CLINICAL STUDY PROTOCOL

Protocol Number: CA-ALT-801-01-11

Protocol Title: A Study of ALT-801 in Patients with Relapsed or Refractory Multiple Myeloma

Date of Protocol:
Version# 01 December 9, 2011

Sponsor Contact:

Altor BioScience CORPORATION

Hing C. Wong, Ph.D.
Altor Bioscience Corporation.
Miramar, Florida 33025
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Safety Data Fax: 954-443-8602

INVESTIGATOR SIGNATURE PAGE

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By my signature below, I hereby attest that I have read, and that I understand and will abide by all the conditions, instructions, and restrictions contained in the attached protocol.

Additionally, I will not initiate this study without approval of the appropriate Institutional Review Board (IRB), and I understand that any changes in the protocol must be approved in writing by the sponsor, the IRB, and, in certain cases the FDA, before they can be implemented, except where necessary to eliminate hazards to subjects.

_____ _____

Principal Investigator's Signature Date

_____

Principal Investigator's Name (Print)

Table of Contents

SYNOPSIS

Sponsor: Altor Bioscience Corporation

Protocol#: CA-ALT-801-01-11

Study Drug Name: Not applicable

Study Treatment

Active agents: ALT-801 (c264scTCR-IL2), recombinant humanized, soluble single-chain TCR-cytokine fusion protein.

Study Type: Interventional

Study Phase: Ib/II

Protocol Title: A Study of ALT-801 in Patients with Relapsed or Refractory Multiple Myeloma

Objectives: To confirm the safety and tolerability of a well-tolerated dose level of ALT-801 in patients with relapsed or refractory multiple myeloma.

To estimate the anti-tumor activity of ALT-801 by radiologic or pathologic disease response, progression free survival, and overall survival in treated patients.

To characterize the immunogenicity and pharmacokinetic profile of ALT-801 in treated patients.

To assess the relationship between tumor presentation of HLA-A*0201/p53 aa 264-272 complex and the safety, immune response and clinical benefit of study treatment.

Study Design: This is a Phase Ib/II, open-label, multi-center and competitive enrollment study of ALT-801 in patients who have relapsed or refractory multiple myeloma.

There are two phases in this study: a dose confirmation phase to confirm a well-tolerated dose (TD) in this patient population and a two-stage expansion phase using the confirmed TD. Each enrolled patient will receive up to two cycles of study treatment

The study will be conducted in conformity with Good Clinical Practice (GCP).

Treatments: All enrolled patients will receive up to two cycles of study treatment with a 13-day rest period between cycles. Each cycle consists of four doses of ALT-801 on Day #1, Day #3, Day #8, and Day #15 in the cycle. The rest period may be extended to include an additional week.

The schedule of study treatment is illustrated below:

Treatment Week	1		2	3	4	5		6	7
Treatment Day	1	3	8	15		29	31	36	43
Dose#	1	2	3	4	Rest	5	6	7	8
ALT-801	X	X	X	X		X	X	X	X

There are no restrictions on further therapies, such as chemotherapy, radiation therapy or surgery to be used after the protocol-specified therapy. Clearly, post-study further treatments could be of significant clinical benefit in selected patients, and these patients will be followed for outcome.

Enrolled patients will receive the study treatment at qualified cancer treatment centers with adequate diagnostic and treatment facilities to provide appropriate management of therapy and complications. ALT-801 will be administered by intravenous infusion into a central or peripheral vein under the supervision of a qualified physician experienced in the use of anti-cancer agents including aldesleukin (Proleukin®).

Dose Confirmation Phase:

In the dose-confirmation phase of the study, six patients will be enrolled at the dose level starting at 0.08 mg/kg, which is one of the well-tolerated dose levels in a Phase Ib/II study of ALT-801 in combination with cisplatin in patients with metastatic melanoma. Enrolled patients will be monitored during the study treatment period for any Dose Limiting Toxicity (DLT).

