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Title:	Reporting and Analysis Plan for A Phase I Open-Label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of GSK2820151 in Subjects with Advanced or Recurrent Solid Tumors [Study 201893]

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TABLE OF CONTENTS

Abbreviations

1,5 AG	1,5 –Anhydroglucitol
ADaM	Analysis Data Model
AE(s)	Adverse event(s)
AESI	Adverse events of special interest
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	Area under the curve
AUC(0-∞)	Area under the curve from zero to infinity
AUC(0-τ)	Area under the plasma concentration-time curve
BET	Bromodomain & Extra-Terminal
BRD	Bromodomain
β-hCG	Beta-human chorionic gonadotropin
BUN	Blood urea nitrogen
Cav	Average observed concentration
CDISC	Clinical Data Interchange Standards Consortium
CK	Creatine kinase
CKMB	Creatine kinase MB isoenzyme
CL/F	Clearance
Cmax	Maximum observed concentration
CPMS	Clinical Pharmacology Modelling and Simulation
CR	Complete response
CRF	Case report form
CSR	Clinical Study Report
Cτ	Trough concentration
CV	Cardiovascular
CV%	Percentage coefficient of variance
DLT	Dose-limiting toxicity
ECG	Electrocardiogram
eCRF	Electronic case report form
FTIH	First time in human
GSK	GlaxoSmithKline
HDL	High-density lipoprotein
HGB	Hemoglobin
ICH	International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDSL	Integrated Data Standards Library
IEC/IRB	Independent ethics committee/institutional review board
IL-6	Interleukin 6
INR	International normalized ratio
LDL	Low-density lipoprotein
LLN	Lower limit of normal

LPS	Lipopolysaccharide
LVEF	Left ventricular ejection fraction
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram(s)
msec	Millisecond(s)
MTD	Maximum tolerated dose
NCI-CTCAE	National Cancer Institute- Common Terminology Criteria for Adverse Events
N-CRM	Neuenschwander - Continuous Reassessment Method
NQ	Non-quantifiable
NT-proBNP	N-terminal pro–B-Type natriuretic peptide
ORR	Objective response rate
PD	Progressive disease
PFS	Progression free survival
PGx	Pharmacogenomics
PK	Pharmacokinetics
PR	Partial response
PT	Preferred term
PTT	Partial thromboplastin time
FACTS	Fixed and Adaptive Clinical Trial Simulator
QTc	Corrected QT interval
QTcF	Corrected QT (Fridericia's formula)
RAP	Reporting and Analysis Plan
RBC	Red Blood Cell
RECIST	Response criteria in solid tumors
Ro	The observed accumulation ratio
RP2D	Recommended Phase 2 dose
SAE(s)	Serious adverse event(s)
SOC	System organ class
SD	Stable disease
t½	Apparent terminal phase half-life
tmax	Time to Cmax
TSH	Thyroid Stimulating Hormone
TTE	Time to event
ULN	Upper limit of normal
Vz/F	Volume of distribution
WBC	White blood cells

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1. INTRODUCTION

This reporting and analysis plan (RAP) details all planned analyses required for a Clinical Study Report of study 201893. This is a first time in human (FTIH), open-label, dose escalation study will assess the safety, pharmacokinetics (PK), pharmacodynamics, and preliminary clinical activity of GSK2820151 in subjects with advanced or recurrent solid tumors.

For further information on the study design, see Protocol Amendment dated 08-JUN-2017 (2014N215112_04).

The RAP was written by staff of ICON Clinical Research. The execution of the RAP, with exception to Neuenschwander - Continual Reassessment Method (N-CRM) - based analyses using the Fixed and Adaptive Clinical Trial Simulator (FACTS), will be undertaken by staff of ICON Clinical Research.

All decisions regarding final analysis, as defined in this RAP document, have been made prior to Database Freeze of the study data. Effective November 17 2017, GSK has made the difficult decision to discontinue the development of GSK2820151 in solid tumors. This decision was made after careful consideration of the following factors:

- With the increasing amount of clinical data now available on Bromodomain & Extra-Terminal (BET) inhibitors, the opportunity for GSK2820151 to show a differentiated profile with significant additional clinical benefit has decreased.
- With more than 15 BET inhibitors in clinical development, it was very challenging to enroll to the BET inhibitor study (201893), which enrolled only 4 subjects over a period of 1.5 years.

At the time the study termination decision was made, one subject was still receiving treatment. The study terminated when the last subject completed last scan on
November 18 2018 and showed disease progression. A total of 5 subjects have enrolled into the study.

Due to the early termination decision and the small number of subjects, only listings of the data will be generated.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Protocol Section	Change from Protocol	Rationale
Section 11.4.2 Interim Analysis	No interim analysis in SAP	Sponsor made the decision to terminate the study early and no interim analysis needed
Section 11.2 Continual Reassessment Method	No N-CRM analysis in SAP	Sponsor made the decision to terminate the study early and did not get into N-CRM analysis phase
Section 11 Statistical Considerations and Data Analyses	No summary tables and figures No statistical analysis of pharmacokinetic parameters	Sponsor made the decision to terminate the study early and no tables/figures needed, only listings provided
Section 8.3.9 Clinical Safety Laboratory Assessments	No Creatinine Phosphokinase	This test was not collected per CRF
Section 11.5.3 Other Analyses	No biomarker, pharmacodynamics exploratory analyses performed	Sponsor made decision that biomarkers samples were not collected after 11Jan2018 and the biomarker samples collected by 11Jan2018 were destroyed.

