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Biomedical Statistical Consulting

QUALITY IN DESIGN, IMPLEMENTATION, & PRESENTATION SINCE 1986

A Phase IIa, Multicenter, Open-label Study Designed to Evaluate the Safety and Efficacy of Escalating Doses of BL-8040 in Adult Subjects with Relapsed/Refractory Acute Myeloid Leukemia

BL-8040

[redacted]

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Statistical Analysis Plan [redacted]

"A Phase IIa, Multicenter, Open-label Study Designed to Evaluate the Safety and Efficacy of Escalating Doses of BL-8040 in Adult Subjects with Relapsed/Refractory Acute Myeloid Leukemia"

SIGNATURE OF APPROVAL

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Statistical Analysis Plan

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Statistical Analysis Plan
Version 1.6 14 January, 2016

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LIST OF ABBREVIATIONS

Abbreviation/Term	Definition
β-hCG	β-human chorionic gonadotropin
µg	Microgram
µL	Microliter
AE	Adverse Event
ALP	Alkaline Phosphatase
ALT/SGPT	Alanine Transaminase/Serum glutamic pyruvic transaminase
AlloSCT	Allogeneic Stem Cell Transplantation
AML	Acute Myeloid Leukemia
aPTT	Activated Partial Thromboplastin Time
Ara-C	Arabinofuranosyl Cytidine / Cytarabine / Cytosine Arabinoside
ASCT	Autologous Stem Cell Transplantation
AST/SGOT	Aspartate Aminotransferase/Serum glutamic oxaloacetic transaminase
AUC	Area under the curve
BM	Bone Marrow
BMI	Body Mass Index
C_{max}	Maximum plasma concentration
CBC	Complete Blood Count
CFR	Code of Federal Regulations
CI	Confidence Interval
CR	Complete response
CRF	Case Report Form
eCRF	Electronic Case Report Form
CRO	Contract Research Organization
CTCAE	Common Terminology Criteria for Adverse Events
CXCR4	CXC Chemokine Receptor Type 4
dL	Deciliter
DLT	Dose limiting toxicity
ECG	Electrocardiogram
ECHO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
EMA	European Medicines Agency
FACS	Fluorescence-activated cell sorting
FDA	Food and Drug Administration
FISH	Fluorescent In Situ Hybridization
g	Gram
GCP	Good Clinical Practice
G-CSF	Granulocyte Colony-Stimulating Factor
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GVHD	graft-versus-host disease
HBsAg	Hepatitis B Surface Antigen

Abbreviation/Term	Definition
HBV	Hepatitis B Virus
HCT	Hematocrit
HCV	Hepatitis C Virus
Hep C Ab	Hepatitis C Antibody
HGB	Hemoglobin
HIV	Human immunodeficiency virus
HSC	Hematopoietic Stem Cells
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
INR	International Normalized Ratio (for blood coagulation tests)
IRB	Institutional Review Board
ITT	Intention-to-treat
IV	Intravenous
kg	Kilogram
λ_z	Elimination rate constant
m	Meter
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
min	Minute
mL	Milliliter
MM	Multiple Myeloma
MTD	Maximum tolerated dose
MUGA	Multiple Gated Acquisition
N	Number of subjects
NCI	National Cancer Institute
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
OR	Overall response
PB	Peripheral blood
PD	Pharmacodynamic
PI	Principal Investigator
PI	Propidium Iodide
PK	Pharmacokinetic
PP	Per Protocol
PR	Partial response
PT	Prothrombin Time
QA	Quality Assurance
QC	Quality Control
RBC	Red Blood Cell
SAE	Serious Adverse Event

SC	Subcutaneous
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard Operation Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
TEAE	Treatment Emergent Adverse Event
TLS	Tumor lysis syndrome
T_{max}	Time to reach the maximum plasma concentration
$T_{1/2}$	Terminal elimination half-life, defined as $0.693/\lambda_z$
ULN	Upper limit of normal
US	United States
USP	United State Pharmacopeia
WBC	White Blood Cell
WFI	Water For Injection
WHO	World Health Organization
WMA	World Medical Association

1.0 Introduction

This Statistical Analysis Plan (SAP) is intended to document the primary, secondary, and supporting objectives of planned statistical analyses as well as the methods to be used to meet these objectives.

The remaining text in this section and the text in Section 2 are taken with reference from the current version of the Clinical Study Protocol (V.7) and is provided here as background.