The tolerability of a dose level is defined as < 2 of 6 patients experiencing any DLT at this dose level. If the tolerability of ALT-801 at a dose level cannot be confirmed, an additional six patients will be enrolled to repeat the dose confirmation phase with a step-down dose level that is 0.02 mg/kg lower than the previous tested dose level until a dose level is confirmed as the Tolerated Dose (TD). Below are the dose levels of the study drug during the dose confirmation phase of the study.

Cohort	ALT-801 Dose (mg/kg)
-2	0.04
-1	0.06
1 (initial)	0.08

DLT is defined as any toxicity of grade 3 that does not resolve to Grade 1 or lower within 72 hours and any toxicity of Grade 4 occurring during the study treatment period with exceptions and details described in the study protocol. Patients experiencing a DLT should discontinue study treatment. Study treatment discontinuation due to adverse events experienced prior to study drug administration, disease progression or patient's decision to withdraw from study treatment without occurrence of any study treatment discontinuation event will not necessarily define a DLT event. Study treatment discontinuation events are defined in the protocol.

Expansion Phase

The two-stage expansion phase at the TD level will be conducted using a modified Simon two-stage design. Objective response (OR) (defined as complete response (CR) + partial response (PR)) will be evaluated and set thresholds of lack of efficacy (OR rate (ORR) = 20%) and an efficacy level of interest (ORR = 40%) will be selected.

Stopping Rule: Patient enrollment will be temporarily suspended based on occurrence of any the following, and the sponsor, the Data Safety Monitoring Board and principal investigators will meet to discuss how to proceed with future patient enrollment in the study:

- During the dose confirmation phase of the study, no dose level can be confirmed as the TD.
- If at any time during the expansion phase of the study, more than 33% of patients experience a possible, probable or definite drug related DLT.

Evaluations: Patients will be evaluated for clinical toxicities during the treatment. Patients' blood samples will be collected to assess the pharmacokinetic profile and immunogenicity of the study drug. The anti-tumor response will be evaluated at week 8 and week 12 from the start of study treatment. All patients who receive at least one dose of the study drug ALT-801 will be included in the anti-tumor response evaluation.

Population: Patients of 18 years of age with relapsed or refractory multiple myeloma. Patients also need to have adequate cardiac, pulmonary, liver and kidney functions and to have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2.

Sample Size: A total of up to 18 assessable patients will be accrued to the dose confirmation phase of the study (Phase Ib). Up to an additional 37 assessable patients will be enrolled at the expansion phase (Stage 1 and 2) of the study (Phase II). A total of approximately 43 assessable patients will be enrolled and complete the study in the event that the TD is 0.08 mg/kg. Assuming a 20% ineligible or non-assessable cases, a total of up to 52 patients may be accrued to the study.

Primary Endpoints:

For Phase Ib only: (1) Confirmation of a well-tolerated dose level of ALT-801.

For Phase Ib & II: (2) Safety profile of ALT-801.
(3) Disease response rate.

Secondary Endpoints:
(1) Duration of response.
(2) Progression free survival.
(3) Overall survival.
(4) Immunogenicity and pharmacokinetics profile of ALT-801.
(5) Relationship between tumor presentation of HLA-A*0201/p53 aa 264-272 complexes and the safety, immune response and clinical benefit of study treatment.

Pharmacokinetics & Biomarkers: Blood samples will be collected to assess typing for HLA-A2, immune cell levels and phenotype, pharmacokinetics and immunogenicity of the study drug ALT-801, and the serum levels of IFN-γ and TNF-α. Unstained slides from a bone marrow biopsy will be used to test HLA-A*0201/p53 aa 264-272 complex presentation. Blood samples for pharmacokinetic analysis of

ALT-801 will be taken on the first day of ALT-801 administration in the initial study treatment cycle. Venous blood will be obtained at Time 0 (before the start of infusion), at 30 minutes (15 minutes after completion of infusion), and 1, 3 and 6 hours from Time 0 for the assessment of ALT-801 serum concentration. Non-compartmental and compartmental analyses will be conducted. In addition, the same blood samples collected for PK analysis will be used to assess the serum levels of IFN-γ and TNF-α. Fresh blood samples for HLA-A2 typing, immune cell levels and phenotype testing will be collected before the start of first and fourth dose of study drug infusion in each treatment cycle. HLA-A2 typing will be performed only once. Bone marrow samples will be collected for future analysis of molecular markers associated with responses or resistance to ALT-801 in patients with relapsed or refractory multiple myeloma.