2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary	
• To determine the safety, tolerability and maximum tolerated dose (MTD) of GSK2820151 in subjects 18 years or older with advanced or recurrent solid tumors.	• Adverse events (AEs), serious adverse events (SAEs), dose reductions or delays, withdrawals due to toxicities and changes in safety assessments (e.g., laboratory parameters, vital signs, electrocardiogram (ECG), cardiotoxicity, gastrointestinal, etc.)
Secondary	

Objectives	Endpoints
• To determine a recommended Phase 2 dose (RP2D) of GSK2820151 in subjects 18 years or older.	• Safety profile (AEs, SAEs, dose-limiting toxicities [DLTs]), clinical response, and pharmacodynamics data
• To characterize the PK of GSK2820151 in subjects 18 years or older.	• PK parameter values for GSK2820151 following single and repeat-dose oral administration in subjects 18 years or older.
• To evaluate the effect of treatment with GSK2820151 on tumor growth and subject survival.	• Objective response rate (ORR) by various imaging modalities and progression free survival (PFS).
• To evaluate cardiac safety, including the potential for corrected QT interval (QTc) prolongation, of GSK2820151 and to assess PK/QTc relationship.	• Changes in cardiac safety including QTc following single and repeat-dose oral administration of GSK2820151.
Exploratory	
• To evaluate the exposure response (pharmacokinetic/pharmacodynamics [PK/PD]) relationship between GSK2820151 and safety and efficacy parameters.	• Dose-related change in molecular markers (e.g., gene transcription and/or expression of proteins regulated by BRD proteins) in peripheral blood samples.
• To evaluate systemic and ex vivo on-target BET inhibitory effects	• Changes from baseline and dose/response relationship in ex vivo lipopolysaccharide (LPS)-induced cytokines, including interleukin 6 (IL-6), in whole blood, and systemic cytokines, including IL-6.
• To identify potential indicators of sensitivity or response to GSK2820151.	• Transcriptomic studies of blood; correlation of baseline genetic and genomic profiles with response.

2.3. Statistical Hypotheses

The primary endpoints of this study are safety and tolerability; the MTD and RP2D will also be determined. No formal statistical hypotheses will be tested. The primary focus will be on determining the recommended dose for further exploration, the safety profile, and the PK of GSK2820151 in subjects with advanced cancer. Analyses will be descriptive and exploratory.

2.4. Pharmacokinetic (PK) and PK/Pharmacodynamic Hypotheses

There is no formal statistical hypothesis for PK and pharmacodynamic analyses.

2.5. Study Design

This study is a single-agent, open-label, dose-escalation study to determine the MTD (and RP2D), based on the safety, pharmacokinetic, and pharmacodynamic profiles observed after oral administration of GSK2820151. Eligible subjects with advanced or recurrent solid tumors will be enrolled in the dosing cohorts until MTD is established. All subjects will receive study drug. Subjects may continue treatment in the study until disease progression, unacceptable toxicity, or withdrawal of consent (for specific stopping criteria, see Protocol Section 5.4). The duration of study will depend on recruitment rates and the timing of subjects' duration on study (withdrawal rates due to toxicity or progression).

This study will utilize an accelerated dose escalation phase in order to minimize suboptimal drug exposures, followed by a conventional 3+3 dose escalation phase to achieve MTD. Initially, one subject per dose cohort will be recruited (accelerated dose escalation phase) until the first instance of a ≥ Grade 2 drug related non-hematological
toxicity or dose-limiting toxicity (DLT, see Protocol Section 4.2.4). Further cohorts will be recruited in blocks of three subjects (3+3 dose escalation phase). Additional subjects may be enrolled at previously cleared dose levels in order to obtain further data for PK and/or pharmacodynamic analysis. Once MTD is determined, additional subjects (18 subjects total at MTD) may be enrolled to collect additional safety data (Figure 1). The total duration of study for each subject will be dependent upon the safety, tolerability and efficacy of GSK2820151.

In the accelerated dose escalation cohorts and the 3+3 dose escalation cohorts, the dose will be escalated based on PK data, the safety profile of the current and prior cohorts, as well as the predicted DLT rates on all potential doses from the N-CRM analysis [Neuenschwander, 2008]. N-CRM design is a type of Bayesian adaptive dose-escalation scheme (see Protocol Section 11.2). The method is fully adaptive and makes use of all the DLT information available at the time of each dose assignment. The DLT information of all subjects enrolled in the trial are used to update the estimated dose-toxicity relationship and provide supportive information in addition to the 3+3 design in the next escalation/de-escalation decision.

The RP2D will be determined based on the MTD or biologically active dose (example:clinical response), the safety profile, and available pharmacodynamic data generated from all subjects. If necessary alternate schedules can be explored to determine additional biologically active doses even after a RP2D is defined.

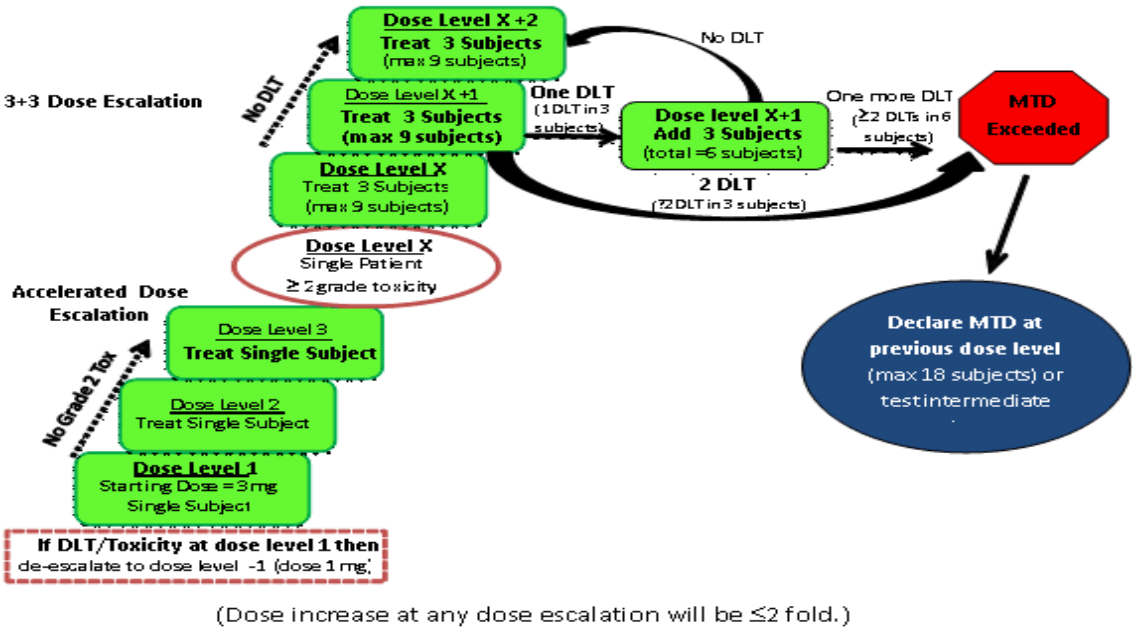

Figure 1: Dose Escalation Scheme

Projected dose levels are 3 mg, 6 mg, 12 mg, 20 mg, 40 mg, 60 mg, 100 mg, 150 mg, 200 mg, and 300 mg. Additional doses and schedules may be explored based on emerging safety, PK, and pharmacodynamic data. Actual dose escalation doses and decisions, based on observed data, will be executed based on guidance described in Protocol Section 4.2.2 and Protocol Section 4.2.3.

