Cycle 1	1	2013-05-27	14	NCS	LOW
				7	Cycle 1	8	2013-06-04	20	NCS	LOW
				7	Cycle 1	15	2013-06-11	20	NCS	LOW
				7	Cycle 2	1	2013-06-17	25		
				7	Cycle 3	1	2013-07-08	20	NCS	LOW
				7	Cycle 4	1	2013-07-29	18	NCS	LOW
				7	Cycle 5	1	2013-08-19	21	NCS	LOW

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Lymphocytes (%)	7	Cycle 6	1	2013-09-09	18	NCS	LOW
				7	Cycle 7	1	2013-10-10	8	NCS	LOW
			Monocytes (%)	7	Baseline		2013-05-13	11		
				7	Cycle 1	1	2013-05-27	11		
				7	Cycle 1	8	2013-06-04	7		
				7	Cycle 1	15	2013-06-11	5		
				7	Cycle 2	1	2013-06-17	10		
				7	Cycle 3	1	2013-07-08	9		
				7	Cycle 4	1	2013-07-29	12		
				7	Cycle 5	1	2013-08-19	12		
				7	Cycle 6	1	2013-09-09	9		
				7	Cycle 7	1	2013-10-10	8	NCS	
			Neutrophils (%)	7	Baseline		2013-05-13	68		
				7	Cycle 1	1	2013-05-27	74		
				7	Cycle 1	8	2013-06-04	72		
				7	Cycle 1	15	2013-06-11	74		
				7	Cycle 2	1	2013-06-17	65		
				7	Cycle 3	1	2013-07-08	69		
				7	Cycle 4	1	2013-07-29	69		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Neutrophils (%)	7	Cycle 5	1	2013-08-19	67		
				7	Cycle 6	1	2013-09-09	72		
				7	Cycle 7	1	2013-10-10	83	NCS	HIGH
			Platelets (X10^9/L)	7	Baseline		2013-05-13	209		
				7	Cycle 1	1	2013-05-27	212		
				7	Cycle 1	8	2013-06-04	282		
				7	Cycle 1	15	2013-06-11	239		
				7	Cycle 2	1	2013-06-17	190		
				7	Cycle 3	1	2013-07-08	187		
				7	Cycle 4	1	2013-07-29	198		
				7	Cycle 5	1	2013-08-19	193		
				7	Cycle 6	1	2013-09-09	195		
				7	Cycle 7	1	2013-10-10	171		
			WBC (X10^9/L)	7	Baseline		2013-05-13	5.27		
				7	Cycle 1	1	2013-05-27	5.30		
				7	Cycle 1	8	2013-06-04	4.78		
				7	Cycle 1	15	2013-06-11	3.7	NCS	LOW
				7	Cycle 2	1	2013-06-17	4.11		
				7	Cycle 3	1	2013-07-08	5.13		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	WBC (X10^9/L)	7	Cycle 4	1	2013-07-29	4.69		
				7	Cycle 5	1	2013-08-19	4.03		
				7	Cycle 6	1	2013-09-09	4.67		
				7	Cycle 7	1	2013-10-10	9.09		
003	101	AEZS-108	Basophils (%)	4	Baseline		2013-05-23	0.0		
				4	Cycle 1	1	2013-05-30	<2		
				4	Cycle 1	8	2013-06-06	1		
				4	Cycle 1	15	2013-06-17	1		
				4	Cycle 2	1	2013-06-20	2.0		
				4	End of Therapy		2013-07-15	1		
			Eosinophils (%)	4	Baseline		2013-05-23	3.6		
				4	Cycle 1	1	2013-05-30	1		
				4	Cycle 1	8	2013-06-06	2		
				4	Cycle 1	15	2013-06-17	2		
				4	Cycle 2	1	2013-06-20	1.0		
				4	End of Therapy		2013-07-15	1		
			Erythrocytes (X10^12/L)	4	Baseline		2013-05-23	4.50		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	Erythrocytes (X10^12/L)	4	Cycle 1	1	2013-05-30	4.16		
				4	Cycle 1	8	2013-06-06	4.28		
				4	Cycle 1	15	2013-06-17	4.28		
				4	Cycle 2	1	2013-06-20	4.16		
				4	End of Therapy		2013-07-15	4.62		
			Hematocrit (%)	4	Baseline		2013-05-23	39.7		
				4	Cycle 1	1	2013-05-30	36.8		
				4	Cycle 1	8	2013-06-06	39.4		
				4	Cycle 1	15	2013-06-17	38.5		
				4	Cycle 2	1	2013-06-20	35.6		
				4	End of Therapy		2013-07-15	39.5		
			Hemoglobin (G/DL)	4	Baseline		2013-05-23	13.3		
				4	Cycle 1	1	2013-05-30	12.7		
				4	Cycle 1	8	2013-06-06	12.9		
				4	Cycle 1	15	2013-06-17	12.6		
				4	Cycle 2	1	2013-06-20	12.7		
				4	End of Therapy		2013-07-15	13.6		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	Lymphocytes (%)	4	Baseline		2013-05-23	12.8	NCS	LOW
				4	Cycle 1	1	2013-05-30	12	NCS	LOW
				4	Cycle 1	8	2013-06-06	22		
				4	Cycle 1	15	2013-06-17	33		
				4	Cycle 2	1	2013-06-20	33.0		
				4	End of Therapy		2013-07-15	20		
			Monocytes (%)	4	Baseline		2013-05-23	8.5		
				4	Cycle 1	1	2013-05-30	13		
				4	Cycle 1	8	2013-06-06	3		
				4	Cycle 1	15	2013-06-17	29		HIGH
				4	Cycle 2	1	2013-06-20	19.0		HIGH
				4	End of Therapy		2013-07-15	20		HIGH
			Neutrophils (%)	4	Baseline		2013-05-23	75.2		
				4	Cycle 1	1	2013-05-30	2		LOW
				4	Cycle 1	8	2013-06-06	73		HIGH
				4	Cycle 1	15	2013-06-17	34		LOW
				4	Cycle 2	1	2013-06-20	41.0		
				4	End of Therapy		2013-07-15	54		

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Listing 16.2.8.1.1
Hematology Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	Platelets (X10^9/L)	4	Baseline		2013-05-23	276		
				4	Cycle 1	1	2013-05-30	276		
				4	Cycle 1	8	2013-06-06	284		
				4	Cycle 1	15	2013-06-17	375		
				4	Cycle 2	1	2013-06-20	383	NCS	HIGH
				4	End of Therapy		2013-07-15	389		HIGH
			WBC (X10^9/L)	4	Baseline		2013-05-23	7.8		
				4	Cycle 1	1	2013-05-30	6.84		
				4	Cycle 1	8	2013-06-06	4.8		
				4	Cycle 1	15	2013-06-17	3.8	NCS	LOW
				4	Cycle 2	1	2013-06-20	3.4	NCS	LOW
				4	End of Therapy		2013-07-15	7.1		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Alk Phosphatase (IU/L)	6	Baseline		2013-03-04	59		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	72		
				6	Cycle 3	1	2013-04-24*	71		
				6	Cycle 4	1	2013-05-15*	57		
				6	End of Therapy		2013-06-05*	61		
			BUN (MG/DL)	6	Baseline		2013-03-04	13		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	10		
				6	Cycle 3	1	2013-04-24*	14		
				6	Cycle 4	1	2013-05-15*	8		
				6	End of Therapy		2013-06-05*	10		
			Calcium (MG/DL)	6	Baseline		2013-03-04	9.2		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	9.3		
				6	Cycle 3	1	2013-04-24*	9.4		
				6	Cycle 4	1	2013-05-15*	9.6		
				6	End of Therapy		2013-06-05*	9.6		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Creatinine (MG/DL)	6	Baseline		2013-03-04	0.60		LOW
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	0.50	NCS	LOW
				6	Cycle 3	1	2013-04-24*	0.50	NCS	LOW
				6	Cycle 4	1	2013-05-15*	0.5	NCS	LOW
				6	End of Therapy		2013-06-05*	0.40	NCS	LOW
			Gamma GT (IU/L)	6	Baseline		2013-03-04	ND		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	ND		
				6	Cycle 3	1	2013-04-24*	ND		
				6	Cycle 4	1	2013-05-15*	ND		
				6	End of Therapy		2013-06-05*	ND		
			Lactate Dehydrogenase (IU/L)	6	Baseline		2013-03-04	452		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	504		
				6	Cycle 3	1	2013-04-24*	ND		
				6	Cycle 4	1	2013-05-15*	407		
				6	End of Therapy		2013-06-05*	475		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Potassium (MMOL/L)	6	Baseline		2013-03-04	3.9		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	4.1		
				6	Cycle 3	1	2013-04-24*	4.2		
				6	Cycle 4	1	2013-05-15*	4.3		
				6	End of Therapy		2013-06-05*	4.0		
			SGOT/ASAT (IU/L)	6	Baseline		2013-03-04	23		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	20		
				6	Cycle 3	1	2013-04-24*	21		
				6	Cycle 4	1	2013-05-15*	24		
				6	End of Therapy		2013-06-05*	23		
			SGPT/ALAT (IU/L)	6	Baseline		2013-03-04	32		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	26		
				6	Cycle 3	1	2013-04-24*	15		
				6	Cycle 4	1	2013-05-15*	11		
				6	End of Therapy		2013-06-05*	15		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Sodium (MMOL/L)	6	Baseline		2013-03-04	141		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	139		
				6	Cycle 3	1	2013-04-24*	143		
				6	Cycle 4	1	2013-05-15*	143		
				6	End of Therapy		2013-06-05*	139		
			Total Bilirubin (MG/DL)	6	Baseline		2013-03-04	0.3		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	0.2		
				6	Cycle 3	1	2013-04-24*	0.2		
				6	Cycle 4	1	2013-05-15*	0.3		
				6	End of Therapy		2013-06-05*	0.3		
			Total Protein (G/DL)	6	Baseline		2013-03-04	7.3		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	6.6		
				6	Cycle 3	1	2013-04-24*	6.9		
				6	Cycle 4	1	2013-05-15*	6.7		
				6	End of Therapy		2013-06-05*	7.1		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Uric Acid (MG/DL)	6	Baseline		2013-03-04	ND		
					Cycle 1	1		ND		
				6	Cycle 2	1	2013-03-29	ND		
				6	Cycle 3	1	2013-04-24*	ND		
				6	Cycle 4	1	2013-05-15*	ND		
				6	End of Therapy		2013-06-05*	ND		
	102	AEZS-108	Alk Phosphatase (IU/L)	5	Baseline		2013-03-22	162	NCS	HIGH
				5	Cycle 1	1	2013-03-27	156	CS	HIGH
				5	End of Therapy		2013-04-21	88		
			BUN (MG/DL)	5	Baseline		2013-03-22	12		
				5	Cycle 1	1	2013-03-27	14		
				5	End of Therapy		2013-04-21	11		
			Calcium (MG/DL)	5	Baseline		2013-03-22	8.8		
				5	Cycle 1	1	2013-03-27	8.8		
				5	End of Therapy		2013-04-21	7.6	NCS	LOW
			Creatinine (MG/DL)	5	Baseline		2013-03-22	0.50	NCS	LOW
				5	Cycle 1	1	2013-03-27	0.5	NCS	LOW