Monitoring Tests: Blood samples for standard chemistry, and CBC with differential will be obtained at screening, on each study drug infusion day, and at follow-up visits. Blood samples for immunogenicity testing, which include assays for anti-ALT-801 and IL-2 neutralizing antibodies, will be collected prior to dosing on the first ALT-801 infusion day and at Week 8 from the initial dose of study treatment. Blood and urine samples will be collected on each follow-up visit for response assessment.

Response Assessment: There are two response assessments for treated patients: initial assessment at week 8 and confirmatory assessment at week 12 from the start of study treatment. After completion of study treatment, patients who have received at least one dose of study drug will have the response assessments. Responses will be evaluated according to the new International Uniform Response Criteria for Multiple Myeloma proposed by the International Myeloma Working Group. Baseline evaluations should be performed up to 14 days before study treatment starts.

Progression & Survival Assessment: Progression-free survival, overall survival, and duration of response of all treated patients will be assessed at every three months during year 1 and then every 6 months during years 2 and 3 from the start of study treatment, or through the point designated as the end of the study follow up.

Adverse Events: All patients will be monitored and evaluated for clinical toxicities during the treatment period and queried at each follow-up visit for Adverse Events (AEs). Patients may volunteer information concerning AEs. All adverse events will be graded by using the NCI Common Terminology Criteria for Adverse Events version 4.0 (CTCAE v4.0), and logged in the patient Case Report Form. The study centers should report all Serious Adverse Events (SAEs) and all events that trigger patient's study treatment discontinuation to the sponsor via phone, fax or email (or a combination) no more than 24 hours after learning of the event. The sponsor will use the information to manage and coordinate the dose confirmation, cohort expansion and patient enrollment. The sponsor will then inform all of the participating clinical

sites of the current dose level and the number of patients to be enrolled at that level, or of any patient enrollment suspension via phone, fax or email within 24 hours of learning of the event. The study centers should report all other adverse events to the sponsor following the guidelines defined in the study protocol. All study drug related AEs that are both serious and unexpected will be reported to the FDA in an expedited manner in accordance with 21 CFR §312.32.

Statistical Plan: For each cohort, all AEs will be tabulated and examined and all safety, pharmacokinetic and tumor response data will be evaluated. For estimation of duration of response and progression free survival, the Kaplan-Meier method will be used. P-values of ≤ 0.05 (two-sided) will be considered to indicate statistical significance.