The schedule for study assessments can be found in Protocol Section 8.

3. PLANNED ANALYSES

In line with ICH E9 [European Agency for the Evaluation of Medicinal Products, 1998], membership of the analysis populations will be determined using the definitions in Section 5 of this RAP.

3.1. Interim Analyses

Interim PK data was reviewed at dose escalation meeting at each dose by GSK. Non Compartment analyses for Dose Escalation Cohorts was performed using Phoenix Winnonlin version 6.4 or higher under the supervision of clinical Pharmacology Modeling and Simulation (CPMS), GSK.

No N-CRM analysis was performed for the study due to the termination of the study.

3.2. Final Analyses

Final analyses will be performed after all subjects have permanently discontinued study treatment and the final study database is frozen.

See Sections 5 to 16 for details regarding the planned analyses and description of displays to be produced.

4. SAMPLE SIZE CONSIDERATIONS

4.1. Sample Size Assumptions

The total number of subjects to be enrolled into this study will depend on the number of subjects needed to characterize individual dose cohorts for the determination of the maximum tolerated dose of GSK2820151; the final sample size is not driven by statistical considerations. However, it is anticipated that approximately 30 to 50 subjects will be enrolled with a maximum of 80 subjects.

4.2. Sample Size Re-estimation or Adjustment

No sample size re-estimation will be performed.

5. ANALYSIS POPULATIONS

5.1. All Enrolled Population

The **All Enrolled Population** is defined as all subjects who have consented to participate in the study and have not screen failed.

5.2. All Treated Population

The **All Treated Population** is defined as all subjects who receive at least one dose of GSK2820151. Safety and anti-cancer activity will be evaluated based on this analysis population.

5.3. PK Population

The **PK Population** will consist of all subjects from the All Treated Population for whom a PK sample is obtained and analysed.

5.4. Analysis Datasets

Analysis datasets will be created according to Clinical Data Interchange Standards Consortium (CDISC) version 3.1.3/ Analysis Data Model (ADaM) version 1.0 standards, and data will be listed according to GSK Integrated Data Standards Library (IDSL) reporting standards. Formatting for dates, times, and decimal places will follow GSK standards except where specified.

6. TREATMENT COMPARISONS

There are no treatment comparisons in the study.

6.1. Data Display Treatment and Other Subgroup Descriptors

Unless otherwise stated, all data will be pooled and listed by investigated GSK2820151 dose cohorts.

7. GENERAL CONSIDERATIONS FOR DATA ANALYSES

SAS 9.3 or higher version will be used to perform all data analyses and generate listings. Data in the database will be presented in by-subject data listings.

8. DATA HANDLING CONVENTIONS

8.1. Premature Withdrawal and Missing Data

Because study treatment is dependent on the study endpoints (e.g., progression, i.e. not a fixed treatment duration), the length of treatment for each subject will depend on the efficacy and toxicity of the treatment, so the duration of treatment will vary across subjects. Similarly the duration of follow up will also vary. All available PFS data will be analyzed using suitable statistical methods; subjects with shorter treatment and follow-up due to the natural history of their disease or medical necessities of the treatment of their disease will not be considered to have missing PFS data. For endpoints which determine the percentage of responders, subjects with unknown/not evaluable or missing best overall response will be assumed to be non-responders, and will be included in the denominator when calculating the percentages.

In the event that the study is terminated, all available data will be listed.

Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument. These data will be indicated by the use of a "blank" in subject listing displays. Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.

There will be no other imputation for missing data other than what's described in Section 8.2 for partial dates and for missing exposure end dates.

8.2. Derived and Transformed Data

The following sections provide a general description of the derived and transformed variables used to describe and analyze the data. Separate analysis dataset specifications provide full details on all data derivations and transformations including descriptions of core standard algorithms and standard oncology algorithms. The analysis dataset specifications will clearly communicate the content and source of the datasets supporting the statistical analyses.

8.2.1. Reference dates

Unless otherwise stated, the safety reference (start) date will be the start of treatment of GSK2820151. This will also be the efficacy reference date for this study. The reference date for baseline characteristics (e.g. age) will be the date of screening.

8.2.2. Study Day for Safety Measures

If the date of interest occurs on or after the safety reference date then the safety study day will be calculated as (date of interest - safety reference date) + 1. If the date of interest occurs before the safety reference date then the safety study day will be calculated as (date of interest-safety reference date). There is no safety study day 0.

8.2.3. Study Day for Efficacy

If the date of interest occurs on or after the efficacy reference date then efficacy study day will be calculated as (date of interest - efficacy reference date) + 1. If the date of interest occurs prior to the efficacy reference date

then efficacy study day will be calculated as (date of interest – efficacy reference date). There is no efficacy study day 0.

8.2.4. Duration and Elapsed Time

Durations (e.g., the duration of an AE, duration of exposure, etc.) are calculated as the stop date minus the start date plus one.

For elapsed time (e.g., the time since initial diagnosis):

- If the reference date is on or after the event date, then the elapsed time is the reference date minus the event date + 1.
- If the reference date is before the event date then the elapsed time is the reference date minus the event date.

When reporting time to event (TTE) durations in months, divide the number of days by 30.4375; to report in weeks divide the number of days by 7; to report in years divide the number of days by 365.25. These algorithms for time to event return decimal numbers, and ignore the actual numbers of days in the months or years between start date and stop date. The "year" used in these algorithms is 365.25 days long, and the "month" is one twelfth of that year.

8.2.5. Imputation of Partial Dates

Imputed partial dates will not be used to derive study day, duration (e.g., duration of AEs), or elapsed time variables. In addition, imputed dates are not used for deriving the last contact date in progression free survival analysis dataset.

Imputed dates will not be displayed in listings. However, where necessary, display macros may impute dates as temporary variables for the purpose of sorting data in listings only. Partial dates may be imputed as outlined below.