Acute myeloid leukemia (AML) represents a group of clonal hematopoietic stem cell disorders in which both failure to differentiate and overproliferation in the stem cell compartment result in accumulation of non-functional cells termed myeloblasts. The annual age-adjusted incidence of AML in the US is 3.6 cases per 100,000 people (2005 - 2009), with a median age at diagnosis of 66 years. The five-year relative survival in US patients diagnosed over the period 2002-2008 was 23.4%. Both prognosis and treatment are based on the presence or absence of specific genetic abnormalities, which play an important role as diagnostic criteria for sub-classification of AML.

The standard treatment paradigm for AML is remission induction chemotherapy with an anthracycline/cytarabine based combination, followed by either consolidation chemotherapy or allogeneic stem cell transplantation, depending on the AML risk group. The AML risk group predicts the likelihood of cure with chemotherapy alone (based on cytogenetic and molecular parameters) and the patient's expected ability to tolerate an allogeneic stem cell transplant (highly dependent on age, performance status and co-morbidities). Approximately 70-80% of subjects enter complete disease remission with several anthracycline-based chemotherapy combinations. Consolidation with high-dose cytarabine or allogeneic stem-cell transplantation in high-risk patients limit overall relapse rate to approximately 50%.

Another potential consolidative approach is the employment of autologous stem cell transplantation.

BL-8040, formerly BKT-140, is a highly selective CXC chemokine receptor 4 (CXCR4) antagonist co-developed by [redacted] and BioLineRx Ltd. as a novel therapy for treatment of cancer. The investigational drug binds to CXCR4 with high affinity (IC_{50} 0.5-10 nM) and inhibits its function. The chemokine CXCL12 (SDF-1-stromal- derived-factor-1) and its receptor, CXCR4, play a pivotal role in the trafficking of hematopoietic stem cells to the bone marrow (BM). In addition, BL-8040 exhibits CXCR4-dependent selective cytotoxicity toward malignant cells of hematopoietic origin in both in vitro and in vivo models. BL-8040 significantly and preferentially stimulated leukemic apoptotic cell death. BL-8040 treatment induced morphological changes, phosphatidylserine externalization, decreased mitochondrial membrane potential, caspase-3 activation, sub-G1 arrest and DNA double-stranded breaks.

2.0 Study Objectives and Design

2.1 Primary Study Objective

The primary objective of this study is to evaluate the safety and tolerability of multiple escalating doses of BL-8040 when administered as monotherapy for two days, followed by five days of combined administration with high-dose Ara-C in AML adult subjects with relapsed or refractory disease:

- Assessing the frequency, severity and duration of treatment-related adverse events (AEs); and
- Monitoring changes in:
  - vital signs
  - physical examination findings
  - 12-lead electrocardiograms (ECGs)
  - Laboratory parameters

2.2 Secondary Study Objectives

The secondary objectives of this study are:

- To assess the clinical efficacy (response rates) of escalating repeated doses of BL-8040 administered as monotherapy for two days, followed by five days of combined administration with high-dose Ara-C in AML adult subjects
- To assess the apoptotic effect of BL-8040 on leukemic blasts when administered as monotherapy
- To assess the effect of BL-8040 on mobilization of AML blasts to peripheral blood (PB) when administered as monotherapy
- To assess the single and multiple dose pharmacokinetic (PK) profile of BL-8040.

[redacted]

2.4 Study Design Synopsis

2.4.1 Dose escalation protocol

This will be an open-label, multicenter, phase IIa, dose escalating study in subjects with relapsed/refractory AML, defined according to WHO criteria including subjects who failed chemotherapy only and those who failed previous Autologous Stem Cell Transplantation (ASCT)/ Allogeneic Stem Cell Transplantation (AlloSCT), provided at least 6 months have passed from transplant.

Eligible subjects will receive SC injections of BL-8040 alone ("monotherapy period") over two days (one injection per day) followed by concurrent administration of BL-8040 with standard salvage chemotherapy ("combined period") over 5 days. During the "combined period," BL-8040 will be

administered 4 hours prior to chemotherapy. The chemotherapy will consist of cytarabine (Ara-C) 1.5 or 3 g/m^2/d per dose (based on age), administered IV over 3 hours, for 5 days[a] and will not be escalated.

The first part of the study (Part 1) will include escalating dose groups and be considered the **'escalation phase'**. Six potential levels will be investigated starting at dose level 0.5 mg/kg. Patients will be accrued in a conventional 3+3 design. Applying this study design, the first cohort of 3 patients will be treated at dose level 1 and evaluated for dose escalation.

