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CLINICAL STATISTICAL ANALYSIS PLAN

Syntrix Biosystems Inc.

A PHASE 2 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL TO ESTABLISH THE EFFICACY AND SAFETY OF ONCE WEEKLY ORAL AMINOPTERIN FOR THE TREATMENT OF SUBJECTS WITH MODERATE-TO-SEVERE PSORIASIS
Client: Syntrix Biosystems Inc.

Protocol: Syntrix-AMT-PSO-201 Version 1.8, 01DEC2018

SAP Version: 0.4
Date of Version: 2020-10-21

Confidentiality Statement

SPONSOR APPROVAL

By signing below, I certify that I approve of the Statistical Analysis Plan for this project.

Printed Name and Title:

Stuart Kahn, Medical Director, Syntrix Biosystems, Inc.

Signature and Approval Date:

DocuSigned by:
Stuart Kahn
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2/13/2023

DF/NET APPROVAL

By signing below, I certify that I approve of the Statistical Analysis Plan for this project. I also certify that the analyses will be performed in accordance with this Statistical Analysis Plan.

Printed Name and Title:

Joe Jiang, DF/Net Research Inc.

Signature and Approval Date:

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Joe Jiang
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2/13/2023

Revision History

Version	Date	Author(s)	Organization(s)	Purpose
0.1	27MAR2017	Matt Johnson	DF/Net Research, Inc.	New document
0.2	25MAR2019	Matt Johnson	DF/Net Research, Inc.	Revised version based on updated protocol
0.3	28MAY2019	Matt Johnson	DF/Net Research, Inc.	Edits based on DF/Net review
0.4	21OCT2022	John Zebala	Syntrix Biosystems, Inc.	Early termination by LOCF

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1-INTRODUCTION

The purpose of this document is to describe the reporting and statistical analyses that will guide the preparation of the clinical portion of the final study report for Syntrix Biosystems Inc study AMT-PSO-201.

The study report will be prepared after all study subjects have completed the follow-up, all data in the database through the follow-up have been reviewed, all data queries have been resolved, and the database has been locked.

All individual subject listings, summary tables, and statistical analyses described below will be provided in separate appendices to the study report. Unless other indicated, all listings and summary tables will be provided by treatment group.

This SAP is written with consideration of the recommendations outlined in the International Conference on Harmonization (ICH) E9 Guideline entitled Guidance for Industry: Statistical Principles for Clinical Trials [ICH 1998] and the ICH E3 Guideline entitled Guidance for Industry: Structure and Content of Clinical Study Reports [ICH 1995].

2-STUDY OBJECTIVES

The purpose of this study is to determine the efficacy and safety of LD-AMT in adult subjects with moderate-to-severe psoriasis who have not been treated with MTX

2.1 Primary Objective

To determine the efficacy of 3 mg oral LD-AMT in the treatment of moderate-to-severe psoriasis compared to a placebo.

2.2 Secondary Objectives

To determine the safety of 3 mg oral LD-AMT in the treatment of moderate-to-severe psoriasis compared to a placebo.

2.3 Exploratory Objectives

To assess the relationship of each subjects' cytoplasmic and mitochondrial folate metabolism to the subjects' efficacy and safety outcomes.

3-STUDY ENDPOINTS

3.1 Primary Endpoint

The co-primary endpoints are:

1. Proportion of subjects achieving Psoriasis Activity and Severity Index of 75% (PASI 75) at study Day 98 (14 weeks).
2. Static Physician Global Assessment (sPGA) dichotomized to success or failure at study Day 98 (14 weeks).

3.2 Secondary Endpoints

1. Proportion of subjects achieving PASI 50 at study Day 98 (14 weeks).
2. Mean reduction in the PASI at study Day 98 (14 weeks).
3. Proportion of subjects achieving “success” in erythema at study Day 98 (14 weeks).
4. Proportion of subjects achieving “success” in scaling at study Day 98 (14 weeks).
5. Proportion of subjects achieving “success” in plaque induration at study Day 98 (14 weeks).

3.3 Safety Endpoints

Safety endpoints are adverse events, including changes in laboratory values and the occurrence of dose limiting toxicity. Safety endpoints will be evaluated throughout the study and for an additional 42 days after a subject completes the treatment period of the study at Study Day 98.