8. STUDY CALENDAR, CLINICAL PROCEDURES & TESTS

8.1 Study calendar

TESTS & PROCEDURES	SCREEN/ BASELINE[1]	TREATMENT CYCLE #1					TREATMENT CYCLE #2				1ST ASSESSMENT	2ND ASSESSMENT	FOLLOW-UPS						
Study Month		1					2					3	6	9	12	18	24	30	36
Study Week		1		2	3	4	5		6	7	8	12							
Day of Week		M	W	M	M		M	W	M	M									
Study Day		*1*	*3*	*8*	*15*	*16-28*	*29*	*31*	*36*	*43*									
Medical history	X																		
Serum pregnancy test[2]	X																		
Complete physical exam	X	X					X				X	X							
Vital signs, weight, Height[3]	X	X	X	X	X		X	X	X	X	X	X							
Concurrent medication	X	X	X	X	X		X	X	X	X	X	X							
Adverse event assessment[4]	X	X	X	X	X		X	X	X	X	X	X							
CBC with Differential	X	X	X	X	X		X	X	X	X	X	X							
Blood Chemistry	X	X	X	X	X		X	X	X	X	X	X							
EKG	X	X[5]					X												
Response evaluation[6]											X	X							
Serum quantitative immunoglobulins	X										X	X							
SPEP	X										X	X							
UPEP-random	X										X	X							
SIFE	X										X	X							
UIFE -random	X										X	X							
Serum FLC assay[6.1]	X										X	X							
Bone marrow plasma cell percentage[6.2]	X										X	X							
Bone marrow immunohistochemistry or immunofluorescence[6.3]											X	X							
Soft tissue plasmacytomas assessment[6.4]											X	X							
Disease & survival follow-up[7]													X	X	X	X	X	X	X
Immune cell levels & phenotype[8,12]		X[8]			X[8]		X[8]			X[8]									
HLA A2 Blood Typing[9] & p53 tumor typing		X																	
PK, IFNγ, TNFα[10,12]		X[10]																	
Immunogenicity tests[11, 12]		X[11]									X								
Study drug (ALT-801)		**a1**	**a2**	**a3**	**a4**		**a5**	**a6**	**a7**	**a8**									

[1]Screening/baseline evaluations are performed ≤ 14 days prior to start of therapy. If the patient's condition is deteriorating, laboratory evaluations should be repeated within 48 hours prior to initiation of study treatment infusion. [2]Pregnancy test is for women with childbearing potential only. [3]Vital signs (especially blood pressure), clinical status and laboratory tests should be reviewed before start of therapy. Vital signs will be evaluated every 2 hours after drug infusion and before discharge, and body weight before infusion on drug infusion day. [4]Patients who have an on-going study drug-related SAE upon study completion or at discontinuation of study will be contacted by the investigator or his/her designee every week until the event is resolved or determined to be irreversible. [5]If the screening EKG was performed within 14 days prior to start of study treatment, the EKG is not required [6]Disease response and progression assessment will be evaluated using the new International Uniform Response Criteria for Multiple Myeloma proposed by the International Myeloma Working Group;. [6.1]only when serum and urine M-protein are unmeasurable [6.2] only when serum and urine M-protein and serum FLC are unmeasurable and bone marrow plasma cell percentage > 30% at baseline; [6.3]only when sCR is to be determined; [6.4]only when present at baseline, and to confirm CR or PR by X-rays, MRI or CT scans. [7]Information about tumor assessment & other therapies received after completion of study treatment will be collected if available. [8]Fresh blood samples for HLA A2 blood typing, immune cell levels & phenotype testing will be collected before dosing. [9] Use the blood sample collected for immune cell levels & phenotype.[10]Collect blood samples at Time 0 (before drug infusion), at 30 min (15 min after completion of infusion, +/- 5 min), 1 hour (+/- 10 min), 3 hour (+/- 30 min), 6 hour (+/- 60 min) from Time 0. IFNγ and TNFα assays are performed using the same samples and at the same schedule as PK. [11]Use the sample collected before dosing for PK test. [12]Residual samples may be used by Sponsor for research studies of other biomarkers.

APPROVAL PAGE

PROTOCOL TITLE:	A Study of ALT-801 in Patients with Relapsed or Refractory Multiple Myeloma
INVESTIGATIONAL DRUG:	ALT-801; c264scTCR-IL2 Fusion Protein
CLINICAL PROTOCOL NUMBER:	CA-ALT-801-01-11
Version# 01	December 9, 2011
SPONSOR:	Altor Bioscience Corporation 2810 North Commerce Parkway Miramar, FL 33025-3958