The partial date imputation will follow ADaM conventions. The ADaM approach is to populate the numeric date variables with the imputed date and add a flag variable to the dataset that indicates the level of imputation.

The flag variable can contain the values: blank, 'D', 'M', 'Y'.

blank: indicates that no imputation was done

D='Day': indicates that the day portion of the date is imputed

M='Month': indicates that the month and day portions of the date are imputed

Y='Year': indicates that the entire date (year, month, and day) is imputed

Example of Date Variables:

XYZD_ - character date variable

XYZDT - numeric date variable

XYZDTFL - flag variable

Details on imputing partial dates for specific datasets are outlined below.

Adverse Events (AE):

Imputations in the adverse events dataset are used for slotting events to the appropriate study time periods and for sorting in data listings.

Dataset	Date	Missing Element	Rule
Adverse Events (AE)	Start Date	day, month, and year	• No Imputation for completely missing dates
		day, month	• If study treatment start date is missing (i.e. subject did not start study treatment), then set start date = January 1. • Else if study treatment start date is not missing: o If year of start date = year of study treatment start date then • If stop date contains a full date and stop date is earlier than study treatment start date then set start date = January 1. • Else set start date = study treatment start date. o Else set start date = January 1.
		day	• If study treatment start date is missing (i.e. subject did not start study treatment), then set start date = 1st of month. • Else if study treatment start date is not missing: o If month and year of start date = month and year of study treatment start date then • If stop date contains a full date and stop date is earlier than study treatment start date then set start date= 1st of month. • Else set start date = study treatment start date. o Else set start date = 1st of month.
	End Date		• No imputation for partial end dates will be performed

Anticancer Therapy and Radiotherapy, Surgery, Concomitant Medication and Blood and Blood Supportive Care Products:

Start dates are generally not imputed. If start dates need to be imputed for sorting in data listings, the rules of imputation is defined as below:

Dataset	Date	Missing Element	Rule
Anticancer Therapy Radiotherapy Surgical Procedures Concomitant Medication Blood and Blood Supportive Care Products	Start Date	day, month, and year	• No Imputation for completely missing dates
		day, month	• If partial date contains a year only set to January 1st.
		day	• If partial date contains a month and year set to the 1st of the month.

Time to Event and Overall Response:

Start dates for follow-up anticancer therapy, radiotherapy (where applicable), and surgical procedures (where applicable) will be temporarily imputed in order to define event and censoring rules for progression-free survival, response rate, or duration of response (i.e. start date for new anticancer therapy). Dates will only be imputed when a month and year are available but the day is missing. The imputed date(s) will not be stored on the anticancer therapy, radiotherapy, or surgical procedure datasets. The following rules will be used to impute the date when partial start dates are present on anticancer therapy radiotherapy, and/or surgical procedures dataset[s]:

Dataset	Date	Missing Element	Rule
Anticancer Therapy Where applicable: Radiotherapy Surgical Procedures	Start Date	day, month, and year	• No Imputation for completely missing dates

Dataset	Date	Missing Element	Rule
		day, month	• No imputation for missing day and month (note the eCRF should only allow for missing day)
		day	• If partial date falls in the same month as the last dose of study treatment, then assign to earlier of (date of last dose of study treatment+1, last day of month). • If partial date falls in the same month as the subject's last assessment and the subject's last assessment is PD, then assign to earlier of (date of PD+1, last day of month). • If both rules above apply, then assign to latest of the 2 dates • Otherwise, impute missing day to the first of the month.
	End Date		• No imputation for partial end dates will be performed

The date of new anticancer therapy is derived as the earliest date of new anticancer therapy (e.g., chemotherapy), radiotherapy (where applicable), or cancer related surgical procedure (where applicable) and will include imputed dates.

8.2.6. Imputation of Missing Exposure End Dates

In general, completely missing dates are not imputed. However, subjects in oncology trials may still be on study treatment when analyses are performed and so may have missing exposure end dates in their last dosing record. Missing exposure end dates will be imputed. For subjects with missing exposure end dates at the time of data cutoff, the exposure end date will be imputed to the earliest of: the date of the data cutoff, the date of withdrawal from the study, or the death date. The imputed exposure end date will be used to calculate cumulative dose and exposure duration. Imputed exposure end dates will be stored on the study treatment end date variable.

8.2.7. Baseline Definition

Baseline will be defined as the most recent, non-missing value prior to or on the first study treatment dose date for GSK2820151. For laboratory data, baseline will be defined as the most recent, non-missing value from a central laboratory prior to or on the first study treatment dose date. If there are no central labs collected for a subject and lab test prior to or on the first dose of study treatment, the most recent, non-missing value from a local laboratory prior to or on the first dose of study treatment will be defined as the baseline value.

If the latest pre-dose value is collected on the day of treatment, the time of treatment will be used to identify the baseline value. If the pre-dose time point value is identified as baseline, and the data is recorded in triplicate the average will be used.

For subjects who did not receive study treatment during the study, baseline will be defined as the latest, non-missing collected value.

8.2.8. Change from baseline

Change from baseline will be presented for ECG and ECOG data as described in Section 11.

Change from baseline is calculated as:

- For records occurring after baseline: (visit value) – baseline value.

For the triplicate measurements, the average value will be used as visit value.

Unless otherwise stated, if either the baseline or visit value is missing, the change from baseline and/or percent change from baseline is set to missing as well.

8.2.9. Multiple Assessments

Data from all assessments (scheduled and unscheduled), including multiple assessments, will be included in listings.

8.2.10. Actual Treatment

A subjects' actual treatment will be derived from exposure data.

8.2.11. Extended Loss to Follow-up or Extended Time without an Adequate Assessment

If two or more scheduled disease assessments are missed and are then followed by an assessment of progressive disease (PD) or death, PFS will be censored at the last adequate assessment prior to PD or death. As the scheduled disease assessment is every 8 weeks, a window of 119 days (16 weeks + 7 day window) will be used to determine whether there was an extended time without adequate assessment. That is, if the time difference between PD/death and last adequate assessment is more than 119 days, then PFS will be censored at the last adequate assessment prior to PD/death.