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	Creatinine (MG/DL)	5	End of Therapy		2013-04-21	0.37	NCS	LOW
			Gamma GT (IU/L)	5	Baseline		2013-03-22	ND		
				5	Cycle 1	1	2013-03-27	ND		
				5	End of Therapy		2013-04-21	ND		
			Lactate Dehydrogenase (IU/L)	5	Baseline		2013-03-22	ND		
				5	Cycle 1	1	2013-03-27	ND		
				5	End of Therapy		2013-04-21	ND		
			Potassium (MMOL/L)	5	Baseline		2013-03-22	4.0		
				5	Cycle 1	1	2013-03-27	4.1		
				5	End of Therapy		2013-04-21	3.8	NCS	
			SGOT/ASAT (IU/L)	5	Baseline		2013-03-22	102	NCS	HIGH
				5	Cycle 1	1	2013-03-27	139	CS	HIGH
				5	End of Therapy		2013-04-21	117	NCS	HIGH
			SGPT/ALAT (IU/L)	5	Baseline		2013-03-22	65	NCS	HIGH
				5	Cycle 1	1	2013-03-27	64	CS	HIGH

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	102	AEZS-108	SGPT/ALAT (IU/L)	5	End of Therapy		2013-04-21	30		
			Sodium (MMOL/L)	5	Baseline		2013-03-22	141		
				5	Cycle 1	1	2013-03-27	140		
				5	End of Therapy		2013-04-21	136	NCS	LOW
			Total Bilirubin (MG/DL)	5	Baseline		2013-03-22	0.4		
				5	Cycle 1	1	2013-03-27	0.4		
				5	End of Therapy		2013-04-21	0.5		
			Total Protein (G/DL)	5	Baseline		2013-03-22	7.3		
				5	Cycle 1	1	2013-03-27	7.5		
				5	End of Therapy		2013-04-21	ND		
			Uric Acid (MG/DL)	5	Baseline		2013-03-22	ND		
				5	Cycle 1	1	2013-03-27	ND		
				5	End of Therapy		2013-04-21	ND		
	103	AEZS-108	Alk Phosphatase (IU/L)	5	Baseline		2013-04-04	114		
				5	Cycle 1	1	2013-04-16	124		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Alk Phosphatase (IU/L)	5	Cycle 2	1	2013-05-07	112		
				5	Cycle 3	1	2013-05-28	140	NCS	HIGH
				6	Cycle 4	1	2013-06-18	111		
				5	Cycle 5	1	2013-07-06	85		
				5	Cycle 6	1	2013-07-26	78		
				5	Cycle 7	1	2013-08-22	71		
				5	Cycle 8	1	2013-09-12	81		
				5	End of Therapy		2013-10-03	84		
			BUN (MG/DL)	5	Baseline		2013-04-04	19	NCS	HIGH
				5	Cycle 1	1	2013-04-16	21	NCS	HIGH
				5	Cycle 2	1	2013-05-07	20	NCS	HIGH
				5	Cycle 3	1	2013-05-28	16		
				6	Cycle 4	1	2013-06-18	18	NCS	HIGH
				5	Cycle 5	1	2013-07-06	17		
				5	Cycle 6	1	2013-07-26	17		
				5	Cycle 7	1	2013-08-22	23	NCS	HIGH
				5	Cycle 8	1	2013-09-12	18	NCS	HIGH
				5	End of Therapy		2013-10-03	20	NCS	HIGH
			Calcium (MG/DL)	5	Baseline		2013-04-04	10.6	NCS	HIGH

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Calcium (MG/DL)	5	Cycle 1	1	2013-04-16	9.7		
				5	Cycle 2	1	2013-05-07	9.7		
				5	Cycle 3	1	2013-05-28	9.5		
				6	Cycle 4	1	2013-06-18	9.1		
				5	Cycle 5	1	2013-07-06	9.5		
				5	Cycle 6	1	2013-07-26	9.4		
				5	Cycle 7	1	2013-08-22	10.0		
				5	Cycle 8	1	2013-09-12	10.3	NCS	HIGH
				5	End of Therapy		2013-10-03	9.9		
			Creatinine (MG/DL)	5	Baseline		2013-04-04	0.80		
				5	Cycle 1	1	2013-04-16	0.80		
				5	Cycle 2	1	2013-05-07	0.70		
				5	Cycle 3	1	2013-05-28	0.60		LOW
				6	Cycle 4	1	2013-06-18	0.70		
				5	Cycle 5	1	2013-07-06	0.70		
				5	Cycle 6	1	2013-07-26	0.80		
				5	Cycle 7	1	2013-08-22	0.90		
				5	Cycle 8	1	2013-09-12	0.60		LOW
				5	End of Therapy		2013-10-03	0.80		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Gamma GT (IU/L)	5	Baseline		2013-04-04	ND		
				5	Cycle 1	1	2013-04-16	ND		
				5	Cycle 2	1	2013-05-07	ND		
				5	Cycle 3	1	2013-05-28	ND		
				6	Cycle 4	1	2013-06-18	ND		
				5	Cycle 5	1	2013-07-06	ND		
				5	Cycle 6	1	2013-07-26	ND		
				5	Cycle 7	1	2013-08-22	ND		
				5	Cycle 8	1	2013-09-12	ND		
				5	End of Therapy		2013-10-03	ND		
			Lactate Dehydrogenase (IU/L)	5	Baseline		2013-04-04	ND		
				5	Cycle 1	1	2013-04-16	ND		
				5	Cycle 2	1	2013-05-07	ND		
				5	Cycle 3	1	2013-05-28	ND		
				6	Cycle 4	1	2013-06-18	ND		
				5	Cycle 5	1	2013-07-06	ND		
				5	Cycle 6	1	2013-07-26	ND		
				5	Cycle 7	1	2013-08-22	ND		
				5	Cycle 8	1	2013-09-12	ND		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Lactate Dehydrogenase (IU/L)	5	End of Therapy		2013-10-03	ND		
			Potassium (MMOL/L)	5	Baseline		2013-04-04	3.8		
				5	Cycle 1	1	2013-04-16	4.3		
				5	Cycle 2	1	2013-05-07	4.5		
				5	Cycle 3	1	2013-05-28	4.2		
				6	Cycle 4	1	2013-06-18	4.5		
				5	Cycle 5	1	2013-07-06	4.0		
				5	Cycle 6	1	2013-07-26	4.3		
				5	Cycle 7	1	2013-08-22	4.3		
				5	Cycle 8	1	2013-09-12	4.3		
				5	End of Therapy		2013-10-03	4.6		
			SGOT/ASAT (IU/L)	5	Baseline		2013-04-04	72	NCS	HIGH
				5	Cycle 1	1	2013-04-16	108	CS	HIGH
				5	Cycle 2	1	2013-05-07	44		
				5	Cycle 3	1	2013-05-28	30		
				6	Cycle 4	1	2013-06-18	37		
				5	Cycle 5	1	2013-07-06	41		
				5	Cycle 6	1	2013-07-26	33		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	SGOT/ASAT (IU/L)	5	Cycle 7	1	2013-08-22	49	NCS	HIGH
				5	Cycle 8	1	2013-09-12	34		
				5	End of Therapy		2013-10-03	44		
			SGPT/ALAT (IU/L)	5	Baseline		2013-04-04	198	NCS	HIGH
				5	Cycle 1	1	2013-04-16	277	CS	HIGH
				5	Cycle 2	1	2013-05-07	77	NCS	HIGH
				5	Cycle 3	1	2013-05-28	40		
				6	Cycle 4	1	2013-06-18	46		
				5	Cycle 5	1	2013-07-06	31		
				5	Cycle 6	1	2013-07-26	26		
				5	Cycle 7	1	2013-08-22	42		
				5	Cycle 8	1	2013-09-12	26		
				5	End of Therapy		2013-10-03	41		
			Sodium (MMOL/L)	5	Baseline		2013-04-04	143		
				5	Cycle 1	1	2013-04-16	141		
				5	Cycle 2	1	2013-05-07	143		
				5	Cycle 3	1	2013-05-28	143		
				6	Cycle 4	1	2013-06-18	144		
				5	Cycle 5	1	2013-07-06	144		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Sodium (MMOL/L)	5	Cycle 6	1	2013-07-26	143		
				5	Cycle 7	1	2013-08-22	143		
				5	Cycle 8	1	2013-09-12	141		
				5	End of Therapy		2013-10-03	144		
			Total Bilirubin (MG/DL)	5	Baseline		2013-04-04	0.6		
				5	Cycle 1	1	2013-04-16	0.7		
				5	Cycle 2	1	2013-05-07	0.3		
				5	Cycle 3	1	2013-05-28	0.6		
				6	Cycle 4	1	2013-06-18	0.7		
				5	Cycle 5	1	2013-07-06	0.5		
				5	Cycle 6	1	2013-07-26	0.4		
				5	Cycle 7	1	2013-08-22	0.5		
				5	Cycle 8	1	2013-09-12	0.4		
				5	End of Therapy		2013-10-03	0.4		
			Total Protein (G/DL)	5	Baseline		2013-04-04	7.7		
				5	Cycle 1	1	2013-04-16	7.9		
				5	Cycle 2	1	2013-05-07	0.3		LOW
				5	Cycle 3	1	2013-05-28	7.1		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Total Protein (G/DL)	6	Cycle 4	1	2013-06-18	7.1		
				5	Cycle 5	1	2013-07-06	7.3		
				5	Cycle 6	1	2013-07-26	7.7		
				5	Cycle 7	1	2013-08-22	7.7		
				5	Cycle 8	1	2013-09-12	7.2		
				5	End of Therapy		2013-10-03	7.5		
			Uric Acid (MG/DL)	5	Baseline		2013-04-04	ND		
				5	Cycle 1	1	2013-04-16	ND		
				5	Cycle 2	1	2013-05-07	ND		
				5	Cycle 3	1	2013-05-28	ND		
				6	Cycle 4	1	2013-06-18	ND		
				5	Cycle 5	1	2013-07-06	ND		
				5	Cycle 6	1	2013-07-26	ND		
				5	Cycle 7	1	2013-08-22	ND		
				5	Cycle 8	1	2013-09-12	ND		
				5	End of Therapy		2013-10-03	ND		
	104	SSCC	Alk Phosphatase (IU/L)	5	Baseline		2013-12-16	89		
				5	Cycle 2	1	2014-01-08	92		
				5	Cycle 3	1	2014-01-29	94		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Alk Phosphatase (IU/L)	5	Cycle 4	1	2014-02-18*	86		
				5	Cycle 5	1	2014-03-11*	79		
				5	Cycle 6	1	2014-04-02*	93		
				5	Cycle 7	1	2014-04-23*	89		
				5	End of Therapy		2014-05-13*	171	NCS	HIGH
			BUN (MG/DL)	5	Baseline		2013-12-16	11		
				5	Cycle 2	1	2014-01-08	16		
				5	Cycle 3	1	2014-01-29	12		
				5	Cycle 4	1	2014-02-18*	10		
				5	Cycle 5	1	2014-03-11*	13		
				5	Cycle 6	1	2014-04-02*	10		
				5	Cycle 7	1	2014-04-23*	10		
				5	End of Therapy		2014-05-13*	8		
			Calcium (MG/DL)	5	Baseline		2013-12-16	9.5		
				5	Cycle 2	1	2014-01-08	10.1		
				5	Cycle 3	1	2014-01-29	9.0		
				5	Cycle 4	1	2014-02-18*	9.0		
				5	Cycle 5	1	2014-03-11*	9.2		
				5	Cycle 6	1	2014-04-02*	9.1		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Calcium (MG/DL)	5	Cycle 7	1	2014-04-23*	9.3		
				5	End of Therapy		2014-05-13*	9.3		
			Creatinine (MG/DL)	5	Baseline		2013-12-16	0.90		
				5	Cycle 2	1	2014-01-08	0.90		
				5	Cycle 3	1	2014-01-29	0.90		
				5	Cycle 4	1	2014-02-18*	0.70		
				5	Cycle 5	1	2014-03-11*	0.80		
				5	Cycle 6	1	2014-04-02*	0.70		
				5	Cycle 7	1	2014-04-23*	0.70		
				5	End of Therapy		2014-05-13*	0.76		
			Gamma GT (IU/L)	5	Baseline		2013-12-16	ND		
				5	Cycle 2	1	2014-01-08	ND		
				5	Cycle 3	1	2014-01-29	ND		
				5	Cycle 4	1	2014-02-18*	ND		
				5	Cycle 5	1	2014-03-11*	ND		
				5	Cycle 6	1	2014-04-02*	ND		
				5	Cycle 7	1	2014-04-23*	ND		
				5	End of Therapy		2014-05-13*	ND		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Lactate Dehydrogenase (IU/L)	5	Baseline		2013-12-16	ND		
				5	Cycle 2	1	2014-01-08	ND		
				5	Cycle 3	1	2014-01-29	ND		
				5	Cycle 4	1	2014-02-18*	ND		
				5	Cycle 5	1	2014-03-11*	ND		
				5	Cycle 6	1	2014-04-02*	ND		
				5	Cycle 7	1	2014-04-23*	ND		
				5	End of Therapy		2014-05-13*	ND		
			Potassium (MMOL/L)	5	Baseline		2013-12-16	4.5		
				5	Cycle 2	1	2014-01-08	4.9		
				5	Cycle 3	1	2014-01-29	4.5		
				5	Cycle 4	1	2014-02-18*	4.5		
				5	Cycle 5	1	2014-03-11*	4.5		
				5	Cycle 6	1	2014-04-02*	4.5		
				5	Cycle 7	1	2014-04-23*	4.0		
				5	End of Therapy		2014-05-13*	4.0		
			SGOT/ASAT (IU/L)	5	Baseline		2013-12-16	44		
				5	Cycle 2	1	2014-01-08	51	NCS	HIGH