Hing C. Wong, Ph.D.
Chief Clinical Officer

12-9-11
Date

Jeff Weber, M.D., Ph.D.
Consulting Medical Director

12-6-11
Date

Peter Rhode, Ph.D.
Vice President, Research and Development

Dec 9, 2011
Date

Bee Y. Huang, M.S.
Director, Clinical Development

Dec 9, 2011
Date

CLINICAL STUDY PROTOCOL

Protocol Number: CA-ALT-801-01-11

Protocol Title: A Study of ALT-801 in Patients with Relapsed or Refractory Multiple Myeloma

Date of Protocol:

Version# 01 December 9, 2011

Version# 02 January 9, 2012

Sponsor Contact:

Altor BioScience CORPORATION

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INVESTIGATOR SIGNATURE PAGE

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By my signature below, I hereby attest that I have read, and that I understand and will abide by all the conditions, instructions, and restrictions contained in the attached protocol.

Additionally, I will not initiate this study without approval of the appropriate Institutional Review Board (IRB), and I understand that any changes in the protocol must be approved in writing by the sponsor, the IRB, and, in certain cases the FDA, before they can be implemented, except where necessary to eliminate hazards to subjects.

_____ _____
Principal Investigator's Signature Date

_____
Principal Investigator's Name (Print)

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SYNOPSIS

Sponsor: Altor Bioscience Corporation

Protocol#: CA-ALT-801-01-11

Study Drug Name: Not applicable

Study Treatment

Active agents: ALT-801 (c264scTCR-IL2), recombinant humanized, soluble single-chain TCR-cytokine fusion protein.

Study Type: Interventional

Study Phase: Ib/II

Protocol Title: A Study of ALT-801 in Patients with Relapsed or Refractory Multiple Myeloma

Objectives: To evaluate the safety and tolerability and to determine the maximum tolerated dose level (MTD) of ALT-801 in patients with relapsed or refractory multiple myeloma.

To estimate the anti-tumor activity of ALT-801 by radiologic or pathologic disease response, progression free survival, and overall survival in treated patients.

To characterize the immunogenicity and pharmacokinetic profile of ALT-801 in treated patients.

To assess the relationship between tumor presentation of HLA-A*0201/p53 aa 264-272 complex and the safety, immune response and clinical benefit of study treatment.

Study Design: This is a Phase Ib/II, open-label, multi-center and competitive enrollment study of ALT-801 in patients who have relapsed or refractory multiple myeloma.

The study includes a dose escalation phase to determine the maximum tolerated dose level (MTD) using a (3+3) dose escalation design and a two-stage expansion phase at the MTD using a Simon two-stage design. There are four escalating dose levels of ALT-801. Each enrolled patient will receive up to two cycles of study treatment

The study will be conducted in conformity with Good Clinical Practice (GCP).

Treatments: All enrolled patients will receive up to two cycles of study treatment with a 13-day rest period between cycles. Each cycle consists of four doses of ALT-801 on Day #1, Day #3, Day #8, and Day #15 in the cycle. The rest period may be extended to include an additional week.

The schedule of study treatment is illustrated below:

Treatment Cycle	Cycle #1					Cycle #2			
Treatment Week	1		2	3	4	5		6	7
Treatment Day	1	3	8	15	Rest	29	31	36	43
Dose#	1	2	3	4		5	6	7	8
ALT-801	X	X	X	X		X	X	X	X

There are no restrictions on further therapies, such as chemotherapy, radiation therapy or surgery to be used after the protocol-specified therapy. Clearly, post-study further treatments could be of significant clinical benefit in selected patients, and these patients will be followed for outcome.

Enrolled patients will receive the study treatment at qualified cancer treatment centers with adequate diagnostic and treatment facilities to provide appropriate management of therapy and complications. ALT-801 will be administered by intravenous infusion into a central or peripheral vein under the supervision of a qualified physician experienced in the use of anti-cancer agents including aldesleukin (Proleukin®).