3.3 Exploratory Endpoints

1. Mean hematologic (e.g., hemoglobin, platelets, leukocytes) and hepatic laboratory (e.g., SGOT, SGPT) values over the treatment-phase.
2. Fraction of abnormal hematologic and hepatic laboratory values over the treatment-phase.
3. Cumulative incidence of abnormal hematologic and hepatic laboratory values as a function of time over the 12-week treatment-phase.
4. Mitochondrial and cytoplasmic folate metabolism correlates with AMT efficacy and toxicity.

4-DEFINITIONS

The following definitions apply to the summary tables and statistical analyses planned for the study report:

Screened population: All subjects who were screened.

Intent-to-treat (ITT) population: All subjects who were randomized to treatment.

Safety population: All subjects who received at least one study dose.

Per-protocol (PP) population: All subjects who received all 14 study drug doses and completed the Day 98 visit.

Baseline value: Most recent value recorded prior to the first study drug administration.

Treatment group: One of the two treatment assignments (3 mg LD-AMT and placebo).

Visit Day: The scheduled Visit Day, for example Day 14.

Study Day: The day on study that a visit actually took place (date of visit minus the date of enrollment, Day 0). For example an adverse event onset might be on Study Day 5; or a scheduled Visit Day 42 evaluation could take place on Study Day 44.

Protocol deviation: Any noncompliance with the clinical trials protocol, Good Clinical Practice (GCP), or SOP requirements. Noncompliance may be either on the part of the subject, the investigator , or the study site staff.

5-STUDY DESIGN

This is a phase 2, multi-center, randomized, double-blind, placebo-controlled, clinical trial to investigate the efficacy, safety, of LD-AMT in the treatment of subjects with moderate psoriasis who have not been treated with MTX. Folate metabolism biomarkers will be studied to determine their correlation with efficacy and safety. Forty-six subjects will be randomized to one of two parallel treatment arms: LD-AMT (3 mg) or placebo, in a 1:1 ratio. LD-AMT tablets or placebo tablets will be administered once weekly for 14 weeks. Randomized subjects will initially enter a 14-week treatment phase, followed by a 6-week post-treatment phase. The first study drug administration will be on Day 0.

Subjects in both treatment groups will receive 14 once weekly oral treatments (6 tablets).

Group	Treatment Assignment	Route	Tablets / dose	Schedule	N=46
1	3.0 mg AMT	oral	6	Once weekly x 14	23
2	placebo	oral	6	Once weekly x 14	23

General safety will be evaluated for each subject on Days 0, 14, 42, 70, 98, 119, and 140. Subjects will be evaluated for signs and symptoms of study drug intolerance. Subjects will complete weekly diaries to record study drug administration, and signs and symptoms of AEs. Blood will be obtained at baseline and on Days 14, 42, 70, and 98.

5.1 Study Schedule

Procedure	Screen	Treatment Phase					Post-Treatment Phase	
	Days -30 to 0	Day 0	Day 14(±2)	Day 42(±3)	Day 70(±3)	Day 98(±3)	Day 119(±4)	Day 140(±4)
		Week 0	Week 2	Week 6	Week 10	Week 14	Week 17	Week 20
Randomization		X						
Study Drug Dispensed		X						
Study Drug Administer[1]		X	X	X	X			
Clinical								
Informed Consent main study	X							
Contraception Requirements[2]	X	X	X	X	X	X	X	X
Medical History & Physical Exam	X	X[3]		X[3]	X[3]	X[3]		
Chest X-ray	X							
Vital Signs	X	X				X		
PASI	X	X				X		
sPGA		X				X		
Dermatology Life Index		X				X		
Review Patient Diary			X	X	X	X		X
Concomitant Medications	X	X	X	X	X	X	X	X
Adverse Events		X	X	X	X	X	X	X
Safety Lab Tests								
CBC with Differential	X		X	X	X	X		
Chemistries[4]	X		X	X	X	X		
HIV1/2, Hepatitis B & C Serology	X							
UA	X					X		
Pregnancy Test[5]	X	X	X	X	X	X		X
Folate Metabolism Studies								
Collect Blood[6]		X						

[1] At each visit study drug is counted and a single dose can be taken if it maintains the exact weekly administration cycle of study drug.
[2] Contraception is to be used while on study and for 90 days after the last study drug dose.
[3] Physical exam performed as directed and required by interim history.
[4] Chemistries include BUN, creatinine, AST, ALT, alkaline phosphatase, total bilirubin, albumin and total protein.
[5] Urine pregnancy tests for women of child-bearing potential only. Tests will be performed during subject's visit, prior to dosing.
[6] The specific amount of blood will be indicated and processed as described in study specific procedures.