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	SGOT/ASAT (IU/L)	5	Cycle 3	1	2014-01-29	66	NCS	HIGH
				5	Cycle 4	1	2014-02-18*	59	NCS	HIGH
				5	Cycle 5	1	2014-03-11*	68	NCS	HIGH
				5	Cycle 6	1	2014-04-02*	51	NCS	HIGH
				5	Cycle 7	1	2014-04-23*	71	NCS	HIGH
				5	End of Therapy		2014-05-13*	71	NCS	HIGH
			SGPT/ALAT (IU/L)	5	Baseline		2013-12-16	27		
				5	Cycle 2	1	2014-01-08	37		
				5	Cycle 3	1	2014-01-29	63	NCS	HIGH
				5	Cycle 4	1	2014-02-18*	39		
				5	Cycle 5	1	2014-03-11*	29		
				5	Cycle 6	1	2014-04-02*	24		
				5	Cycle 7	1	2014-04-23*	22		
				5	End of Therapy		2014-05-13*	17		
			Sodium (MMOL/L)	5	Baseline		2013-12-16	140		
				5	Cycle 2	1	2014-01-08	140		
				5	Cycle 3	1	2014-01-29	140		
				5	Cycle 4	1	2014-02-18*	138		
				5	Cycle 5	1	2014-03-11*	138		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Sodium (MMOL/L)	5	Cycle 6	1	2014-04-02*	139		
				5	Cycle 7	1	2014-04-23*	142		
				5	End of Therapy		2014-05-13*	135	NCS	LOW
			Total Bilirubin (MG/DL)	5	Baseline		2013-12-16	0.3		
				5	Cycle 2	1	2014-01-08	0.4		
				5	Cycle 3	1	2014-01-29	0.3		
				5	Cycle 4	1	2014-02-18*	0.2		
				5	Cycle 5	1	2014-03-11*	0.2		
				5	Cycle 6	1	2014-04-02*	0.2		
				5	Cycle 7	1	2014-04-23*	0.2		
				5	End of Therapy		2014-05-13*	0.2		
			Total Protein (G/DL)	5	Baseline		2013-12-16	7.3		
				5	Cycle 2	1	2014-01-08	7.4		
				5	Cycle 3	1	2014-01-29	7.3		
				5	Cycle 4	1	2014-02-18*	6.7		
				5	Cycle 5	1	2014-03-11*	6.9		
				5	Cycle 6	1	2014-04-02*	6.0	NCS	LOW
				5	Cycle 7	1	2014-04-23*	6.6		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Total Protein (G/DL)	5	End of Therapy		2014-05-13*	6.8		
			Uric Acid (MG/DL)	5	Baseline		2013-12-16	ND		
				5	Cycle 2	1	2014-01-08	ND		
				5	Cycle 3	1	2014-01-29	ND		
				5	Cycle 4	1	2014-02-18*	ND		
				5	Cycle 5	1	2014-03-11*	ND		
				5	Cycle 6	1	2014-04-02*	ND		
				5	Cycle 7	1	2014-04-23*	ND		
				5	End of Therapy		2014-05-13*	ND		
002	101	AEZS-108	Alk Phosphatase (IU/L)	7	Baseline		2013-02-11	106	NCS	HIGH
				7	Cycle 1	1	2013-02-18	102		
				7	Cycle 2	1	2013-03-11	97.4		
				7	Cycle 3	1	2013-04-08	103		
				7	Cycle 4	1	2013-05-02	91.3		
				7	Cycle 5	1	2013-05-28	100		
				7	Cycle 6	1	2013-06-24	90.3		
				7	Cycle 7	1	2013-07-29	89.9		
				7	End of Therapy		2013-09-02	89.8		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	BUN (MG/DL)	7	Baseline		2013-02-11	30.7		
				7	Cycle 1	1	2013-02-18	33.3		
				7	Cycle 2	1	2013-03-11	ND	Invalid	
				7	Cycle 3	1	2013-04-08	32.7		
				7	Cycle 4	1	2013-05-02	42.5		
				7	Cycle 5	1	2013-05-28	43.4	NCS	HIGH
				7	Cycle 6	1	2013-06-24	34.4		
				7	Cycle 7	1	2013-07-29	41.9		
				7	End of Therapy		2013-09-02	33.8		
			Calcium (MG/DL)	7	Baseline		2013-02-11	2.18	NCS	LOW
				7	Cycle 1	1	2013-02-18	2.20		
				7	Cycle 2	1	2013-03-11	2.34		
				7	Cycle 3	1	2013-04-08	2.40		
				7	Cycle 4	1	2013-05-02	2.32		
				7	Cycle 5	1	2013-05-28	2.32		
				7	Cycle 6	1	2013-06-24	2.25		
				7	Cycle 7	1	2013-07-29	2.35		
				7	End of Therapy		2013-09-02	2.43		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Creatinine (MG/DL)	7	Baseline		2013-02-11	0.79		
				7	Cycle 1	1	2013-02-18	0.65		
				7	Cycle 2	1	2013-03-11	0.54		
				7	Cycle 3	1	2013-04-08	0.64		
				7	Cycle 4	1	2013-05-02	0.66		
				7	Cycle 5	1	2013-05-28	0.76		
				7	Cycle 6	1	2013-06-24	0.70		
				7	Cycle 7	1	2013-07-29	ND		
				7	End of Therapy		2013-09-02	0.73		
			Gamma GT (IU/L)	7	Baseline		2013-02-11	34.9		
				7	Cycle 1	1	2013-02-18	33.4		
				7	Cycle 2	1	2013-03-11	22.4		
				7	Cycle 3	1	2013-04-08	20.6		
				7	Cycle 4	1	2013-05-02	17.5		
				7	Cycle 5	1	2013-05-28	18.8		
				7	Cycle 6	1	2013-06-24	15.2		
				7	Cycle 7	1	2013-07-29	19.1		
				7	End of Therapy		2013-09-02	18.9		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Lactate Dehydrogenase (IU/L)	7	Baseline		2013-02-11	253	NCS	HIGH
				7	Cycle 1	1	2013-02-18	196		
				7	Cycle 2	1	2013-03-11	160		
				7	Cycle 3	1	2013-04-08	199		
				7	Cycle 4	1	2013-05-02	222		
				7	Cycle 5	1	2013-05-28	222		
				7	Cycle 6	1	2013-06-24	243		
				7	Cycle 7	1	2013-07-29	239		
				7	End of Therapy		2013-09-02	246		
			Potassium (MMOL/L)	7	Baseline		2013-02-11	4.38		
				7	Cycle 1	1	2013-02-18	4.61		
				7	Cycle 2	1	2013-03-11	3.68		
				7	Cycle 3	1	2013-04-08	4.36		
				7	Cycle 4	1	2013-05-02	4.13		
				7	Cycle 5	1	2013-05-28	3.79		
				7	Cycle 6	1	2013-06-24	4.40		
				7	Cycle 7	1	2013-07-29	3.75		
				7	End of Therapy		2013-09-02	4.53		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	SGOT/ASAT (IU/L)	7	Baseline		2013-02-11	31.8		
				7	Cycle 1	1	2013-02-18	31.8		
				7	Cycle 2	1	2013-03-11	17.1		
				7	Cycle 3	1	2013-04-08	21.6		
				7	Cycle 4	1	2013-05-02	31.6		
				7	Cycle 5	1	2013-05-28	33.3		
				7	Cycle 6	1	2013-06-24	37.5	NCS	HIGH
				7	Cycle 7	1	2013-07-29	53.6	NCS	HIGH
				7	End of Therapy		2013-09-02	53.9	NCS	HIGH
			SGPT/ALAT (IU/L)	7	Baseline		2013-02-11	24.7		
				7	Cycle 1	1	2013-02-18	15.0		
				7	Cycle 2	1	2013-03-11	11.0		
				7	Cycle 3	1	2013-04-08	14.4		
				7	Cycle 4	1	2013-05-02	16.5		
				7	Cycle 5	1	2013-05-28	13.8		
				7	Cycle 6	1	2013-06-24	16.4		
				7	Cycle 7	1	2013-07-29	20.1		
				7	End of Therapy		2013-09-02	24.2		
			Sodium (MMOL/L)	7	Baseline		2013-02-11	137		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Sodium (MMOL/L)	7	Cycle 1	1	2013-02-18	142		
				7	Cycle 2	1	2013-03-11	139		
				7	Cycle 3	1	2013-04-08	141		
				7	Cycle 4	1	2013-05-02	140		
				7	Cycle 5	1	2013-05-28	140		
				7	Cycle 6	1	2013-06-24	139		
				7	Cycle 7	1	2013-07-29	ND		
				7	End of Therapy		2013-09-02	135	NCS	LOW
			Total Bilirubin (MG/DL)	7	Baseline		2013-02-11	0.26		
				7	Cycle 1	1	2013-02-18	0.36		
				7	Cycle 2	1	2013-03-11	0.27		
				7	Cycle 3	1	2013-04-08	0.29		
				7	Cycle 4	1	2013-05-02	0.27		
				7	Cycle 5	1	2013-05-28	0.33		
				7	Cycle 6	1	2013-06-24	0.42		
				7	Cycle 7	1	2013-07-29	0.48	NCS	
				7	End of Therapy		2013-09-02	0.34		
			Total Protein (G/DL)	7	Baseline		2013-02-11	5.83	NCS	LOW