If at dose level 1 and beyond, 0 out of 3 patients experience dose-limiting toxicity (DLT), then the next cohort of 3 patients will be treated at the next dose level. If 1 out of 3 patients develop DLT, an additional 3 patients will be treated at the same dose level. If no more DLT develops at that dose, i.e. 1 out of a total of 6 patients develops DLT, the dose escalation continues to the next dose level. At any given dose, if greater than 1 out of 3 patients or 1 out of 6 patients experience DLT, the dose level exceeds the maximum tolerated dose (MTD). In this situation, 3 more patients will be treated at the next lower dose if there are less than 6 patients already treated at that dose. MTD is defined as the highest dose level in which 6 patients have been treated with less than 2 instances of DLT.

The decision to proceed to the next higher dose level will be made by an independent Data Monitoring Committee (DMC) after review of relevant safety data collected up to and including Day 30 (± 2 days; Day 28 ± 2 of chemotherapy) of the last subject of the previous dose group. The DMC may recommend evaluation of intermediate doses (or doses lower than the starting dose of 0.5 mg/kg) of BL-8040 in combination with Ara-C.

Dose escalation will be permitted until the MTD is established and protocol specific stopping rules for toxicity are met. If no MTD is reached, dose escalation will continue up to dose level 6 (2.0 mg/kg). It is anticipated that up to 36 eligible patients will be required for the dose escalation.

At the discretion of the Sponsor, additional subjects may be enrolled into a selected dose group to confirm safety, efficacy and pharmacokinetic (PK) profile for the selected dose, bringing the study up to approximately 70 subjects in total. This portion of the study will be considered the **'expansion phase'** (Part 2). The DMC, in consultation with the Sponsor and Investigators, will decide on the selected dose level for expansion based on safety data, MTD, other relevant toxicity considerations, and all available PK and correlative PD data.

During Part 2 of the study, at the Investigator's discretion and after discussion with the Sponsor, subjects may be treated with a second cycle of BL-8040 in combination with Ara-C if they are considered to have had clinical benefit during the first treatment cycle, but failed to achieve complete remission (CR or CRi). In the event that subjects receive a second treatment cycle, the dosing regimen will be identical to that in the first treatment cycle. The second treatment cycle will start after clinical response assessment has been completed for the first treatment cycle, i.e., no sooner than Day 30 (± 2 days; Day 28 ± 2 of chemotherapy).

The study will comprise a screening period, a treatment period (monotherapy and combined treatment) and a follow-up period. For each dose group, visit scheduling and assessments will be similar.

2.4.2 Dose limiting toxicity

Dose-limiting toxicity (DLT) is defined as a clinically significant adverse event or abnormal laboratory value assessed as unrelated to disease progression, intercurrent illness or concomitant medications and occurring during the safety period (30 days)[1] that meets any of the following criteria (refer to Table 2 in Clinical Study Protocol for CTCAE severity grading):

- CTCAE grade 3 AST (SGOT) or ALT (SGPT) or bilirubin for ≥ 7 days
- CTCAE grade 4 AST (SGOT) or ALT (SGPT) of any duration
- All other clinically significant, non-hematological NCI common terminology criteria that are CTCAE grade 3 or 4

To be considered a DLT such toxicity must be possibly, probably or definitely related to BL-8040.

During Part 2 of the study, any DLT occurring at a frequency of > 30% in the expanded cohort will stop accrual at the selected dose level. In this situation, the DMC, in consultation with the Sponsor and Investigators, may recommend a lower dose level for the expanded cohort.

2.4.3 Study population

This study will be conducted in subjects aged 18 to 75 years diagnosed with relapsed/refractory AML. The exact number of subjects enrolled will depend on the toxicity observed in each dose group and the number of dose groups required to reach MTD.

2.4.4 Inclusion and exclusion criteria

Inclusion and exclusion criteria are outlined in Section 4.1 and 4.2, respectively, of the Clinical Study Protocol.

2.5 Criteria for evaluation

2.5.1 Safety

The DLT and MTD for repeated doses of BL-8040 will be assessed by evaluating the frequency, severity and duration of treatment-related AEs, and clinically-significant changes in 12-lead ECGs, vital signs and physical examination findings. All patients will be monitored for safety continually throughout the dosing period and up to 6 weeks after initiation of salvage chemotherapy with Ara-C (up to Day 44). Expansion phase subjects who receive a second treatment cycle will also be followed for up to 6 weeks after initiation of Ara-C during the second cycle, i.e., up to Day 44 of the second cycle.