8.2.12. Date Associated with Response

For each disease assessment after baseline, a date will be associated with the response based on collective group of disease assessments made within the protocol visit window. For complete response (CR) and partial response (PR), this will be assigned to the latest date within the disease assessments. For stable disease (SD), Non-CR/Non-PD or Not Evaluable, this will be assigned to the earliest date within the disease assessments. For PD, assign to the earliest assessment date associated with the progression.

8.3. Values of Potential Clinical Importance

8.3.1. Laboratory Parameters

Reference ranges for all laboratory parameters collected throughout the study are provided by the laboratory. A laboratory value that is outside the reference range is considered either high abnormal (value above the upper limit of the reference range) or low abnormal (value below the lower limit of the reference range). Note: a high abnormal or low abnormal laboratory value is not necessarily of clinical concern. The laboratory reference ranges will be provided on the listings of laboratory data. Clinical laboratory test results outside of the reference range will be flagged in the listings.

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v4.03 [NCI-CTCAE, 2010]) will be used to assign grades to the relevant laboratory parameters.

8.3.2. Vital Signs

To identify heart rate values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Sinus bradycardia', 'Sinus tachycardia', 'Supraventricular tachycardia', and 'Ventricular tachycardia'.

The following criteria will be used to flag vital sign values that are values of potential clinical importance:

Vital Sign Parameter	**Potential Clinical Importance (PCI) Range**	**Unit**
Decrease from baseline Heart Rate	Decrease to <60	bpm
Increase from baseline Heart Rate	Increase to >100	bpm

To identify blood pressure values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypertension'.

Vital Sign Parameter	**Potential Clinical Importance (PCI) Range**	**Unit**
Increase from baseline Systolic Blood Pressure	≥120 to <140 (Grade 1) ≥140 to <160 (Grade 2) ≥160 (Grade 3)	mmHg
Increase from baseline Diastolic Blood Pressure	≥80 to <90 (Grade 1) ≥90 to <100 (Grade 2) ≥100 (Grade 3)	mmHg

Systolic blood pressure below 120 mmHg and diastolic blood pressure below 80 mmHg are considered as normal range and will receive Grade 0 designations.

To identify temperature values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypothermia' and 'Fever'.

Vital Sign Parameter	Potential Clinical Importance (PCI) Range	Unit
Increase from baseline temperature	Increase to ≥38	Degrees C
Decrease from baseline temperature	Decrease to ≤35	Degrees C

9. STUDY POPULATION ANALYSES

Unless otherwise stated, all data listings in this section will be based on the All Treated Population.

9.1. Disposition of Subjects

A listing of reasons for study withdrawal will be generated. A listing of study treatment discontinuation will be generated. The listing will include last dose date, and reasons for study treatment discontinuation.

9.2. Protocol Deviations

All protocol deviations will be listed. A separated listing of inclusion/exclusion deviations will also be provided.

9.3. Demographic and Baseline Characteristics

The demographic characteristics (e.g., age, sex, ethnicity, race, baseline height, and baseline weight, body mass index) will be listed.

Race and racial combinations, and family history will be listed.

Disease characteristics, as well as these medical conditions, will be presented in data listings.

Prior anti-cancer therapy will be coded using GSK Drug coding dictionary and listed. A listing of prior anti-cancer therapy will show the relationship between Anatomical Therapeutic Chemical (ATC) Level 1, Ingredient, and verbatim text.

Prior anti-cancer radiotherapy will be listed. Prior cancer and non-cancer related surgeries will be listed.

9.4. Treatment Compliance

A listing of scheduled and actual treatments will be produced.

9.5. Concomitant Medications

Concomitant medications will be coded using GSK Drug coding dictionary and listed. Listing for blood products or blood supportive care products will be provided.

9.6. Subsequent Anticancer Therapies

Follow-up anticancer therapy will be coded using GSK Drug coding dictionary. A data listing for follow up anticancer therapy will be provided.

Any follow-up anticancer surgeries will be listed.

10. EFFICACY ANALYSES

The evaluation of anticancer activity will be evaluated based on the All Treated Population as defined in Section 5 unless otherwise specified. Since this is a Phase I study, anticancer activity will be evaluated based on clinical evidence and response criteria. Due to the very limited number of subjects, ORR was not calculated. It can be counted from the investigator assessed response listings if need.

Lesion Assessment and Response

Lesion assessment method and timing, evaluation of disease, disease progression and response criteria will be conducted according to Response Evaluation Criteria in Solid Tumors (RECIST version 1.1) [Eisenhauer EA. etc, 2009] as outlined in Appendix 8 of the protocol. Data listings for response will be provided.

Progression-Free Survival (PFS)

PFS is defined as the interval of time (in weeks) between the start date of treatment and the earlier of the date of disease progression and the date of death due to any cause. Disease progression will be based on the assessments by the Investigator.

The date of documented disease progression will be defined as the date of disease progression based on eCRF entries. If an assessment occurs over multiple days, the earliest date of progression will be used. The date of death should be taken from the Record of Death page. Death on study due to any cause will be included.

If there is no adequate baseline assessment, the subjects will be censored at their start date of treatment. Subjects without any adequate post-baseline tumor assessments will be censored at the start date of treatment. If the subject received subsequent anti-cancer therapy prior to the date of documented events, PFS will be censored at the last adequate assessment (e.g. assessment where visit level response is CR, PR, or SD) prior to the initiation of therapy. Progressive disease (PD) will also be defined per RECIST 1.1 criteria. Otherwise, if the subject does not have a documented date of events, PFS will be censored at the date of the last adequate assessment.

Subjects who progressed or died after an extended period without adequate assessment will be censored at their date of last adequate assessment prior to progression or death even if subsequent information is available regarding progression or death. The date of response at that assessment will be used for censoring. As the assessment schedule may change through the course of the protocol, specific rules for identifying extended loss to follow-up or extended time without an adequate assessment are provided in Section 8.2.11.

For subjects who receive subsequent anticancer therapy the following rules will apply:

- If the start date of the anticancer therapy is partial (i.e. either missing the day but has the month and year available or missing both day and month), the imputation rules described in Section 8.2.5 will be applied. No imputation will be made for completely missing dates.

- If anticancer therapy is started without documented disease progression or is started prior to documented disease progression, then PFS will be censored at the date of the last adequate assessment that is no later than the date of initiation of anticancer therapy (i.e. if an assessment occurs on the same day as the start of new anticancer therapy the assessment will be used - as it will be assumed the assessment occurred prior to the administration of new anticancer therapy). The date of response at the last adequate assessment will be used as the censoring value.