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	Total Protein (G/DL)	7	Cycle 1	1	2013-02-18	5.85	NCS	LOW
				7	Cycle 2	1	2013-03-11	6.31	NCS	LOW
				7	Cycle 3	1	2013-04-08	6.27	NCS	LOW
				7	Cycle 4	1	2013-05-02	5.99	NCS	LOW
				7	Cycle 5	1	2013-05-28	6.10	NCS	LOW
				7	Cycle 6	1	2013-06-24	5.99	NCS	LOW
				7	Cycle 7	1	2013-07-29	6.12	NCS	LOW
				7	End of Therapy		2013-09-02	6.33	NCS	LOW
			Uric Acid (MG/DL)	7	Baseline		2013-02-11	5.32		
				7	Cycle 1	1	2013-02-18	5.97		
				7	Cycle 2	1	2013-03-11	5.97		
				7	Cycle 3	1	2013-04-08	5.42		
				7	Cycle 4	1	2013-05-02	6.34	NCS	HIGH
				7	Cycle 5	1	2013-05-28	6.18	NCS	HIGH
				7	Cycle 6	1	2013-06-24	5.99		
				7	Cycle 7	1	2013-07-29	6.55	NCS	HIGH
				7	End of Therapy		2013-09-02	5.07		
	102	SSCC	Alk Phosphatase (IU/L)	7	Baseline		2013-05-13	71		
				7	Cycle 1	1	2013-05-27	79.6		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Alk Phosphatase (IU/L)	7	Cycle 2	1	2013-06-17	ND		
				7	Cycle 3	1	2013-07-08	71.6		
				7	Cycle 4	1	2013-07-29	62.8		
				7	Cycle 5	1	2013-08-19	67.8		
				7	Cycle 6	1	2013-09-09	85.2		
				7	Cycle 7	1	2013-10-10	99.1		
			BUN (MG/DL)	7	Baseline		2013-05-13	25.1		
				7	Cycle 1	1	2013-05-27	23.4		
				7	Cycle 2	1	2013-06-17	28.9		
				7	Cycle 3	1	2013-07-08	33.6		
				7	Cycle 4	1	2013-07-29	29.1		
				7	Cycle 5	1	2013-08-19	41.0		
				7	Cycle 6	1	2013-09-09	24.6		
				7	Cycle 7	1	2013-10-10	38.4		
			Calcium (MG/DL)	7	Baseline		2013-05-13	2.45		
				7	Cycle 1	1	2013-05-27	2.48		
				7	Cycle 2	1	2013-06-17	2.24		
				7	Cycle 3	1	2013-07-08	2.45		
				7	Cycle 4	1	2013-07-29	2.34		

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Program: L_LAB Date Produced: 26AUG2015

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Calcium (MG/DL)	7	Cycle 5	1	2013-08-19	2.39		
				7	Cycle 6	1	2013-09-09	2.33		
				7	Cycle 7	1	2013-10-10	2.31		
			Creatinine (MG/DL)	7	Baseline		2013-05-13	0.79		
				7	Cycle 1	1	2013-05-27	0.81		
				7	Cycle 2	1	2013-06-17	0.82		
				7	Cycle 3	1	2013-07-08	0.81		
				7	Cycle 4	1	2013-07-29	0.77		
				7	Cycle 5	1	2013-08-19	0.76		
				7	Cycle 6	1	2013-09-09	0.79		
				7	Cycle 7	1	2013-10-10	0.68		
			Gamma GT (IU/L)	7	Baseline		2013-05-13	12.8		
				7	Cycle 1	1	2013-05-27	12.6		
				7	Cycle 2	1	2013-06-17	14.5		
				7	Cycle 3	1	2013-07-08	14.0		
				7	Cycle 4	1	2013-07-29	15.5		
				7	Cycle 5	1	2013-08-19	15.5		
				7	Cycle 6	1	2013-09-09	14.4		
				7	Cycle 7	1	2013-10-10	14.4		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Lactate Dehydrogenase (IU/L)	7	Baseline		2013-05-13	365	NCS	HIGH
				7	Cycle 1	1	2013-05-27	417	NCS	HIGH
				7	Cycle 2	1	2013-06-17	247	NCS	HIGH
				7	Cycle 3	1	2013-07-08	204		
				7	Cycle 4	1	2013-07-29	236		
				7	Cycle 5	1	2013-08-19	302	NCS	HIGH
				7	Cycle 6	1	2013-09-09	383	NCS	HIGH
				7	Cycle 7	1	2013-10-10	358	NCS	HIGH
			Potassium (MMOL/L)	7	Baseline		2013-05-13	4.15		
				7	Cycle 1	1	2013-05-27	4.05		
				7	Cycle 2	1	2013-06-17	4.31		
				7	Cycle 3	1	2013-07-08	4.48		
				7	Cycle 4	1	2013-07-29	4.35		
				7	Cycle 5	1	2013-08-19	4.25		
				7	Cycle 6	1	2013-09-09	4.14		
				7	Cycle 7	1	2013-10-10	4.28		
			SGOT/ASAT (IU/L)	7	Baseline		2013-05-13	74	NCS	HIGH
				7	Cycle 1	1	2013-05-27	101	NCS	HIGH

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	SGOT/ASAT (IU/L)	7	Cycle 2	1	2013-06-17	35.8	NCS	HIGH
				7	Cycle 3	1	2013-07-08	37.6	NCS	HIGH
				7	Cycle 4	1	2013-07-29	58.0	NCS	HIGH
				7	Cycle 5	1	2013-08-19	48.5	NCS	HIGH
				7	Cycle 6	1	2013-09-09	42.4	NCS	HIGH
				7	Cycle 7	1	2013-10-10	48	NCS	HIGH
			SGPT/ALAT (IU/L)	7	Baseline		2013-05-13	19		
				7	Cycle 1	1	2013-05-27	17.1		
				7	Cycle 2	1	2013-06-17	24.1		
				7	Cycle 3	1	2013-07-08	34.3		
				7	Cycle 4	1	2013-07-29	59.7	NCS	HIGH
				7	Cycle 5	1	2013-08-19	48	NCS	HIGH
				7	Cycle 6	1	2013-09-09	27		
				7	Cycle 7	1	2013-10-10	15		
			Sodium (MMOL/L)	7	Baseline		2013-05-13	138		
				7	Cycle 1	1	2013-05-27	138		
				7	Cycle 2	1	2013-06-17	139		
				7	Cycle 3	1	2013-07-08	141		
				7	Cycle 4	1	2013-07-29	138		

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Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Sodium (MMOL/L)	7	Cycle 5	1	2013-08-19	138		
				7	Cycle 6	1	2013-09-09	137		
				7	Cycle 7	1	2013-10-10	137		
			Total Bilirubin (MG/DL)	7	Baseline		2013-05-13	0.30		
				7	Cycle 1	1	2013-05-27	0.58		
				7	Cycle 2	1	2013-06-17	0.54		
				7	Cycle 3	1	2013-07-08	0.53		
				7	Cycle 4	1	2013-07-29	0.93		
				7	Cycle 5	1	2013-08-19	0.71		
				7	Cycle 6	1	2013-09-09	0.60		
				7	Cycle 7	1	2013-10-10	0.91		
			Total Protein (G/DL)	7	Baseline		2013-05-13	6.84		
				7	Cycle 1	1	2013-05-27	6.81		
				7	Cycle 2	1	2013-06-17	6.58		
				7	Cycle 3	1	2013-07-08	6.53		
				7	Cycle 4	1	2013-07-29	6.53		
				7	Cycle 5	1	2013-08-19	6.46		
				7	Cycle 6	1	2013-09-09	6.64		

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Program: L_LAB Date Produced: 26AUG2015

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	Total Protein (G/DL)	7	Cycle 7	1	2013-10-10	6.66		
			Uric Acid (MG/DL)	7	Baseline		2013-05-13	7.20	NCS	HIGH
				7	Cycle 1	1	2013-05-27	7.10	NCS	HIGH
				7	Cycle 2	1	2013-06-17	6.18	NCS	HIGH
				7	Cycle 3	1	2013-07-08	6.68	NCS	HIGH
				7	Cycle 4	1	2013-07-29	6.46	NCS	HIGH
				7	Cycle 5	1	2013-08-19	6.39	NCS	HIGH
				7	Cycle 6	1	2013-09-09	6.54	NCS	HIGH
				7	Cycle 7	1	2013-10-10	4.65		
003	101	AEZS-108	Alk Phosphatase (IU/L)		Baseline			ND		
				4	Baseline		2013-05-23	59		
				4	Cycle 1	1	2013-05-30	59		
				4	Cycle 2	1	2013-06-20	50		
				4	End of Therapy		2013-07-15	49		
			BUN (MG/DL)		Baseline			ND		
				4	Baseline		2013-05-23	ND		
				4	Cycle 1	1	2013-05-30	9		
				4	Cycle 2	1	2013-06-20	6	NCS	LOW

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	BUN (MG/DL)	4	End of Therapy		2013-07-15	10		
			Calcium (MG/DL)		Baseline			ND		
				4	Baseline		2013-05-23	2.42		
				4	Cycle 1	1	2013-05-30	2.38		
				4	Cycle 2	1	2013-06-20	2.30		
				4	End of Therapy		2013-07-15	2.57		
			Creatinine (MG/DL)		Baseline			0.70		
				4	Baseline		2013-05-23	0.70		
				4	Cycle 1	1	2013-05-30	0.80		
				4	Cycle 2	1	2013-06-20	0.91		
				4	End of Therapy		2013-07-15	0.89		
			Gamma GT (IU/L)		Baseline			ND		
				4	Baseline		2013-05-23	21		
				4	Cycle 1	1	2013-05-30	18		
				4	Cycle 2	1	2013-06-20	16		
				4	End of Therapy		2013-07-15	18		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	Lactate Dehydrogenase (IU/L)		Baseline			ND		
				4	Baseline		2013-05-23	411	NCS	HIGH
				4	Cycle 1	1	2013-05-30	248	NCS	HIGH
				4	Cycle 2	1	2013-06-20	366	NCS	HIGH
				4	End of Therapy		2013-07-15	293		HIGH
			Potassium (MMOL/L)		Baseline			ND		
				4	Baseline		2013-05-23	4.4		
				4	Cycle 1	1	2013-05-30	3.6		
				4	Cycle 2	1	2013-06-20	4.0		
				4	End of Therapy		2013-07-15	4.5		
			SGOT/ASAT (IU/L)		Baseline			ND		
				4	Baseline		2013-05-23	22		
				4	Cycle 1	1	2013-05-30	19		
				4	Cycle 2	1	2013-06-20	34	NCS	HIGH
				4	End of Therapy		2013-07-15	23		
			SGPT/ALAT (IU/L)		Baseline			ND		
				4	Baseline		2013-05-23	22		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	SGPT/ALAT (IU/L)	4	Cycle 1	1	2013-05-30	22		
				4	Cycle 2	1	2013-06-20	23		
				4	End of Therapy		2013-07-15	17		
			Sodium (MMOL/L)		Baseline			ND		
				4	Baseline		2013-05-23	137		
				4	Cycle 1	1	2013-05-30	138		
				4	Cycle 2	1	2013-06-20	137		
				4	End of Therapy		2013-07-15	140		
			Total Bilirubin (MG/DL)		Baseline			ND		
				4	Baseline		2013-05-23	0.3		
				4	Cycle 1	1	2013-05-30	0.4		
				4	Cycle 2	1	2013-06-20	0.3		
				4	End of Therapy		2013-07-15	0.2		
			Total Protein (G/DL)		Baseline			ND		
				4	Baseline		2013-05-23	7.4		
				4	Cycle 1	1	2013-05-30	6.9		
				4	Cycle 2	1	2013-06-20	6.4	NCS	LOW