6-STUDY POPULATION

The study population is MTX-naïve subjects with moderate psoriasis 21 years of age or older. A subject is considered enrolled or randomized in the study once they have completed the informed consent, completed the baseline assessments indicating that they are eligible, and have been assigned a participant identification number (PID#).

6.1 Inclusion Criteria

1. Be 21 years of age or older.
2. Have a diagnosis of moderate psoriasis for at least 6 months confirmed by a dermatologist, defined here as plaque-type psoriasis affecting a body surface area of 3% to 10%.
3. Agree to avoid prolonged sun exposure and avoid use of tanning booths or other ultraviolet light sources during the study.
4. Ability to understand and sign written informed consent.
5. For sexually active men and for women of childbearing potential, an adequate form of contraception.
6. For pre-menopausal women, a negative pregnancy test, obtained within 1 week prior to first study drug dose.
7. Negative serology for HIV1/2, hepatitis B and hepatitis C.
8. The following screening laboratory blood tests must have the following values, or not clinically significant as determined by the PI and Medical Monitor: WBC WNL; absolute neutrophil count > lower limit of normal; platelet count WNL; hemoglobin >10.0 g/dL; AST < 2.5 x the upper limit of normal.
9. Adequate renal function: GFR estimated by Cockcroft-Gault formula >60 ml/min

6.2 Exclusion Criteria

Subjects who meet ANY of the following criteria will be excluded from the study (ineligible):

1. Known history of hepatitis, HIV infection, interstitial lung disease.
2. Greater than moderate alcohol consumption on a regular basis (moderate consumption for females is 1 drink or 1 glass of wine a day; for males is 2 drinks or 2 glasses of wine a day) and unwilling, or unable, to control consumption during the study period.
3. Prior use of MTX, AMT, cyclosporine, biologic drug therapy (e.g., etanercept, adalimumab, infliximab), or interleukin-2-diptheria-toxin.
4. Within 4 weeks prior to randomization and at any time while on study, use of phototherapy (e.g., UVB, narrow band UVB, Goeckerman regimen, Ingram regimen, PUVA), systemic medications (e.g. acitretin, mycophenolate mofetil, tacrolimus/FK506, azathioprine, 6-thiogaunine, sulfasalazine, hydroyurea, calcitriol, any systemic immunosuppressants), lithium, or any treatments that could affect psoriasis or sPGA evaluations. Subjects are eligible 4 weeks after the last dose of any of the aforementioned treatments was received.
5. Within 2 weeks prior to randomization and at any time while on study, use of any topical medications or treatments that could affect psoriasis evaluations (e.g., corticosteroids,

anthralin, vitamin D3/calcitriol and analogues such calcipotriene and tacalcitol, synthetic retinoids such as tazarotene, coal tar, and keratolytics such as salicylic acid, lactic acid and urea including those contained in over-the-counter medicated shampoos). Subjects are eligible 2 weeks after the last dose of any of the aforementioned treatments was received.

6. Use of emollients on the morning of the first (Week 0) study visit.
7. Within 2 weeks prior to Study Day 0, or on Study Day 0, or at any time during the study, use of any of the following medications that may result in drug/drug interactions with AMT: trimethoprim with or without sulfamethoxazole; sulfonamides; sulfonylureas; pyrimethamine; triamethamine; salicylates; non-steroidal anti-inflammatory (NSAID) drugs including ibuprofen; dipyridamole; colchicine; probenecid; aminoglycosides; theophylline; phenytoin; and folinic acid (i.e., leucovorin).
8. Known concurrent malignancy except basal or squamous cell skin carcinoma, or cervical carcinoma in situ.
9. Concurrent participation in another clinical trial involving experimental treatment within 30 days of Study Day 0.
10. Current and uncontrolled infection, cardiovascular, renal, pulmonary, hepatic or GI conditions that will interfere with the conduct of the trial or pose a morbid risk.
11. Investigator's opinion that a concurrent disease or condition impairs the subject's ability to complete the trial: includes psychological, familial, sociological, geographical or medical conditions.