A summary of the assignments for progression and censoring dates for PFS are specified in the following table.

Table 1. Assignments for Progression and Censoring Dates for PFS Analysis

Situation	**Date of Event (Progression/Death) or Censoring**	**Outcome Event (Progression/Death) Or Censored**
No *(or inadequate)* baseline tumor assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	Start Date of Treatment	Censored
No post-baseline assessments and the subject has not died (if the subject has died follow the rules for death indicted at the bottom of the table)	Start Date of Treatment	Censored
Progression documented between scheduled visits	Date of assessment of progression[1]	Event
No progression *(or death)* and no initiation of new anti-cancer therapy	Date of last 'adequate' assessment of response[2]	Censored
Received subsequent anti-cancer therapy prior to the date of documented events	Date of last 'adequate' assessment of respnose[2,3] (*prior to starting initiation of therapy*)	Censored
Received subsequent anti-cancer therapy prior to any adequate assessment	Start Date of Treatment	Censored
Received subsequent anti-cancer therapy and no progression *(or death)*	Date of last 'adequate' assessment of respnose[2,3] (*prior to starting initiation of therapy*)	Censored
Death or progression after more than one missed visit	Date of last 'adequate' assessment of response[2] *(prior to missed assessments)*	Censored
Death	Date of Death	Event

1. The earliest of (i) Date of radiological assessment showing new lesion (if progression is based on new lesion); or (ii) Date of radiological assessment showing unequivocal progression in non-target lesions, or (iii) Date of last radiological assessment of measured lesions (if progression is based on increase in sum of measured lesions)
2. An adequate assessment is defined as an assessment where the Investigator determined response is CR, PR, or SD.
3. If PD and New anti-cancer therapy occur on the same day assume the progression was documented first e.g., outcome is progression and the date is the date of the assessment of progression). If anti-cancer therapy is started prior to any adequate assessments, censoring date should be the start date of treatment.

11. SAFETY ANALYSES

Unless otherwise specified, all the safety analyses will be based on the All Treated Population as defined in Section 5.

11.1. Extent of Exposure

Extent of exposure to GSK2820151 will be listed. The subject's average daily dose, defined as the cumulative dose divided by the duration of exposure for each subject, will be listed.

All dose reductions and dose interruptions will be listed separately.

11.2. Adverse Events

AEs will be coded to the preferred term (PT) level using the Medical Dictionary for Regulatory Affairs (MedDRA dictionary version 21.1) and grouped by system organ class (SOC). AEs will be graded by the investigator according to the NCI-CTCAE v4.03.

All AEs will be listed.

11.3. Adverse Events of Special Interest

For any cardiovascular events detailed in Protocol Appendix 6 and all deaths, whether or not they are considered SAEs, specific Cardiovascular (CV) and Death sections of the eCRF will be required to be completed. These sections include questions regarding cardiovascular (including sudden cardiac death) and non-cardiovascular death. CV and death data will be listed separately.

11.4. Deaths and Serious Adverse Events (SAEs)

In the event that a subject has withdrawn consent, no data after the withdrawal of consent date from this subject including death is supposed to appear in the database, which should be part of the data cleaning process. A listing will be generated to provide subject-specific details on subjects who died.

SAEs are included in the listing of all adverse events. Separate supportive listings with subject-level details will be generated for

- Fatal SAEs
- Non-Fatal SAEs.

Primary and secondary cause of death will be presented in subject data listings.

11.5. Adverse Events Leading to Discontinuation of Study Treatment and/or Withdrawal from the Study and Other Significant Adverse Events

Separate AEs supportive listings will be generated with subject level details for those subjects:

- AEs leading to discontinuation of study treatment
- AEs leading to withdrawal from the study
- AEs leading to dose interruptions
- AEs leadings to dose reductions

11.6. Clinical Laboratory Evaluations

The assessment of laboratory toxicities will examine the following laboratory tests:

Clinical Chemistry: Total and direct bilirubin, Aspartate aminotransferase (AST), Alanine aminotransferase (ALT), Alkaline phosphatase, Total Protein, Albumin, Sodium, Potassium, Calcium, Blood Urea Nitrogen (BUN), Creatinine, Chloride, Fasting Glucose, Ionized Calcium, Gamma-glutamyltransferase, Total carbon dioxide , Uric Acid, and Magnesium.

Hematology: Hemoglobin (HGB), Platelet count, Red Blood Cell (RBC) count, White Blood Cell (WBC) count, Neutrophils (Absolute), Lymphocytes (Absolute), Monocytes (Absolute), Eosinophils (Absolute), Basophils (Absolute), Neutrophils (%), Lymphocytes (%), Monocytes (%), Eosinophils (%) and Basophils (%).

Thyroid Function Test: Thyroid-stimulating hormone (TSH) and free thyroxine (T4 and T3) test.

Urinalysis: pH, Microscopic examination, Specific gravity, Ketones, Protein, Glucose, Blood.

Coagulation Test: Prothrombin Time, Partial Thromboplastin Time (PTT), International Normalized Ratio (INR), and Fibrinogen.

Pancreatic Markers: Amylase, Lipase.

Lipid Panel: Triglycerides, Total Cholesterol, low density lipoprotein (LDL), and high density lipoprotein (HDL).

Serum: Creatine Kinase (CK), Creatine Kinase-MB isoenzyme (CKMB), Troponin I, Troponin T, N-terminal pro–B-Type natriuretic peptide (NT-proBNP), Thyroid-stimulating hormone (TSH), C-Peptide, 1,5-Anhydroglucitol (1,5 AG), Hemoglobin A1C, and Insulin.

Laboratory grades will be reported, where applicable, using the Common Terminology Criteria for Adverse Events (CTCAE v4.03). Listings of laboratory data will be provided.

11.7. Other Safety Measures

Vital Signs

A listing will be provided. Categories defined in Section 8.3.2 will be presented in the listing as well.

Performance Status

ECOG performance status will be listed. Change from baseline will be presented in the listing as well.

ECG

Listings of abnormal ECG findings and a listing of ECG values will be provided.

Left ventricular ejection fraction (LVEF)

LVEF results will be listed with subject level details including absolute change from baseline.