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.2
Chemistry Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
003	101	AEZS-108	Total Protein (G/DL)	4	End of Therapy		2013-07-15	7.3		
			Uric Acid (MG/DL)		Baseline			ND		
				4	Baseline		2013-05-23	ND		
				4	Cycle 1	1	2013-05-30	5.7		HIGH
				4	Cycle 2	1	2013-06-20	5.3		
				4	End of Therapy		2013-07-15	5.8		HIGH

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
001	101	SSCC	6	Baseline		2013-03-04	Normal		
				Cycle 1	1		ND		
				Cycle 2	1		ND		
			6	Cycle 3	1	2013-04-24*	Normal		
				Cycle 4	1		ND		
				End of Therapy			ND		
	102	AEZS-108	5	Baseline		2013-03-12	Abnormal		NCS
							Abnormal	SPECIFIC GRAVITY (UA), KETONES (UA), UROBILINOGEN (UA), AND SQUAM EPITHEL (UA)	
							Abnormal	Protein	
			5	Cycle 1	1	2013-03-27	Abnormal		NCS
							Abnormal	Erythrocytes	
							Abnormal	Leukocytes	

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
001	102	AEZS-108	5	Cycle 1	1	2013-03-27	Abnormal	CASTS AND CRYSTALS	
			5	End of Therapy		2013-04-16	Abnormal		NCS
							Abnormal	SPECIFIC GRAVITY, UA	
	103	AEZS-108	5	Baseline		2013-04-04	Abnormal		NCS
							Abnormal	Erythrocytes	
							Abnormal	Leukocytes	
							Abnormal	BLOOD,CAST,CRYSTALS,RBC'S, WBC'S	
			5	Cycle 1	1	2013-04-16	Abnormal		NCS
							Abnormal	BLOOD	
			1	Cycle 2	1	2013-05-07	Abnormal		NCS
							Abnormal	Erythrocytes	
							Abnormal	Leukocytes	
			5	Cycle 3	1	2013-05-28	Normal		
							Abnormal	BLOOD	

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
001	103	AEZS-108	5	Cycle 4	1	2013-06-18	Abnormal		NCS
							Abnormal	Erythrocytes	
							Abnormal	Leukocytes	
							Abnormal	BLOOD	
			5	Cycle 5	1	2013-07-09	Abnormal		NCS
							Abnormal	Leukocytes	
							Abnormal	BLOOD 150	
							Abnormal	Protein	
			5	Cycle 6	1	2013-07-26	Abnormal		NCS
							Abnormal	Erythrocytes	
							Abnormal	Leukocytes	
							Abnormal	CASTS, CRYSTALS, BACTERIA	
							Abnormal	Protein	
			5	Cycle 7	1	2013-08-22	Abnormal		NCS
							Abnormal	Leukocytes	
							Abnormal	BLOOD PRESENT OF 50	
							Abnormal	Protein	

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
001	103	AEZS-108	5	Cycle 8	1	2013-09-12	Abnormal		NCS
							Abnormal	BLOOD 50	
							Abnormal	Protein	
			5	End of Therapy		2013-10-03	Abnormal		NCS
							Abnormal	Leukocytes	
							Abnormal	BLOOD	
							Abnormal	Protein	
	104	SSCC	5	Baseline		2013-12-16	Normal		
				Cycle 2	1		ND		
				Cycle 3	1		ND		
				Cycle 4	1		ND		
				Cycle 5	1		ND		
				Cycle 6	1		ND		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
001	104	SSCC		Cycle 7	1		ND		
				End of Therapy			ND		
002	101	AEZS-108	7	Baseline		2013-02-18	Normal		
			7	Cycle 1	1	2013-02-18	Normal		
			7	Cycle 2	1	2013-03-11	Normal		
			7	Cycle 3	1	2013-04-08	Normal		
			7	Cycle 4	1	2013-04-29	Abnormal		NCS
							Abnormal	Leukocytes	
							Abnormal	NITRIT POS	
			7	Cycle 5	1	2013-05-29	Normal		
			7	Cycle 6	1	2013-06-17	Normal		
			7	Cycle 7	1	2013-07-23	Normal		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
002	101	AEZS-108	7	End of Therapy		2013-08-21	Normal		
	102	SSCC	7	Baseline		2013-05-27	Normal		
			7	Cycle 1	1	2013-05-27	Normal		
			7	Cycle 2	1	2013-06-17	Normal		
			7	Cycle 3	1	2013-07-08	Normal		
			7	Cycle 4	1	2013-07-29	Normal		
			7	Cycle 5	1	2013-08-19	Normal		
			7	Cycle 6	1	2013-09-09	Normal		
			7	Cycle 7	1	2013-10-10	Normal		
003	101	AEZS-108	4	Baseline		2013-05-23	Normal		
			4	Cycle 1	1	2013-05-30	Normal		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.3
Urinalysis Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Name [1]	Visit	Study Day	Collection Date	Result	Abnormalities	Relevance [2]
003	101	AEZS-108	4	Cycle 2	1	2013-06-20	Normal		
			4	End of Therapy		2013-07-15	Normal		
							Abnormal	Leukocytes	

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
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Listing 16.2.8.1.4
Hormone Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	101	SSCC	Estradiol (ng/l)	5	Baseline		2013-03-04	7.06		
				5	Cycle 3	1	2013-04-19	12.24		
				6	End of Therapy		2013-06-05*	9.19		
			FSH (IU/L)	5	Baseline		2013-03-04	32.9	NCS	
				5	Cycle 3	1	2013-04-19	87.9	NCS	
				6	End of Therapy		2013-06-05*	60.6	NCS	
			LH (IU/L)	5	Baseline		2013-03-04	6.6		
				5	Cycle 3	1	2013-04-19	41.8		
				6	End of Therapy		2013-06-05*	32.1		
	102	AEZS-108	Estradiol (ng/l)	5	Baseline		2013-03-15	80.38		
				5	End of Therapy		2013-04-24	<11.8	NCS	
			FSH (IU/L)	5	Baseline		2013-03-15	15.8		
				5	End of Therapy		2013-04-24	21.6		
			LH (IU/L)	5	Baseline		2013-03-15	20.5		
				5	End of Therapy		2013-04-24	3.5		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.4
Hormone Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	103	AEZS-108	Estradiol (ng/l)	1	Baseline		2013-04-04	11.30		
				5	Cycle 3	1	2013-06-18	5.00		
				5	Cycle 5	1	2013-07-09	5.00		
					Cycle 7	1		ND		
				5	End of Therapy		2013-10-03	5.00		
			FSH (IU/L)	1	Baseline		2013-04-04	83.5	NCS	HIGH
				5	Cycle 3	1	2013-06-18	66.3		
				5	Cycle 5	1	2013-07-09	62.0		
					Cycle 7	1		ND		
				5	End of Therapy		2013-10-03	56.4	NCS	
			LH (IU/L)	1	Baseline		2013-04-04	59.0		
				5	Cycle 3	1	2013-06-18	27.4		
				5	Cycle 5	1	2013-07-09	27.0		
					Cycle 7	1		ND		
				5	End of Therapy		2013-10-03	29.8		
	104	SSCC	Estradiol (ng/l)	5	Baseline		2013-12-16	5.00		
					Cycle 3	1		ND		
					Cycle 5	1		ND		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
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Listing 16.2.8.1.4
Hormone Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
001	104	SSCC	Estradiol (ng/l)	6	Cycle 7	1	2014-04-23*	5.00		
				5	End of Therapy		2014-05-13*	15	NCS	
			FSH (IU/L)	5	Baseline		2013-12-16	51.5	NCS	
					Cycle 3	1		ND		
					Cycle 5	1		ND		
				6	Cycle 7	1	2014-04-23*	1.7		
				5	End of Therapy		2014-05-13*	2.2	NCS	
			LH (IU/L)	5	Baseline		2013-12-16	7.6		
					Cycle 3	1		ND		
					Cycle 5	1		ND		
				6	Cycle 7	1	2014-04-23*	0.1		
				5	End of Therapy		2014-05-13*	0.2	NCS	
002	101	AEZS-108	Estradiol (ng/l)	7	Baseline		2013-02-11	18.0		
				7	Cycle 3	1	2013-04-08	10		
				7	Cycle 5	1	2013-05-28	10		
				7	Cycle 7	1	2013-07-23	10		
				7	End of Therapy		2013-09-02	10		

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[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
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Listing 16.2.8.1.4
Hormone Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	101	AEZS-108	FSH (IU/L)	7	Baseline		2013-02-11	44.9		
				7	Cycle 3	1	2013-04-08	33.3		
				7	Cycle 5	1	2013-05-28	33		
				7	Cycle 7	1	2013-07-23	ND		
				7	End of Therapy		2013-09-02	30.5		
			LH (IU/L)	7	Baseline		2013-02-11	27.2		
				7	Cycle 3	1	2013-04-08	9.98		LOW
				7	Cycle 5	1	2013-05-28	14		LOW
				7	Cycle 7	1	2013-07-23	16.5		LOW
				7	End of Therapy		2013-09-02	8.19		LOW
	102	SSCC	Estradiol (ng/l)	7	Baseline		2013-05-27	10.0		
				7	Cycle 3	1	2013-07-08	10		
				7	Cycle 5	1	2013-08-19	<10		
				7	Cycle 7	1	2013-10-10	11.0		
			FSH (IU/L)	7	Baseline		2013-05-27	55.5		
				7	Cycle 3	1	2013-07-08	59.4		
				7	Cycle 5	1	2013-08-19	66.9		
				7	Cycle 7	1	2013-10-10	50.0		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.1.4
Hormone Labs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Lab Test (Units)	Lab Name [1]	Visit	Study Day	Collection Date	Result	Relevance [2]	High/ Low Flag
002	102	SSCC	LH (IU/L)	7	Baseline		2013-05-27	25.2		
				7	Cycle 3	1	2013-07-08	23.5		
				7	Cycle 5	1	2013-08-19	25.3		
				7	Cycle 7	1	2013-10-10	24.2		
003	101	AEZS-108	Estradiol (ng/l)	4	Baseline		2013-05-23	581.2		HIGH
				4	End of Therapy		2013-07-15	<10		
			FSH (IU/L)	4	Baseline		2013-05-23	2.7		LOW
				4	End of Therapy		2013-07-15	45.6		
			LH (IU/L)	4	Baseline		2013-05-23	5.5		LOW
				4	End of Therapy		2013-07-15	16.2		