6.3 Withdrawal of Study Subject

Subjects will be free to withdraw from the study at any time, for any reason, and without prejudice to further treatment. Any subject who withdraws from the study, regardless of reason, will not be allowed to re-enroll in this study. Reasons for withdrawal will be recorded on the appropriate CRF. The final report will include reasons, if available, for withdrawal and any necessary treatment.

Anytime a subject withdraws from the study, for whatever reason, including voluntary withdrawal, every attempt should be made to evaluate all procedures planned for the Study Day 98 visit.

6.4 Randomization and Blinding

A total of 46 subjects will be enrolled, 23 in the LD-AMT treatment arm, and 23 in the placebo arm. Subjects will be randomly assigned to receive LD-AMT or placebo.

7-SAMPLE SIZE

7.1 Determination of Sample Size

Using a Fisher's exact test and assuming the proportion of PASI 75 achieved in subjects treated with placebo is 15% and those treated with 3.0 mg/week LD-AMT dose is 60%, then at a significance level (1-sided alpha) of 0.05 we expect the study to be sufficiently powered with 46 subjects. This sample size provides approximately 91.25% power to detect a statistically

significant efficacy-response. Moderate loss to follow-up will still result in high power – the power would be approximately 87.5% assuming 10% loss to follow-up.

8-STATISTICAL CONSIDERATIONS

Statistical summaries and analyses of baseline and safety data will be provided for the ITT and safety population. Statistical summaries and analyses of folate metabolism data will be provided for the ITT and per-protocol population.

SAS® version 9.3 will be used for statistical analyses and the production of tables, listings, and figures (TLFs).

Categorical variables will be summarized using the number frequency and percentage by treatment and overall of subjects falling into each category. Continuous variables will be summarized using mean, standard deviation, median, geometric median (where appropriate) minimum and maximum by treatment and overall. Statistical tests will use a significance level of 5% and will be two-tailed unless otherwise stated.

8.1 Primary Efficacy Analyses

The efficacy of LD-AMT established using a step-down analysis approach with one-sided Fisher's exact tests. First, the analysis for subjects attaining PASI 75 will be performed, then, if that analysis shows a significant treatment effect, analysis for subjects attaining a sPGA success will be performed. The following are the first and second step-down efficacy analyses:

1. The proportion of subjects attaining a PASI 75 in the placebo arm vs. active LD-AMT arm.
    - The null hypothesis is no treatment effect or equality of proportions.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of PASI 75 than placebo.
2. The proportion of subjects attaining a sPGA success (a score of 0 or 1) in the placebo arm vs. active LD-AMT arm.
    - The null hypothesis is no treatment effect or equality of proportions.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of sPGA success than placebo.

8.2 Secondary Efficacy Analyses

The efficacy of LD-AMT established using one-sided Fisher's exact tests:

1. Proportion of subjects achieving PASI 50 at study Day 98 (14 weeks).
    - The null hypothesis is no treatment effect or equality of proportions.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of PASI 50 than placebo.
2. Proportion of subjects achieving "success" in erythema at study Day 98 (14 weeks).
    - The null hypothesis is no treatment effect or equality of proportions.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of erythema success than placebo.
3. Proportion of subjects achieving "success" in scaling at study Day 98 (14 weeks).

- The null hypothesis is no treatment effect or equality of proportions.
- The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of scaling success than placebo.

4. Proportion of subjects achieving "success" in plaque induration at study Day 98 (14 weeks).
    - The null hypothesis is no treatment effect or equality of proportions.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater proportion of plaque induration success than placebo.

The efficacy of LD-AMT established using a one-sided Wilcoxon rank-sum test:

5. Mean reduction in the PASI at study Day 98 (14 weeks).
    - The null hypothesis is no treatment effect or equality of means.
    - The alternative hypothesis is that 3 mg LD-AMT/week is effective at providing a greater reduction in mean PASI than placebo.