[1] In case of prolonged BM recovery it will be evaluated again at 6 weeks and considered part of the DLT assessment. The safety period for subjects who receive a second treatment cycle in the expansion phase will be 30 days after the start of the second treatment cycle or up to 6 weeks in the event of delay in BM recovery.

AEs will be monitored continually after administration of study therapy. AEs will be coded by using the MedDRA (currently version 16.1) and graded according to NCI CTCAE, Version 4.03. Toxicities will be classified by type, grade, onset, duration and relationship to study therapy.

The decision to proceed to the next higher dose level will be made by an independent DMC after review of relevant safety data collected up to and including Day 30 (± 2 days; Day 28 ± 2 of chemotherapy) of the last subject of the previous dose group. Until the MTD is established, dose escalation will continue unless protocol specific stopping rules for toxicity are met. If no MTD is reached, dose escalation will continue up to dose level 6 (2.0 mg/kg).

Vital signs (including temperature, blood pressure, pulse rate, respiratory rate, and O2 saturation) will be monitored at the screening visit and prior to BL-8040 administration on each of the 7 days in the treatment period (monotherapy for 2 days and combined therapy for 5 days). For expansion phase subjects receiving a second treatment cycle, vital signs will also be measured daily prior to BL-8040 administration during the second cycle.

Electrocardiograms will be recorded on Days 1, 3 and 7 at pre-dose, 0.5, 1, 2, 4, 8 and 24 hrs post BL-8040 administration. For subjects receiving a second treatment cycle during the expansion phase, ECGs will only be recorded on Days 1 and 7 of the second cycle at pre-dose and 4 hrs post BL-8040 administration.

Hematology (CBC) and biochemistry samples will be collected daily on Days 1-7 prior to BL-8040 administration. Coagulation (PT and PTT) will be evaluated on Day 1 at pre-dose and 24 hrs post-dose, and on Day 7 at 24 hrs post-dose. White blood cell (WBC) counts, including differential and leukemic cell count, will be measured on Days 1, 2, 3 and 7 at 4 and 8 hrs post BL-8040 injection. Partial biochemistry samples (electrolytes and kidney function) will be collected on Days 1, 2, 3 and 7 at 4 and 8 hrs post BL-8040 injection. Subjects considered suitable for a second treatment cycle during the expansion phase will undergo the same laboratory safety evaluations during the second cycle with the exception of coagulation and partial biochemistry evaluation. Additional samples may be collected at the discretion of the Investigator or upon Sponsor's request.

Physical examination, including assessment of cerebellar function will be performed daily on Days 1-7 prior to administration of BL-8040. For expansion phase subjects receiving a second treatment cycle, the same assessments will be performed daily on Days 1-7 prior to administration of BL-8040.

Clinical evaluation of leukostasis related symptoms (visual symptoms, shortness of breath and decreased oxygen saturation in blood measured by pulse oximetry) and TLS (according to Cairo–Bishop criteria) will be assessed on Day 1 and upon commencement of such symptoms or when WBC $\geq$ 30,000/μL.

2.5.2 Efficacy

Efficacy will be assessed by tumor response. The following secondary endpoints will be assessed:

- Response rates as assessed at final BM evaluation based on Cheson 2003 criteria (Clinical Study Protocol, Appendix C):

- Complete response (CR)
- Complete response with incomplete hematological recovery of platelets or neutrophils (CRi)
- Partial response (PR)
- Overall response defined as the sum of CR, CRi and PR
- Composite Complete Response (CRc) defined as the sum of CR and CRi.

- Change in leukemic cell apoptosis in PB and BM.
- Kinetics of mobilization of leukemic blasts from BM to PB.
- Overall survival (OS) during the available follow-up period defined as time from enrollment to death from any cause.

2.5.3 Pharmacokinetics and

PK analyses will be performed by the Sponsor's designee and are therefore not further described in this document.

2.5.4 [redacted]

[redacted]

[1] The SAP described in the next two sections does not pertain to specific measurements that will be analyzed separately by the Sponsor or the Sponsor's designee. These include FACS and FISH as well as several planned measurements that are not part of the CRF including apoptosis and mobilization results.

2.5.4.c [redacted]

[redacted]

2.5.4.d

2.5.4.e Concomitant Medications

Concomitant medication use will be recorded from Baseline (Visit 2) through all study visits. For expansion phase subjects receiving a second treatment cycle, the assessments will be performed in a similar manner.