[1] Lab Name: 1=Jackson Memorial Hospital, 2=Lab Corp, 3=Quest Diagnostics, 4=University of Goettingen Obstetrics and Gynecology, 5=University of Miami Hospital and Clinics, 6=University of Miami Sylvester Cancer Center Deerfield Beech, 7=University of Regensburg Gynecology and Obstetrics.
[2] The relevance of the lab result is recorded if the result is outside the normal range.
* Collection on or after the date that a patient crossed over to AEZS-108.
Key: CS=Clinically Significant, Invalid=Invalid value, NCS=Not Clinically Significant, ND=Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_LAB Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	101	SSCC	Systolic Blood Pressure (mmHg)	Baseline	2013-02-14	121
				Cycle 1	2013-03-08	104
				Cycle 2	2013-03-29	104
				Cycle 3	2013-04-24*	101
				Cycle 4	2013-05-15*	103
				End of Therapy	2013-06-05*	114
			Diastolic Blood Pressure (mmHg)	Baseline	2013-02-14	73
				Cycle 1	2013-03-08	67
				Cycle 2	2013-03-29	65
				Cycle 3	2013-04-24*	62
				Cycle 4	2013-05-15*	67
				End of Therapy	2013-06-05*	65
			Pulse Rate (bpm)	Baseline	2013-02-14	64
				Cycle 1	2013-03-08	86
				Cycle 2	2013-03-29	88
				Cycle 3	2013-04-24*	93
				Cycle 4	2013-05-15*	82
				End of Therapy	2013-06-05*	86
			Weight (kg)	Baseline	2013-02-14	52.61
				Cycle 1	2013-03-08	52.16
				Cycle 2	2013-03-29	52.16
				Cycle 3	2013-04-24*	52.14
				Cycle 4	2013-05-15*	52.61
				End of Therapy	2013-06-05*	53.97

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_VS Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	101	SSCC	Height (cm)	Baseline	2013-02-14	170.8
				Cycle 1	2013-03-08	
				Cycle 2	2013-03-29	
				Cycle 3	2013-04-24*	170.8
				Cycle 4	2013-05-15*	170.8
				End of Therapy	2013-06-05*	
	102	AEZS-108	Systolic Blood Pressure (mmHg)	Baseline	2013-03-22	125
				Cycle 1	2013-03-27	129
				End of Therapy	2013-04-17	113
			Diastolic Blood Pressure (mmHg)	Baseline	2013-03-22	81
				Cycle 1	2013-03-27	80
				End of Therapy	2013-04-17	78
			Pulse Rate (bpm)	Baseline	2013-03-22	138
				Cycle 1	2013-03-27	128
				End of Therapy	2013-04-17	110
			Weight (kg)	Baseline	2013-03-22	56.2
				Cycle 1	2013-03-27	55.8
				End of Therapy	2013-04-17	54
			Height (cm)	Baseline	2013-03-22	160
				Cycle 1	2013-03-27	
				End of Therapy	2013-04-17	

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_VS

Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	103	AEZS-108	Systolic Blood Pressure (mmHg)	Baseline	2013-04-04	126
				Cycle 1	2013-04-16	122
				Cycle 2	2013-05-07	120
				Cycle 3	2013-05-28	133
				Cycle 4	2013-06-18	118
				Cycle 5	2013-07-09	121
				Cycle 6	2013-07-26	121
				Cycle 7	2013-08-22	111
				Cycle 8	2013-09-12	118
				End of Therapy	2013-10-03	108
			Diastolic Blood Pressure (mmHg)	Baseline	2013-04-04	85
				Cycle 1	2013-04-16	83
				Cycle 2	2013-05-07	83
				Cycle 3	2013-05-28	85
				Cycle 4	2013-06-18	81
				Cycle 5	2013-07-09	81
				Cycle 6	2013-07-26	85
				Cycle 7	2013-08-22	78
				Cycle 8	2013-09-12	83
				End of Therapy	2013-10-03	77
			Pulse Rate (bpm)	Baseline	2013-04-04	86
				Cycle 1	2013-04-16	88
				Cycle 2	2013-05-07	86
				Cycle 3	2013-05-28	85
				Cycle 4	2013-06-18	89

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	103	AEZS-108	Pulse Rate (bpm)	Cycle 5	2013-07-09	93
				Cycle 6	2013-07-26	110
				Cycle 7	2013-08-22	87
				Cycle 8	2013-09-12	95
				End of Therapy	2013-10-03	101
			Weight (kg)	Baseline	2013-04-04	69.5
				Cycle 1	2013-04-16	68.5
				Cycle 2	2013-05-07	70.3
				Cycle 3	2013-05-28	69.8
				Cycle 4	2013-06-18	68.4
				Cycle 5	2013-07-09	68.6
				Cycle 6	2013-07-26	66.679
				Cycle 7	2013-08-22	66.3
				Cycle 8	2013-09-12	66.8
				End of Therapy	2013-10-03	65.5
			Height (cm)	Baseline	2013-04-04	165.1
				Cycle 1	2013-04-16	163.8
				Cycle 2	2013-05-07	
				Cycle 3	2013-05-28	
				Cycle 4	2013-06-18	
				Cycle 5	2013-07-09	
				Cycle 6	2013-07-26	
				Cycle 7	2013-08-22	
				Cycle 8	2013-09-12	
				End of Therapy	2013-10-03	

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	104	SSCC	Systolic Blood Pressure (mmHg)	Baseline	2013-12-16	138
				Cycle 1	2013-12-19	122
				Cycle 2	2014-01-08	145
				Cycle 3	2014-01-29	131
				Cycle 4	2014-02-18*	143
				Cycle 5	2014-03-11*	129
				Cycle 6	2014-04-02*	122
				Cycle 7	2014-04-23*	108
				End of Therapy	2014-05-13*	144
			Diastolic Blood Pressure (mmHg)	Baseline	2013-12-16	87
				Cycle 1	2013-12-19	71
				Cycle 2	2014-01-08	94
				Cycle 3	2014-01-29	90
				Cycle 4	2014-02-18*	93
				Cycle 5	2014-03-11*	90
				Cycle 6	2014-04-02*	81
				Cycle 7	2014-04-23*	68
				End of Therapy	2014-05-13*	84
			Pulse Rate (bpm)	Baseline	2013-12-16	95
				Cycle 1	2013-12-19	80
				Cycle 2	2014-01-08	81
				Cycle 3	2014-01-29	80
				Cycle 4	2014-02-18*	96
				Cycle 5	2014-03-11*	98
				Cycle 6	2014-04-02*	88

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
001	104	SSCC	Pulse Rate (bpm)	Cycle 7	2014-04-23*	96
				End of Therapy	2014-05-13*	105
			Weight (kg)	Baseline	2013-12-16	90
				Cycle 1	2013-12-19	86.3
				Cycle 2	2014-01-08	89
				Cycle 3	2014-01-29	89.5
				Cycle 4	2014-02-18*	89.5
				Cycle 5	2014-03-11*	84.5
				Cycle 6	2014-04-02*	83
				Cycle 7	2014-04-23*	80.2
				End of Therapy	2014-05-13*	79.1
			Height (cm)	Baseline	2013-12-16	167
				Cycle 1	2013-12-19	
				Cycle 2	2014-01-08	
				Cycle 3	2014-01-29	
				Cycle 4	2014-02-18*	
				Cycle 5	2014-03-11*	
				Cycle 6	2014-04-02*	
				Cycle 7	2014-04-23*	
				End of Therapy	2014-05-13*	
002	101	AEZS-108	Systolic Blood Pressure (mmHg)	Baseline	2013-02-18	133
				Cycle 1	2013-02-20	121
				Cycle 2	2013-03-11	120
				Cycle 3	2013-04-08	138

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_VS

Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
002	101	AEZS-108	Systolic Blood Pressure (mmHg)	Cycle 4	2013-04-29	135
				Cycle 5	2013-05-29	141
				Cycle 6	2013-06-26	114
				Cycle 7	2013-07-31	121
				End of Therapy	2013-08-21	146
			Diastolic Blood Pressure (mmHg)	Baseline	2013-02-18	75
				Cycle 1	2013-02-20	68
				Cycle 2	2013-03-11	73
				Cycle 3	2013-04-08	83
				Cycle 4	2013-04-29	85
				Cycle 5	2013-05-29	68
				Cycle 6	2013-06-26	57
				Cycle 7	2013-07-31	66
				End of Therapy	2013-08-21	99
			Pulse Rate (bpm)	Baseline	2013-02-18	82
				Cycle 1	2013-02-20	68
				Cycle 2	2013-03-11	70
				Cycle 3	2013-04-08	75
				Cycle 4	2013-04-29	75
				Cycle 5	2013-05-29	86
				Cycle 6	2013-06-26	68
				Cycle 7	2013-07-31	66
				End of Therapy	2013-08-21	86
			Weight (kg)	Baseline	2013-02-18	77

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_VS Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
002	101	AEZS-108	Weight (kg)	Cycle 1	2013-02-20	77
				Cycle 2	2013-03-11	75.2
				Cycle 3	2013-04-08	75
				Cycle 4	2013-04-29	75
				Cycle 5	2013-05-29	74
				Cycle 6	2013-06-26	77.9
				Cycle 7	2013-07-31	76.4
				End of Therapy	2013-08-21	72
			Height (cm)	Baseline	2013-02-18	170
				Cycle 1	2013-02-20	170
				Cycle 2	2013-03-11	170
				Cycle 3	2013-04-08	170
				Cycle 4	2013-04-29	170
				Cycle 5	2013-05-29	170
				Cycle 6	2013-06-26	170
				Cycle 7	2013-07-31	170
				End of Therapy	2013-08-21	168
	102	SSCC	Systolic Blood Pressure (mmHg)	Baseline	2013-05-13	131
				Cycle 1	2013-05-27	123
				Cycle 2	2013-06-17	122
				Cycle 3	2013-07-08	131
				Cycle 4	2013-07-29	111
				Cycle 5	2013-08-19	119
				Cycle 6	2013-09-09	126
				Cycle 7	2013-10-10	123

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
002	102	SSCC	Diastolic Blood Pressure (mmHg)	Baseline	2013-05-13	89
				Cycle 1	2013-05-27	89
				Cycle 2	2013-06-17	80
				Cycle 3	2013-07-08	84
				Cycle 4	2013-07-29	85
				Cycle 5	2013-08-19	85
				Cycle 6	2013-09-09	84
				Cycle 7	2013-10-10	84
			Pulse Rate (bpm)	Baseline	2013-05-13	90
				Cycle 1	2013-05-27	93
				Cycle 2	2013-06-17	83
				Cycle 3	2013-07-08	90
				Cycle 4	2013-07-29	80
				Cycle 5	2013-08-19	81
				Cycle 6	2013-09-09	81
				Cycle 7	2013-10-10	103
			Weight (kg)	Baseline	2013-05-13	76
				Cycle 1	2013-05-27	75
				Cycle 2	2013-06-17	74.6
				Cycle 3	2013-07-08	76
				Cycle 4	2013-07-29	75
				Cycle 5	2013-08-19	75
				Cycle 6	2013-09-09	77
				Cycle 7	2013-10-10	75

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_VS

Date Produced: 26AUG2015

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
002	102	SSCC	Height (cm)	Baseline	2013-05-13	161
				Cycle 1	2013-05-27	161
				Cycle 2	2013-06-17	161
				Cycle 3	2013-07-08	161
				Cycle 4	2013-07-29	161
				Cycle 5	2013-08-19	161
				Cycle 6	2013-09-09	161
				Cycle 7	2013-10-10	161
003	101	AEZS-108	Systolic Blood Pressure (mmHg)	Baseline	2013-05-23	125
				Cycle 1	2013-05-30	130
				Cycle 2	2013-06-20	130
				End of Therapy	2013-07-15	125
			Diastolic Blood Pressure (mmHg)	Baseline	2013-05-23	80
				Cycle 1	2013-05-30	75
				Cycle 2	2013-06-20	70
				End of Therapy	2013-07-15	75
			Pulse Rate (bpm)	Baseline	2013-05-23	76
				Cycle 1	2013-05-30	80
				Cycle 2	2013-06-20	72
				End of Therapy	2013-07-15	60
			Weight (kg)	Baseline	2013-05-23	79.8
				Cycle 1	2013-05-30	79.8
				Cycle 2	2013-06-20	80