8.3 Safety Analyses

8.3.1 Safety Assessments

The safety assessments will be based on clinical AEs reported by the subject or observed by the investigator (or appropriate designee) and laboratory AEs reported as test results. AEs will be recorded on the AE CRF. Clinical AE relationship to study drug will be determined by the investigator (or appropriate designee) and recorded on the AE CRF. Laboratory AE relationship to study drug will be determined or recorded on the AE CRFs. Laboratory AEs considered not clinically significant will not be recorded on the AE CRF. The summaries and statistical analyses of the safety endpoints will be completed for the safety population.

8.3.2 Adverse Events

All AE terms will be coded using MedDRA 21.1 and classified according to preferred term (PT) and system organ class (SOC). Summaries by PT and SOC of the number (%) of subjects in each treatment group and overall with at least one AE, will be provided for:

1. All AEs
2. Related AEs
3. SAEs

Related AEs are defined as AEs that are possibly, probably, or definitely related to study injection. The treatment groups will be compared using Fisher's exact test.

Comparisons of the treatment groups with respect to the incidence of AEs by PT and SOC will also be performed for all events reported by at least 5 subjects overall.

The following additional summaries of AEs will also be provided:

1. Incidence of AEs by severity of event (mild, moderate, severe, potentially life-threatening)
2. Incidence of AEs by relationship to study drug (unrelated, related)

8.3.3 Incidence of Dose-limiting Toxicity

The number (%) of subjects with at least one event of dose-limiting toxicity will be summarized for each treatment group and overall.

8.3.4 Safety Laboratory Tests

Summaries of the actual value and change from baseline for all laboratory tests will be provided for each study visit. A tabulated summary of laboratory abnormalities by toxicity grade will also be provided.

8.4 Exploratory Analyses

Descriptive statistics including mean, standard deviation and range will be presented for the hematologic and hepatic laboratory variables of each of these treatments and overall over by visit day. Furthermore, the fraction and cumulative incidence of abnormal hematologic and hepatic laboratory values will be summarized by treatment and visit day.

Analysis of the role of the cytoplasmic and mitochondrial compartments in folate metabolism will be performed. Assessment of folate metabolism will be performed with blood specimens obtained at baseline. Endpoints of interest include the ratio of mitochondrial to cytoplasmic DNA and the expression levels of DHFR and thymidylate synthase. These results will be correlated with study trial efficacy and safety outcomes. The evaluation of folate metabolism will be performed on subject leukocytes obtained at baseline and on Day 98 and based on measurements of:

1. cytoplasmic and mitochondrial DHFR quantification
2. cytoplasmic and mitochondrial thymidylate synthase quantification
3. nuclear DNA uracil quantification
4. polyglutamated AMT types and quantity.

8.5 Demographic and Other Baseline Characteristics

A table will summarize each treatment group and overall demographics characteristics of subjects in the safety population. Age, gender and race will be compared among treatment groups using Fisher's exact test for categorical variables and either a two-sided t-test or the Wilcoxon rank-sum test for continuous variables depending on the distribution of the underlying data.

8.6 Subject Disposition

A table will summarize each treatment group and overall for:

1. Number of subjects randomized
2. Number (%) of subjects receiving all 14 study drug doses
3. Number (%) of subjects who discontinued the study and reasons for discontinuation
4. Number (%) of subjects in the per-protocol population and reasons for those excluded
5. Number (%) of subjects with at least one protocol violation

8.6 Vital Signs

A table will summarize each treatment group and overall vital sign values for subjects in the safety population.

8.7 Concomitant Medications

Concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary (WHODrug Global B3 September 1, 2017 dictionary). Concomitant medications will be summarized by dose level using descriptive statistics. Tabulation will be made with respect to the proportion of subjects taking at least 1 concomitant medication for each preferred term during the study.

8.8 Physical Exam Findings

Abnormal findings in physical examinations will be summarized by dose level using descriptive statistics.

8.9 Missing Values

The investigators of this study will assume that any data is missing completely at random (MCAR). As such, a complete case analysis will be performed and any missing efficacy data, safety data, and/or folate metabolism data will be excluded without imputation. Early drop-outs will be handled by LOCF.