3.0 Statistical Methods

3.1 Overview

The data collected in this study will be summarized in descriptive statistics tables that provide mean values and mean changes from baseline, median and standard deviations, and number of patients for continuous data, or counts and percentages for categorical data, where appropriate. Summaries will be provided overall by dose group. The data from Part 1 and Part 2 will be summarized in separate tables. Patient listings will be provided for all data summarized in tables. Processing of clinical data and generation of tables and listings will be implemented using SAS™ (SAS Institute, Cary NC), version 9.3 or higher.

3.2 Analysis Sets

3.2.1 Full analysis set (ITT)

All patients enrolled who receive at least one dose of BL-8040 will comprise the intent-to-treat (ITT) full-analysis set. Efficacy and safety analyses will be performed using the ITT analysis set.

3.2.2 Per-protocol set (PP)

All patients enrolled who complete the study according to the protocol without major protocol violations will comprise this analysis set. Efficacy evaluations will be repeated in the Per Protocol analysis set as a sensitivity analysis.

3.3 Baseline Comparability

Patients in each dose group will be summarized using tables and descriptive statistics for demographic and baseline clinical variables. This analysis will be conducted in the ITT population

3.4 Efficacy Analysis

Efficacy analysis will be conducted on all patients who receive at least one dose of study drug (intent-to-treat population). Efficacy evaluations will be repeated in the Per Protocol analysis set as a sensitivity analysis. The clinical efficacy parameters for patients will be response rates at final BM evaluation:

- Complete Response (CR),
- Complete response with incomplete hematological recovery of platelets or neutrophils (CRi)
- Partial response (PR)
- Overall response defined as the sum of CR, CRi, and PR
- Composite Complete Response (CRc) defined as the sum of CR and CRi.
- Overall survival (OS) during study follow-up.

The proportion of patients in the ITT analysis data set having each type of response will be tabulated. This will be repeated for the Per Protocol analysis set.

When determining response for patients receiving two cycles in the expansion phase, the endpoints will be determined after completing the second cycle.

It is noted that the primary endpoint of this study is not efficacy and that results from patients receiving different dose levels of study drug will not be compared directly by statistical means.

3.5 Safety Analysis

The safety analysis will include all patients enrolled in the study who received at least one dose of study drug (i.e., the ITT population). AE data will be listed individually and summarized by System organ class (SOC), high level term (HLT) and preferred terms (PT) for each treatment group. Changes in vital signs and routine laboratory data will be presented with descriptive statistics to demonstrate the trend of change.

Numbers of subjects with physical abnormality at each scheduled visit will be tabulated by body system and by dose level. ECG examination results will be displayed in descriptive statistics and by dose level with number of subjects with abnormal findings tabulated for each schedule visit.

Each AE (based on preferred NCI-CTCAE, Version 4.03, terminology) will be counted only once for a given patient and summarized descriptively by SOC, HLT, and PT using the latest version of MedDRA (version 16.1) and by dose level and part of the study (Part 1 and Part 2). If the same AE occurs on multiple occasions, the highest severity and worst-case relationship will be assumed when constructing summary tables. The number and percentages of patients reporting AEs within SOC, HLT, and PT will be presented.

3.6 Sample Size

The exact number of subjects enrolled will depend on the toxicity observed in each dose group and the number of dose groups required to reach MTD. If all six dose groups are required and if each dose group is expanded to 6 subjects (see stopping rules in the Clinical Protocol Section 6.2.3 and Figure 1), then a total of 36 subjects will be enrolled into the dose escalation part of the study.

Once a dose has been selected for the **expansion phase**, additional subjects may be enrolled in that dose group up to a total of approximately 70 subjects in the study.

3.7 Treatment assignment and blinding

Since this is an open-label study, there is no specific method of assigning patients to the treatment group. All patients who meet the inclusion criteria and do not have any of the exclusion criteria will be entered into this study. There will be no blinding in this study.

3.8 Handling of missing values

Since this is an open-label study with no inferential analysis, there will be no imputation of missing values. All analysis will be based on observed variable values.

3.9 Protocol Deviations analysis populations

All analyses will be conducted on an intention-to-treat (ITT) basis, i.e., all patients will be analyzed. In cases of clinically significant protocol deviations, sensitivity

analyses may be performed excluding such cases (Per Protocol analysis set) with results compared to those from the primary ITT analysis.