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.1
Vital Signs by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test	Visit	Measurement Date	Result
003	101	AEZS-108	Weight (kg)	End of Therapy	2013-07-15	81
			Height (cm)	Baseline	2013-05-23	162
				Cycle 1	2013-05-30	162
				Cycle 2	2013-06-20	162
				End of Therapy	2013-07-15	162

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	101	SSCC	Heart Rate (bpm)	Baseline	2013-03-04 14:38	67	No	
				Cycle 3	2013-04-19 12:09	61	Yes	No
				End of Therapy	2013-06-05* 14:08	92	No	
			PR Interval (msec)	Baseline	2013-03-04 14:38	130	No	
				Cycle 3	2013-04-19 12:09	134	Yes	No
				End of Therapy	2013-06-05* 14:08	130	No	
			QRS Interval (msec)	Baseline	2013-03-04 14:38	78	No	
				Cycle 3	2013-04-19 12:09	74	Yes	No
				End of Therapy	2013-06-05* 14:08	76	No	
			QT Interval (msec)	Baseline	2013-03-04 14:38	406	No	
				Cycle 3	2013-04-19 12:09	400	Yes	No
				End of Therapy	2013-06-05* 14:08	372	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	101	SSCC	QTc Interval Bazett's (msec)**	Baseline	2013-03-04 14:38	429	No	
				Cycle 3	2013-04-19 12:09	403.3	Yes	No
				End of Therapy	2013-06-05* 14:08	460	No	
			QTc Interval Fridericia's (msec)	Baseline	2013-03-04 14:38	421.19	No	
				Cycle 3	2013-04-19 12:09	402.2	Yes	No
				End of Therapy	2013-06-05* 14:08	428.57	No	
	102	AEZS-108	Heart Rate (bpm)	Baseline	2013-03-11 17:01	104	No	
				End of Therapy	2013-04-23 14:44	82	Yes	No
			PR Interval (msec)	Baseline	2013-03-11 17:01	122	No	
				End of Therapy	2013-04-23 14:44	124	Yes	No
			QRS Interval (msec)	Baseline	2013-03-11 17:01	80	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	102	AEZS-108	QRS Interval (msec)	End of Therapy	2013-04-23 14:44	84	Yes	No
			QT Interval (msec)	Baseline	2013-03-11 17:01	350	No	
				End of Therapy	2013-04-23 14:44	366	Yes	No
			QTc Interval Bazett's (msec)**	Baseline	2013-03-11 17:01	460	No	
				End of Therapy	2013-04-23 14:44	427	Yes	No
			QTc Interval Fridericia's (msec)	Baseline	2013-03-11 17:01	419.95	No	
				End of Therapy	2013-04-23 14:44	405.61	Yes	No
	103	AEZS-108	Heart Rate (bpm)	Baseline	2013-04-11 09:55	76	No	
				Cycle 3	2013-05-21 11:06	79	No	
				Cycle 5	2013-07-10 11:48	72	No	
				Cycle 7		ND		
				End of Therapy		ND		

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	103	AEZS-108	PR Interval (msec)	Baseline	2013-04-11 09:55	156	No	
				Cycle 3	2013-05-21 11:06	156	No	
				Cycle 5	2013-07-10 11:48	166	No	
				Cycle 7		ND		
				End of Therapy		ND		
			QRS Interval (msec)	Baseline	2013-04-11 09:55	70	No	
				Cycle 3	2013-05-21 11:06	82	No	
				Cycle 5	2013-07-10 11:48	64	No	
				Cycle 7		ND		
				End of Therapy		ND		
			QT Interval (msec)	Baseline	2013-04-11 09:55	384	No	
				Cycle 3	2013-05-21 11:06	384	No	
				Cycle 5	2013-07-10 11:48	396	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	103	AEZS-108	QT Interval (msec)	Cycle 7		ND		
				End of Therapy		ND		
			QTc Interval Bazett's (msec)**	Baseline	2013-04-11 09:55	432	No	
				Cycle 3	2013-05-21 11:06	440	No	
				Cycle 5	2013-07-10 11:48	433	No	
				Cycle 7		ND		
				End of Therapy		ND		
			QTc Interval Fridericia's (msec)	Baseline	2013-04-11 09:55	415.37	No	
				Cycle 3	2013-05-21 11:06	420.48	No	
				Cycle 5	2013-07-10 11:48	420.3	No	
				Cycle 7		ND		
				End of Therapy		ND		
	104	SSCC	Heart Rate (bpm)	Baseline	2013-12-17 14:44	78	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	104	SSCC	Heart Rate (bpm)	Cycle 3	2014-02-04 10:30	85	No	
				Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	84	Yes	No
				End of Therapy		ND		
			PR Interval (msec)	Baseline	2013-12-17 14:44	140	No	
				Cycle 3	2014-02-04 10:30	156	No	
				Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	136	Yes	No
				End of Therapy		ND		
			QRS Interval (msec)	Baseline	2013-12-17 14:44	80	No	
				Cycle 3	2014-02-04 10:30	78	No	
				Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	82	Yes	No

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	104	SSCC	QRS Interval (msec)	End of Therapy		ND		
			QT Interval (msec)	Baseline	2013-12-17 14:44	362	No	
				Cycle 3	2014-02-04 10:30	362	No	
				Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	378	Yes	No
				End of Therapy		ND		
			QTc Interval Bazett's (msec)**	Baseline	2013-12-17 14:44	412	No	
				Cycle 3	2014-02-04 10:30	430	No	
				Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	446	Yes	No
				End of Therapy		ND		
			QTc Interval Fridericia's (msec)	Baseline	2013-12-17 14:44	394.61	No	
				Cycle 3	2014-02-04 10:30	406.02	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
001	104	SSCC	QTc Interval Fridericia's (msec)	Cycle 5		ND		
				Cycle 7	2014-04-23* 12:30	422.07	Yes	No
				End of Therapy		ND		
002	101	AEZS-108	Heart Rate (bpm)	Baseline	2013-01-28 10:44	72	No	
				Cycle 3	2013-04-02 09:31	81	No	
				Cycle 5	2013-05-27 09:05	75	No	
				Cycle 7	2013-07-15 09:45	70	No	
				End of Therapy	2013-09-09 10:08	84	No	
			PR Interval (msec)	Baseline	2013-01-28 10:44	200	No	
				Cycle 3	2013-04-02 09:31	200	No	
				Cycle 5	2013-05-27 09:05	200	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
002	101	AEZS-108	PR Interval (msec)	Cycle 7	2013-07-15 09:45	240	No	
				End of Therapy	2013-09-09 10:08	200	No	
			QRS Interval (msec)	Baseline	2013-01-28 10:44	100	No	
				Cycle 3	2013-04-02 09:31	100	No	
				Cycle 5	2013-05-27 09:05	100	No	
				Cycle 7	2013-07-15 09:45	80	No	
				End of Therapy	2013-09-09 10:08	60	No	
			QT Interval (msec)	Baseline	2013-01-28 10:44	290	No	
				Cycle 3	2013-04-02 09:31	295	No	
				Cycle 5	2013-05-27 09:05	290	No	
				Cycle 7	2013-07-15 09:45	360	No	
				End of Therapy	2013-09-09 10:08	360	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.
Program: L_ECG

Date Produced: 26AUG2015

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
002	101	AEZS-108	QTc Interval Bazett's (msec)**	Baseline	2013-01-28 10:44	300	No	
				Cycle 3	2013-04-02 09:31	310	No	
				Cycle 5	2013-05-27 09:05	300	No	
				Cycle 7	2013-07-15 09:45	387	No	
				End of Therapy	2013-09-09 10:08	439	No	
			QTc Interval Fridericia's (msec)	Baseline	2013-01-28 10:44	296.63	No	
				Cycle 3	2013-04-02 09:31	304.92	No	
				Cycle 5	2013-05-27 09:05	296.63	No	
				Cycle 7	2013-07-15 09:45	377.78	No	
				End of Therapy	2013-09-09 10:08	410.91	No	
	102	SSCC	Heart Rate (bpm)	Baseline	2013-05-17 12:25	74	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
002	102	SSCC	Heart Rate (bpm)	Cycle 3	2013-07-08 12:06	70	No	
				Cycle 5	2013-08-19 08:45	58	No	
				Cycle 7	2013-09-30 11:07	61	No	
			PR Interval (msec)	Baseline	2013-05-17 12:25	158	No	
				Cycle 3	2013-07-08 12:06	175	No	
				Cycle 5	2013-08-19 08:45	180	No	
				Cycle 7	2013-09-30 11:07	157	No	
			QRS Interval (msec)	Baseline	2013-05-17 12:25	79	No	
				Cycle 3	2013-07-08 12:06	75	No	
				Cycle 5	2013-08-19 08:45	70	No	
				Cycle 7	2013-09-30 11:07	79	No	
			QT Interval (msec)	Baseline	2013-05-17 12:25	385	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
002	102	SSCC	QT Interval (msec)	Cycle 3	2013-07-08 12:06	375	No	
				Cycle 5	2013-08-19 08:45	420	No	
				Cycle 7	2013-09-30 11:07	401	No	
			QTc Interval Bazett's (msec)**	Baseline	2013-05-17 12:25	428	No	
				Cycle 3	2013-07-08 12:06	389	No	
				Cycle 5	2013-08-19 08:45	440	No	
				Cycle 7	2013-09-30 11:07	404	No	
			QTc Interval Fridericia's (msec)	Baseline	2013-05-17 12:25	413.16	No	
				Cycle 3	2013-07-08 12:06	384.28	No	
				Cycle 5	2013-08-19 08:45	433.23	No	
				Cycle 7	2013-09-30 11:07	403	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.2
ECG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Test (Units)	Visit	ECG Date/Time	Result	Any Abnormalities	Any Clinically Significant Abnormalities
003	101	AEZS-108	Heart Rate (bpm)	Baseline	2013-05-23 13:35	71	No	
				End of Therapy	2013-07-09 09:13	68	No	
			PR Interval (msec)	Baseline	2013-05-23 13:35	160	No	
				End of Therapy	2013-07-09 09:13	0	No	
			QRS Interval (msec)	Baseline	2013-05-23 13:35	86	No	
				End of Therapy	2013-07-09 09:13	86	No	
			QT Interval (msec)	Baseline	2013-05-23 13:35	382	No	
				End of Therapy	2013-07-09 09:13	410	No	
			QTc Interval Bazett's (msec)**	Baseline	2013-05-23 13:35	416	No	
				End of Therapy	2013-07-09 09:13	437	No	
			QTc Interval Fridericia's (msec)	Baseline	2013-05-23 13:35	404.34	No	
				End of Therapy	2013-07-09 09:13	427.81	No	

*Test measured on or after the date that a patient crossed over to AEZS-108.
**Reported QTc.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy; ND = Not Done.