12. HEALTH OUTCOMES ANALYSES

No health outcomes analyses were planned for the study.

13. PHARMACOKINETIC ANALYSES

PK analysis of GSK2820151 drug concentration-time data and derivation of PK parameters will be conducted by non-compartmental methods using Phoenix WinNonlin Version 6.4 or higher under the direction of Clinical Pharmacology Modelling and Simulation (CPMS), GSK. Unless otherwise stated, all listings in this section will be based on the Pharmacokinetic population.

13.1. Drug Concentration Measures

Drug concentration-time data will be listed for each subject.

13.2. Deriving and Summarizing Pharmacokinetic Parameters

For subjects in the active treatment group, the pharmacokinetic parameters will be determined directly from the concentration-time data and will be extracted from the pharmacokinetic concentration file by CPMS GSK.

For the calculation of individual pharmacokinetic profiles, if one or more non-quantifiable (NQ) values occur in a profile before the first measurable concentration, they will be assigned a value of zero concentration. If a single NQ value occurs between measurable concentrations in a profile, the NQ should generally be omitted (set to missing) in the derivation of pharmacokinetic parameters. If two or more NQ values occur in succession between measurable concentrations, these NQs and any subsequent measurable concentrations will be omitted (set to missing) for the derivation of pharmacokinetic parameters.

NQs which occur after the last measurable concentration will be omitted (set to missing) in the derivation of pharmacokinetic parameters.

The following PK parameters will be determined if data permit:

- maximum observed concentration (Cmax)
- time to Cmax (tmax)
- area under the plasma concentration-time curve (AUC(0-t), AUC(0-∞) (Week1 Day1 only), AUC(0-τ))
- apparent terminal phase half-life (t½)
- Trough concentration (Cτ)
- The observed accumulation ratio (Ro)

  The ratio of AUC(0-τ) on Week 3 Day 4 / Week 1 Day 1 AUC(0-τ) will be calculated to assess time invariance.
- Clearance (CL/F) and Volume of distribution (Vz/F)

All derived PK parameters will be listed.

14. PHARMACOGENETIC DATA ANALYSES

Further details on PGx analyses discussed in the protocol may be identified/addressed in a separate RAP, if applicable.

15. REFERENCES

Eisenhauer EA, Therasse P, Bogaerts J, Schwartz LH, et al. New response evaluation criteria in solid tumors: Revised RECIST guidelines (version 1.1). Eur J Cancer. 2009; 45: 228-247.

NCI-CTCAE (NCI Common Terminology Criteria for Adverse Events), Version 4.03, DCTD, NCI, NIH, DHHS, June 14, 2010.

Neuenschwander B, Branson M, Gsponer T. Critical aspects of the Bayesian approach to phase I cancer trials. *Statistics Med*. 2008; 27:2420-2439.

16. APPENDIX 1: LIST OF DATA DISPLAYS

16.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Listings
ICH Listings	1 to 46
Non-ICH Listings	47 to 53

16.2. Deliverable

Delivery	Description
SAC	Final Statistical Analysis Complete

16.3. ICH Listings

No.	Population	Title	Programming Notes	Deliverable
Subject Disposition				
1.	All Treated	Listing of Subject Consent	ICH E3	SAC
2.	All Treated	Listing of Scheduled and Actual Treatment	ICH E3	SAC
3.	All Treated	Listing of Reasons for Study Withdrawal	ICH E3	SAC
4.	All Treated	Listing of GSK2820151 Treatment Discontinuations	ICH E3	SAC
Protocol Deviations				
5.	All Treated	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3	SAC
6.	All Treated	Listing of Protocol Deviations		
Demographic and Baseline Characteristics				
7.	All Treated	Listing of Demographic Characteristics	ICH E3	SAC
8.	All Treated	Listing of Race	ICH E3	SAC
9.	All Treated	Listing of Family History	ICH E3	SAC
10.	All Treated	Listing of Medical Conditions	ICH E3	SAC
11.	All Treated	Listing of Disease Characteristics at Initial Diagnosis	ICH E3	SAC
12.	All Treated	Listing of Disease Characteristics at Screening	ICH E3	SAC
Prior and Concomitant Medications				
13.	All Treated	Listing of Prior Anti-Cancer Therapy	Study specific	SAC
14.	All Treated	Listing of Prior Anti-Cancer Radiotherapy	Study specific	SAC

No.	Population	Title	Programming Notes	Deliverable
15.	All Treated	Listing of Prior Cancer and Non-Cancer Related Surgical Procedures	Study specific	SAC
16.	All Treated	Listing of Concomitant Medications	ICH E3	SAC
17.	All Treated	Listing of Blood Products and Blood Supportive Care Products	Study specific	SAC
18.	All Treated	Listing of Follow-Up Anti-Cancer Therapy	Study specific	SAC
19.	All Treated	Listing of Follow-Up Surgical Procedures	Study specific	SAC
Exposure and Treatment Compliance				
20.	All Treated	Listing of Exposure to GSK2820151	ICH E3	SAC
21.	All Treated	Listing of Dose Interruptions	ICH E3	SAC
22.	All Treated	Listing of Dose Reductions	ICH E3	SAC
Adverse Events				
23.	All Treated	Listing of Adverse Events Profiles	ICH E3	SAC
Serious and Other Significant Adverse Events				
24.	All Treated	Listing of Fatal Serious Adverse Events	ICH E3	SAC
25.	All Treated	Listing of Non-Fatal Serious Adverse Events	ICH E3	SAC
26.	All Treated	Listing of Adverse Events Leading to Discontinuations of GSK2820151 Treatment Profiles	ICH E3	SAC
27.	All Treated	Listing of Adverse Events Leading to Dose Interruptions	ICH E3	SAC
28.	All Treated	Listing of Adverse Events Leading to Dose Reductions	ICH E3	SAC
29.	All Treated	Listing of Adverse Events Recorded as Dose-Limiting Toxicities	Study specific	SAC
30.	All Treated	Listing of Adverse Events of Special Interest	Study specific	SAC
31.	All Treated	Listing of Deaths	ICH E3	SAC
32.	All Treated	Listing of Subject Numbers for Specific Causes of Deaths	ICH E3	SAC
All Laboratory				
33.	All Treated	Listing of Clinical Chemistry Data	ICH E3	SAC
34.	All Treated	Listing of Hematology Data	ICH E3	SAC
35.	All Treated	Listing of Thyroid Function Test Data	ICH E3	SAC
36.	All Treated	Listing of Urinalysis Data	ICH E3	SAC
37.	All Treated	Listing of Coagulation Data	ICH E3	SAC