Dose Escalation Phase:

In this phase of the study, a minimum of 3 patients will be enrolled at each dose level. All patients will be monitored for Dose Limiting Toxicity (DLT) during the treatment period. There are four escalating dose levels of ALT-801 (0.04 mg/kg, 0.06 mg/kg and 0.08 mg/kg, and 0.10 mg/kg). If 0/3 patients have dose-limiting toxicity, the next cohort will be opened for enrollment. If one patient at a dose-level develops DLT, up to six patients will be enrolled at that dose level and each subsequent higher dose level. If 0 or 1 of 6 patients in a cohort of 6 patients experiences DLT, then the next cohort will be opened for enrollment. If 2 or more out of 3-6 patients in a dose escalation cohort experience DLT, that dose level will be designated as exceeding the maximum tolerated dose. If there are fewer than 6 enrolled patients in the dose level below this level, then additional patients (up to 6 total) will be enrolled at that dose level. When there is a dose level with 0 or 1 out of 6 patients with DLT, which is either the maximum planned dose level (level 4) or which is one level below a dose that was not tolerated, this dose level is defined as the maximum tolerated dose (MTD). If the MTD of ALT-801 cannot be reached during the dose escalation phase or more than one of six patients experience DLT at the initial dose (0.04 mg/kg), the sponsor, the Data Safety Monitoring Board and the principal investigators will meet to determine how to proceed with the study.

Below are the dose levels of the study drug during the dose escalation phase of the study.

Cohort	ALT-801 Dose (mg/kg)
1 (initial)	0.04
2	0.06
3	0.08
4	0.10

DLT is defined as any toxicity of grade 3 that does not resolve to Grade 1 or lower within 72 hours and any toxicity of Grade 4 occurring during the study treatment period with exceptions and details described in the study protocol. Patients experiencing a DLT should discontinue study treatment. Study treatment discontinuation due to adverse events experienced prior to study drug administration, disease progression or patient's decision to withdraw from study treatment without occurrence of any study treatment discontinuation event will not necessarily define a DLT event. Study treatment discontinuation events are defined in the protocol.

Expansion Phase

The two-stage expansion phase at the MTD level will be conducted using a Simon two-stage design. Objective response (OR) (defined as complete response (CR) + partial response (PR)) will be evaluated and set thresholds of lack of efficacy (OR rate (ORR) = 20%) and an efficacy level of interest (ORR = 40%) will be selected.

Stopping Rule:

Patient enrollment will be temporarily suspended based on occurrence of any the following, and the sponsor, the Data Safety Monitoring Board and principal investigators will meet to discuss how to proceed with future patient enrollment in the study:

- During the dose escalation phase of the study, no dose level can be designated as the MTD.
- If at any time during the expansion phase of the study, more than 33% of patients experience a possible, probable or definite drug related DLT.

Evaluations:

Patients will be evaluated for clinical toxicities during the treatment. Patients' blood samples will be collected to assess the pharmacokinetic profile and immunogenicity of the study drug. The anti-tumor response will be evaluated at week 8 and week 12 from the start of study treatment. All patients who receive at least one dose of the study drug ALT-801 will be included in the anti-tumor response evaluation.

Population:

Patients of 18 years of age with relapsed or refractory multiple myeloma. Patients also need to have adequate cardiac, pulmonary, liver and kidney functions and to have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2.

Sample Size:

A total of up to 24 assessable patients will be accrued to the dose escalation phase of the study (Phase Ib). Up to an additional 37 assessable patients will be enrolled at the expansion phase (Stage 1 and 2) of the study (Phase II). A

total of approximately 55 assessable patients will be enrolled to complete the study. Assuming a 20% ineligible or non-assessable cases, a total of up to 66 patients may be accrued to the study.

Primary Endpoints:

For Phase Ib only: (1) Determination of the MTD of ALT-801.

For Phase Ib & II: (2) Safety profile of ALT-801.
(3) Disease response rate.

Secondary Endpoints:

(1) Duration of response.
(2) Progression free survival.
(3) Overall survival.
(4) Immunogenicity and pharmacokinetics profile of ALT-801.
(5) Relationship between tumor presentation of HLA-A*0201/p53 aa 264-272 complexes and the safety, immune response and clinical benefit of study treatment.