Listing 16.2.8.2.3
ECG Abnormalities by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	ECG Date/Time	Description of Abnormality
001	101	SSCC	Cycle 3	2013-04-19 12:09	NONSPECIFIC ST ABNORMALITY
	102	AEZS-108	End of Therapy	2013-04-23 14:44	ST ELEVATION HAS REPLACED ST DEPRESSION IN LATERAL LEADS; T WAVE AMPLITUDE HAS INCREASED IN LATERAL LEADS.
	104	SSCC	Cycle 7	2014-04-23* 12:30	SINUS RHYTHM WITH PREMATURESUPRAVENTRICULAR COMPLEXES

*Test measured on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_ECGAB

Date Produced: 26AUG2015

Listing 16.2.8.2.4
Physical Exam by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Exam Performed	Exam Date	Body System Abnormality	Type of Abnormality	Change Since Baseline	Type of Change
001	101	SSCC	Baseline	Yes	2013-02-14				
			Cycle 1	Yes	2013-03-08			No	
			Cycle 2	Yes	2013-03-29			No	
			Cycle 3	Yes	2013-04-24*			No	
			Cycle 4	Yes	2013-05-15*	Musculoskeletal		Yes	STERNAL PAIN
			End of Therapy	Yes	2013-06-05*			No	
	102	AEZS-108	Baseline	Yes	2013-03-22	Respiratory	DYSPNEA (SHORTNESS OF BREATH)		
			Cycle 1	Yes	2013-03-27			No	
			End of Therapy	Yes	2013-04-17	Respiratory		Yes	RIGHT UPPER LOBE INFILTRATE,DYSNEA, AND HYPERVENTILATION
	103	AEZS-108	Baseline	Yes	2013-04-04				
			Cycle 1	Yes	2013-04-16	Neurological/Cns		Yes	LATERAL RETUS PALSY LEFT EYE
			Cycle 2	Yes	2013-05-07	Heent		Yes	ALOPECIA
			Cycle 3	Yes	2013-05-28			No	
			Cycle 4	Yes	2013-06-18			No	
			Cycle 5	Yes	2013-07-09			No	
			Cycle 6	Yes	2013-07-26			No	
			Cycle 7	Yes	2013-08-22			No	
			Cycle 8	Yes	2013-09-12			No	

*Physical exam performed on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_PE Date Produced: 26AUG2015

Listing 16.2.8.2.4
Physical Exam by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Exam Performed	Exam Date	Body System Abnormality	Type of Abnormality	Change Since Baseline	Type of Change
001	103	AEZS-108	End of Therapy	Yes	2013-10-03			No	
	104	SSCC	Baseline	Yes	2013-12-16	Breast	LARGE MASS IN PARASTERNALREGION 6 X 5 CM MODERATLEY TENDER TO PALPATION		
			Cycle 1	Yes	2013-12-16			No	
			Cycle 2	Yes	2014-01-08	Brest		Yes	LEFT PARASTERNAL REGION MASS 10 CM X 9.5 CM MODERATLEY TENDER TO PALPATION.
			Cycle 3	Yes	2014-01-29	Musculoskeletal		Yes	CHEST WALL SOF TISSUE MASS HAS INCREASED IN SIZE. PD AT THIS TIME POINT.
			Cycle 4	Yes	2014-02-18*	Respiratory		Yes	DECREASED BREATH SOUND IN THE RIGHT BASE HALFWAY UP
			Cycle 5	Yes	2014-03-11*	Respiratory		Yes	EXCERBATION OF HER ASTHMA - RESOLVED

*Physical exam performed on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_PE

Date Produced: 26AUG2015

Listing 16.2.8.2.4
Physical Exam by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Exam Performed	Exam Date	Body System Abnormality	Type of Abnormality	Change Since Baseline	Type of Change
001	104	SSCC	Cycle 6	Yes	2014-04-02*	Breast		Yes	LEFT PARASTERNAL MASS 9.75 X 10CM MEDERATLY TENDER TO PALPATION
			Cycle 7	Yes	2014-04-23*	Musculoskeletal		Yes	CHEST WALL MASS STRENUM INCREASED IN SIZE 10.5CM X 9.5CM
			End of Therapy	Yes	2014-05-13*	Musculoskeletal		Yes	CHEST WALL MASS STRENUM INCREASED IN SIZE TO 13CM X 10CM
002	101	AEZS-108	Baseline	Yes	2013-02-18				
			Cycle 1	Yes	2013-02-20			No	
			Cycle 2	Yes	2013-03-11			No	
			Cycle 3	Yes	2013-04-08			No	
			Cycle 4	Yes	2013-04-29			No	
			Cycle 5	Yes	2013-05-29			No	
			Cycle 6	Yes	2013-06-26			No	
			Cycle 7	Yes	2013-07-31			No	
			End of Therapy	Yes	2013-08-21	Dermatology		Yes	HERPES ZOSTER
	102	SSCC	Baseline	Yes	2013-05-22	Respiratory	CAUGHING		
			Cycle 1	Yes	2013-05-27			No	

*Physical exam performed on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.4
Physical Exam by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Exam Performed	Exam Date	Body System Abnormality	Type of Abnormality	Change Since Baseline	Type of Change
002	102	SSCC	Cycle 2	Yes	2013-06-17			No	
			Cycle 3	Yes	2013-07-08			No	
			Cycle 4	Yes	2013-07-29			No	
			Cycle 5	Yes	2013-08-19	Dermatology		Yes	REDNESS LEFT KNEE DUE TO BORRELIOSIS
			Cycle 6	Yes	2013-09-09			No	
			Cycle 7	Yes	2013-10-10			No	
003	101	AEZS-108	Baseline	Yes	2013-05-23				
			Cycle 1	Yes	2013-05-30			No	
			Cycle 2	Yes	2013-06-20			No	
			End of Therapy	Yes	2013-07-15			No	

*Physical exam performed on or after the date that a patient crossed over to AEZS-108.
Key: SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_PE

Date Produced: 26AUG2015

Listing 16.2.8.2.5
ECOG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Measurement Date	ECOG [1]
001	101	SSCC	Baseline	2013-02-14	0
			Cycle 1	2013-03-08	0
			Cycle 2	2013-03-29	1
			Cycle 3	2013-04-24*	0
			Cycle 4	2013-05-15*	1
			End of Therapy	2013-06-05*	0
	102	AEZS-108	Baseline	2013-03-22	2
			Cycle 1	2013-03-27	2
			End of Therapy	2013-04-17	2
	103	AEZS-108	Baseline	2013-04-04	0
			Cycle 1	2013-04-16	0
			Cycle 2	2013-05-07	0
			Cycle 3	2013-05-28	0
			Cycle 4	2013-06-18	0
			Cycle 5	2013-07-09	0
			Cycle 6	2013-07-26	0
			Cycle 7	2013-08-22	0
			Cycle 8	2013-09-12	0
			End of Therapy	2013-10-03	0
	104	SSCC	Baseline	2013-12-16	0
			Cycle 1	2013-12-19	0
			Cycle 2	2014-01-08	0
			Cycle 3	2014-01-29	0

[1] ECOG=Eastern Cooperative Oncology Group.
* ECOG measured on or after the date that a patient crossed over to AEZS-108.
Key: ND = Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.5
ECOG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Measurement Date	ECOG [1]
001	104	SSCC	Cycle 4	2014-02-18*	0
			Cycle 5	2014-03-11*	1
			Cycle 6	2014-04-02*	0
			Cycle 7	2014-04-23*	0
			End of Therapy	2014-05-13*	0
002	101	AEZS-108	Baseline	2013-02-18	0
			Cycle 1	2013-02-20	0
			Cycle 2	2013-03-11	0
			Cycle 3	2013-04-08	0
			Cycle 4	2013-04-29	0
			Cycle 5	2013-05-29	0
			Cycle 6	2013-06-26	0
			Cycle 7	2013-07-31	0
			End of Therapy	2013-08-21	1
	102	SSCC	Baseline	2013-05-13	0
			Cycle 1	2013-05-27	0
			Cycle 2	2013-06-17	0
			Cycle 3	2013-07-08	0
			Cycle 4	2013-07-29	0
			Cycle 5	2013-08-19	0
			Cycle 6	2013-09-09	0
			Cycle 7	2013-10-10	2
003	101	AEZS-108	Baseline	2013-05-23	1

[1] ECOG=Eastern Cooperative Oncology Group.
* ECOG measured on or after the date that a patient crossed over to AEZS-108.
Key: ND = Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.

Listing 16.2.8.2.5
ECOG by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Measurement Date	ECOG [1]
003	101	AEZS-108	Cycle 1	2013-05-30	1
			Cycle 2	2013-06-20	0
			End of Therapy	2013-07-15	0

[1] ECOG=Eastern Cooperative Oncology Group.
* ECOG measured on or after the date that a patient crossed over to AEZS-108.
Key: ND = Not Done, SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_ECOG

Date Produced: 26AUG2015

Listing 16.2.8.2.6
Cardiac Function by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Cardiac Function Measured	Measurement Date	Method	LVEF (%)
001	101	SSCC	Baseline	Yes	2013-03-04	MUGA Scan	64.6
			Cycle 3	Yes	2013-04-18	MUGA Scan	68
			End of Therapy	Yes	2013-06-03*	MUGA Scan	67
	102	AEZS-108	Baseline	Yes	2013-03-20	Echocardiogram	55
			End of Therapy	Yes	2013-04-25	Echocardiogram	55
	103	AEZS-108	Baseline	Yes	2013-04-11	Echocardiogram	55-60
			Cycle 3	Yes	2013-05-21	Echocardiogram	55-60
			Cycle 5	Yes	2013-07-10	Echocardiogram	55-60
			End of Therapy	Yes	2013-09-09	Echocardiogram	50-55
	104	SSCC	Baseline	Yes	2013-12-17	Echocardiogram	60-65
			Cycle 3	Yes	2014-02-04	Echocardiogram	60-65
			Cycle 5	No			
			Cycle 7	Yes	2014-04-16*	Echocardiogram	60-65
			End of Therapy	No			
002	101	AEZS-108	Baseline	Yes	2013-01-28	Echocardiogram	70
			Cycle 3	No			
			Cycle 5	Yes	2013-05-27	Echocardiogram	70
			Cycle 7	Yes	2013-07-15	Echocardiogram	70
			End of Therapy	Yes	2013-09-09	Echocardiogram	70
	102	SSCC	Baseline	Yes	2013-05-17	Echocardiogram	60
			Cycle 3	Yes	2013-07-08	Echocardiogram	64

*Cardiac function measured on or after the date that a patient crossed over to AEZS-108.
Key: LVEF=Left Ventricular Ejection Fraction, SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_CF Date Produced: 26AUG2015

Listing 16.2.8.2.6
Cardiac Function by Patient
Safety Population

Site Number	Patient Number	Treatment Group	Visit	Cardiac Function Measured	Measurement Date	Method	LVEF (%)
002	102	SSCC	Cycle 5	Yes	2013-08-19	Echocardiogram	62
			Cycle 7	Yes	2013-09-30	Echocardiogram	60
003	101	AEZS-108	Baseline	Yes	2013-05-23	Echocardiogram	55
			End of Therapy	Yes	2013-07-09	Echocardiogram	55

*Cardiac function measured on or after the date that a patient crossed over to AEZS-108.
Key: LVEF=Left Ventricular Ejection Fraction, SSCC = Standard Single Agent Cytotoxic Chemotherapy.
Program: L_CF Date Produced: 26AUG2015