3.10 [redacted]

[redacted]

[redacted]

4.0 Presentation of Results

4.1 Handling of Dose Groups

[redacted]

4.2 Enrollment & Demographic and Baseline comparisons- ITT analysis set

[redacted]

4.3 Exposure-ITT analysis set

[redacted]

[redacted] analysis set

4.4.1 Adverse Events

[redacted]

[redacted]

4.4.2 Vital Signs and ECOG

[redacted]

4.4.3 Physical Examination

[redacted]

4.4.4 Analysis of Laboratory Data

[redacted]

4.4.5 ECG

[redacted]

[redacted]

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4.4.6 Efficacy

[redacted]

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4.4.7 End-of-Study Status

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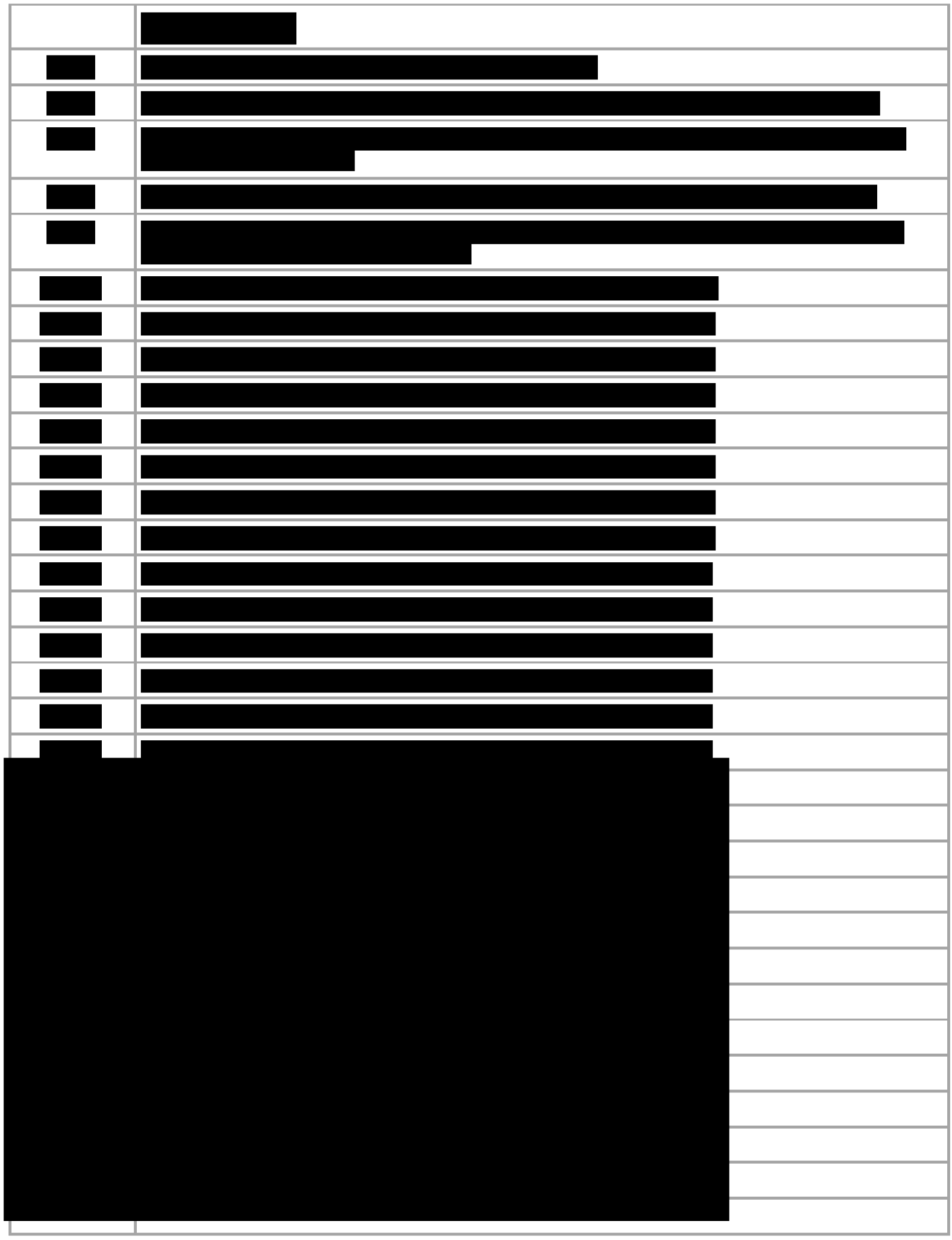

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