Pharmacokinetics & Biomarkers:

Blood samples will be collected to assess typing for HLA-A2, immune cell levels and phenotype, pharmacokinetics and immunogenicity of the study drug ALT-801, and the serum levels of IFN-γ and TNF-α. Unstained slides from a bone marrow biopsy will be used to test HLA-A*0201/p53 aa 264-272 complex presentation. Blood samples for pharmacokinetic analysis of ALT-801 will be taken on the first day of ALT-801 administration in the initial study treatment cycle. Venous blood will be obtained at Time 0 (before the start of infusion), at 30 minutes (15 minutes after completion of infusion), and 1, 3 and 6 hours from Time 0 for the assessment of ALT-801 serum concentration. Non-compartmental and compartmental analyses will be conducted. In addition, the same blood samples collected for PK analysis will be used to assess the serum levels of IFN-γ and TNF-α. Fresh blood samples for HLA-A2 typing, immune cell levels and phenotype testing will be collected before the start of first and fourth dose of study drug infusion in each treatment cycle. HLA-A2 typing will be performed only once. Bone marrow samples will be collected for future analysis of molecular markers associated with responses or resistance to ALT-801 in patients with relapsed or refractory multiple myeloma.

Monitoring Tests:

Blood samples for standard chemistry, and CBC with differential will be obtained at screening, on each study drug infusion day, and at follow-up visits. Blood samples for immunogenicity testing, which include assays for anti-ALT-801 and IL-2 neutralizing antibodies, will be collected prior to dosing on the first ALT-801 infusion day and at Week 8 from the initial dose of study treatment. Blood and urine samples will be collected on each follow-up visit for response assessment.

Response Assessment:

There are two response assessments for treated patients: initial assessment at week 8 and confirmatory assessment at week 12 from the start of study

treatment. After completion of study treatment, patients who have received at least one dose of study drug will have the response assessments. Responses will be evaluated according to the new International Uniform Response Criteria for Multiple Myeloma proposed by the International Myeloma Working Group. Baseline evaluations should be performed up to 14 days before study treatment starts.

Progression & Survival Assessment: Progression-free survival, overall survival, and duration of response of all treated patients will be assessed at every three months during year 1 and then every 6 months during years 2 and 3 from the start of study treatment, or through the point designated as the end of the study follow up.

Adverse Events: All patients will be monitored and evaluated for clinical toxicities during the treatment period and queried at each follow-up visit for Adverse Events (AEs). Patients may volunteer information concerning AEs. All adverse events will be graded by using the NCI Common Terminology Criteria for Adverse Events version 4.0 (CTCAE v4.0), and logged in the patient Case Report Form. The study centers should report all Serious Adverse Events (SAEs) and all events that trigger patient's study treatment discontinuation to the sponsor via phone, fax or email (or a combination) no more than 24 hours after learning of the event. The sponsor will use the information to manage and coordinate the dose escalation, cohort expansion and patient enrollment. The sponsor will then inform all of the participating clinical sites of the current dose level and the number of patients to be enrolled at that level, or of any patient enrollment suspension via phone, fax or email within 24 hours of learning of the event. The study centers should report all other adverse events to the sponsor following the guidelines defined in the study protocol. All study drug related AEs that are both serious and unexpected will be reported to the FDA in an expedited manner in accordance with 21 CFR §312.32.

Statistical Plan: For each cohort, all AEs will be tabulated and examined and all safety, pharmacokinetic and tumor response data will be evaluated. For estimation of duration of response and progression free survival, the Kaplan-Meier method will be used. P-values of ≤ 0.05 (two-sided) will be considered to indicate statistical significance.