10-SUGGESTED TABLES/LISTINGS/FIGURES

Type	Title	Population
Listing	L16.2.1-Disposition	Screened
Listing	L16.2.2-Protocol Deviations	Screened
Listing	L16.2.3-Patients Excluded from PP Population	Safety
Listing	L16.2.4-Demographics	Safety
Listing	L16.2.5.1-Study Drug Accounting	Safety
Listing	L16.2.5.2-Concomitant Medications	Safety
Listing	L16.2.6.1-PASI	PP
Listing	L16.2.6.3-sPGA	PP
Listing	L16.2.7.1-Adverse Events (AE)	Safety
Listing	L16.2.7.2-Serious Adverse Events (SAE)	Safety
Listing	L16.2.7.3-Related Adverse Events (TRAE)	Safety
Listing	L16.2.7.4-Dose-Limiting Toxicity (DLT)	Safety
Listing	L16.2.8.1-Abnormal Laboratory Results	Safety
Listing	L16.2.8.2-Laboratory Results (Hemogram, Differential, Serum Chemistry, Urinalysis)	Safety
Listing	L16.2.8.3-Folate Metabolism	Safety
Listing	L16.2.9-Vital Signs	Safety
Listing	L16.2.10-Physical Exam Findings	Safety
Listing	L16.2.11- Medical History	Safety
Listing	L16.4-Patient Profile	Safety
Table	T14.1.1-Disposition Summary	Screened
Table	T14.1.2-Demographics Summary	Safety
Table	T14.2.1-Primary-PASI 75 Analysis	PP
Table	T14.2.2-Primary-sPGA Analysis	PP
Table	T14.2.3-Secondary-PASI 50 Analysis	PP
Table	T14.2.4-Secondary-Erythema Analysis	PP
Table	T14.2.5-Secondary-Scaling Analysis	PP
Table	T14.2.6-Secondary-Plaque Induration Analysis	PP
Table	T14.2.7-Secondary-PASI Reduction Analysis	PP
Table	T14.2.8-Exploratory-Folate Metabolism Summary	PP
Table	T14.3.1.1-Adverse Events (AE) Summary	Safety
Table	T14.3.1.2-Adverse Events (AE) by SOC/PT Summary	Safety
Table	T14.3.2.1-Serious Adverse Events (SAE) Summary	Safety
Table	T14.3.2.2-Serious Adverse Events (SAE) by SOC/PT Summary	Safety
Table	T14.3.3.1-Related Adverse Events (RAE) Summary	Safety
Table	T14.3.3.2-Related Adverse Events (RAE) by SOC/PT Summary	Safety
Table	T14.3.3.3-Incidence of AEs by Severity	Safety
Table	T14.3.3.4-Incidence of AEs by Relationship	Safety
Table	T14.3.3.5-Dose-Limiting Toxicity (DLT) Summary	Safety
Table	T14.4-Concomitant Medication Summary	Safety

APPENDIX I: ABBREVIATIONS

Abbreviation	Meaning
ACPA	Anti-citrullinated protein antibody
ACR	American College of Rheumatology
ACR20	American College of Rheumatology 20% Improvement Criteria
AE	Adverse Event
AMT	Aminopterin
CFR	Code of Federal Regulations
CRF	Case Report Form
CRP	C-Reactive Protein
CRO	Contract Research Organization
DAS	Disease Activity Score
DLT	Dose Limiting Toxicity
DMARD	Disease Modifying Anti-Rheumatic Drug
ESR	Erythrocyte Sedimentation Rate
EULAR	European League Against Rheumatism
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Assurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
IND	Investigational New Drug
IRB	Institutional Review Board
ITT	Intention-To-Treat
LD-AMT	LD-aminopterin
LOCF	Last Observation Carried Forward
MTD	Maximum Tolerated Dose
MedDRA ©	Medical Dictionary for Regulatory Activities
MTX	Methotrexate
N	Number (typically refers to subjects)
NDA	New Drug Application
PG	Polyglutamate

PI	Principal Investigator
PK	Pharmacokinetics
QA	Quality Assurance
QC	Quality Control
RA	Rheumatoid Arthritis
RF	Rheumatoid Factor
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WNL	Within Normal Limits