8. STUDY CALENDAR, CLINICAL PROCEDURES & TESTS

8.1 Study calendar

TESTS & PROCEDURES	SCREEN/ BASELINE[1]	TREATMENT CYCLE #1					TREATMENT CYCLE #2				1ST ASSESSMENT	2ND ASSESSMENT	FOLLOW-UPS						
Study Month		1					2					3	6	9	12	18	24	30	36
Study Week		1		2	3	4	5		6	7	8	12							
Day of Week		M	W	M	M		M	W	M	M									
Study Day		*1*	*3*	*8*	*15*	*16-28*	*29*	*31*	*36*	*43*									
Medical history	X																		
Serum pregnancy test[2]	X																		
Complete physical exam	X	X					X				X	X							
Vital signs, weight, Height[3]	X	X	X	X	X		X	X	X	X	X	X							
Concurrent medication	X	X	X	X	X		X	X	X	X	X	X							
Adverse event assessment[4]	X	X	X	X	X		X	X	X	X	X	X							
CBC with Differential	X	X	X	X	X		X	X	X	X	X	X							
Blood Chemistry	X	X	X	X	X		X	X	X	X	X	X							
EKG	X	X[5]					X												
Response evaluation[6]											X	X							
Serum quantitative immunoglobulins	X										X	X							
SPEP	X										X	X							
UPEP-random	X										X	X							
SIFE	X										X	X							
UIFE -random	X										X	X							
Serum FLC assay[6.1]	X										X	X							
Bone marrow plasma cell percentage[6.2]	X										X	X							
Bone marrow immunohistochemistry or immunofluorescence[6.3]											X	X							
Soft tissue plasmacytomas assessment[6.4]											X	X							
Disease & survival follow-up[7]													X	X	X	X	X	X	X
Immune cell levels & phenotype[8,12]		X[8]			X[8]		X[8]			X[8]									
HLA A2 Blood Typing[9] & p53 tumor typing		X																	
PK, IFNγ, TNFα[10,12]		X[10]																	
Immunogenicity tests[11, 12]		X[11]									X								
Study drug (ALT-801)		**a1**	**a2**	**a3**	**a4**		**a5**	**a6**	**a7**	**a8**									

[1]Screening/baseline evaluations are performed ≤ 14 days prior to start of therapy. If the patient's condition is deteriorating, laboratory evaluations should be repeated within 48 hours prior to initiation of study treatment infusion. [2]Pregnancy test is for women with childbearing potential only. [3]Vital signs (especially blood pressure), clinical status and laboratory tests should be reviewed before start of therapy. Vital signs will be evaluated every 2 hours after drug infusion and before discharge, and body weight before infusion on drug infusion day. [4]Patients who have an on-going study drug-related SAE upon study completion or at discontinuation of study will be contacted by the investigator or his/her designee every week until the event is resolved or determined to be irreversible. [5]If the screening EKG was performed within 14 days prior to start of study treatment, the EKG is not required [6]Disease response and progression assessment will be evaluated using the new International Uniform Response Criteria for Multiple Myeloma proposed by the International Myeloma Working Group;. [6.1]only when serum and urine M-protein are unmeasurable [6.2] only when serum and urine M-protein and serum FLC are unmeasurable and bone marrow plasma cell percentage > 30% at baseline; [6.3]only when sCR is to be determined; [6.4]only when present at baseline, and to confirm CR or PR by X-rays, MRI or CT scans. [7]Information about tumor assessment & other therapies received after completion of study treatment will be collected if available. [8]Fresh blood samples for HLA A2 blood typing, immune cell levels & phenotype testing will be collected before dosing. [9] Use the blood sample collected for immune cell levels & phenotype.[10]Collect blood samples at Time 0 (before drug infusion), at 30 min (15 min after completion of infusion, +/- 5 min), 1 hour (+/- 10 min), 3 hour (+/- 30 min), 6 hour (+/- 60 min) from Time 0. IFNγ and TNFα assays are performed using the same samples and at the same schedule as PK. [11]Use the sample collected before dosing for PK test. [12]Residual samples may be used by Sponsor for research studies of other biomarkers.