No.	Population	Title	Programming Notes	Deliverable
38.	All Treated	Listing of Pancreatic Markers Data	ICH E3	SAC
39.	All Treated	Listing of Lipid Panel Data	ICH E3	SAC
40.	All Treated	Listing of Serum Data	ICH E3	SAC
Vital Signs				
41.	All Treated	Listing of Vital Signs	ICH E3	SAC
ECOG				
42.	All Treated	Listing of ECOG Performance Status Scale	ICH E3	SAC
ECG and LVEF				
43.	All Treated	Listing of Abnormal ECG Findings	ICH E3	SAC
44.	All Treated	Listing of ECG Values	ICH E3	SAC
45.	All Treated	Listing of Change from Baseline ECG Values	ICH E3	SAC
46.	All Treated	Listing of Left Ventricular Ejection Fraction (LVEF) ECHO Results	ICH E3	SAC

16.4. Non-ICH Listings

No.	Population	Title	Programming Notes	Deliverable
Efficacy Endpoints				
47.	All Treated	Listing of Investigator-Assessed Response (RECIST 1.1)	Study specific	SAC
48.	All Treated	Listing of Investigator–Assessed Target Lesions (RECIST 1.1)	Study specific	SAC
49.	All Treated	Listing of Investigator–Assessed Non-Target Lesions (RECIST 1.1)	Study specific	SAC
50.	All Treated	Listing of Investigator–Assessed New Lesions	Study specific	SAC
51.	All Treated	Listing of Progression Free Survival (RECIST 1.1)	Study specific	

No.	Population	Title	Programming Notes	Deliverable
Pharmacokinetic				
52.	PK Population	Listing of GSK2820151 Pharmacokinetic Concentration-Time Data	ICH E3	SAC
53.	PK Population	Listing of Derived GSK2820151 Pharmacokinetic Parameters	ICH E3	SAC

Listing 1
Listing of Subject Consent

Country: xxxxxx
Investigator: xxxxx xxxxxx

Center/ Subject ID	Original Informed Consent			Reconsented			Pharmacogenetic Research Consent		
	Date	Consent Version	Protocol Version	Date	Consent Version	Protocol Version	Date	Reason	Date of Withdrawal
xxxx/ xxxxxx	ddMMMyyyy	xxx	xxx	ddMMMyyyy	xxx	xxx	ddMMMyyyy		
xxxx/ xxxxxx	ddMMMyyyy	xxx	xxx	ddMMMyyyy	xxx	xxx		xxx	
xxxx/ xxxxxx	ddMMMyyyy	xxx	xxx	ddMMMyyyy	xxx	xxx	ddMMMyyyy		ddMMMyyyy

Listing 2
Listing of Scheduled and Actual Treatment

Country: xxxxxx
Center: XXXX
Investigator: xxxxxx xxxxxx

Subject ID	Planned Treatment	Actual Treatment
xxxx	3 mg	3 mg
	6 mg	6 mg

Listing 3
Listing of Reasons for Study Withdrawal

Treatment = GSK2820151 xxx mg

Center/ Subject ID	Date of Withdrawal	Study Day	Primary Reason	Subreason
xxxx/ xxxxxx	ddMMMyyyy	x	Study closed/terminated	
xxxx/ xxxxxx	ddMMMyyyy	x	Lost to Follow-up	
xxxx/ xxxxxx	ddMMMyyyy	xx	Investigator discretion	
…				

Listing 4
Listing of GSK2820151 Treatment Discontinuations

Treatment = xxxxxx

Center/ Subject ID	Cumulative Dose (mg)	Date of Last Dose	Study Day	Primary Reason for Treatment Discontinuation
xxxxx/ xxxxxx	xxx	ddMMMyyyy	xx	xxxxxxxxxxxxxxxx
xxxxx/ xxxxxx	xxx	ddMMMyyyy	xx	xxxxxxxxxxxxxxxx
xxxxx/ xxxxxx	xxx	ddMMMyyyy	xx	xxxxxxxxxxxxxxxx
xxxxx/ xxxxxx	xxx	ddMMMyyyy	xx	Xxxxxxxxxxxxxxxx

Listing 5
Listing of Subjects with Inclusion/Exclusion Criteria Deviations

Treatment = xxxxxx

Center/ Subject ID	Type	Criterion
xxxxx/ xxxxxx	Inclusion	Written informed consent provided
xxxxx/ xxxxxx	Exclusion	Prior malignancy of the central nervous system or malignancies related to human immunodeficiency virus (HIV) or solid organ transplant
xxxxx/ xxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Listing 6
Listing of Protocol Deviations

Treatment = xxxxxx

Center/ Subject ID	Date of Deviation/ Study day	Category	Description
xxxxxx/ xxxxxx	ddMMMyyyy/ xx	Prohibited medication or device	xxxxxxxxxxxx
	ddMMMyyyy/ xx	Assessments and/or procedures/ Study treatment supply procedure	xxxxxxxxxxx
xxxxxx/ xxxxxxx	ddMMMyyyy/ xx	Eligibility criteria not met	xxxxxxx
xxxxx/ xxxxxx	ddMMMyyyy/ xx	Not withdrawn after developing withdrawal criteria/ Not discontinued from study treatment	xxxxxxx

Listing 7
Listing of Demographic Characteristics

Treatment = xxxxxx

Center/ Subject ID	Year of Birth[1]	Age (Years)	Sex	Child-bearing Potential	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
xxxxx/ xxxxxx	xxxx	xx	F	Pre-menarcheal	Hispanic or Latino	xxx.x	xx.x	xx.x
xxxxx/ xxxxxx	xxxx	xx	F	xxxxxxxxxxxxx	Not Hispanic or Latino	xxx.x	xx.x	xx.x
xxxxx/ xxxxxx	xxxx	xx	M		Not Hispanic or Latino	xxx.x	xx.x	xx.x

[1] For calculating age, birthdate is imputed as June 30 in the year of birth.

Listing 8
Listing of Race

Treatment = xxxxxx

Center/ Subject ID	Race
xxxxx/ xxxxxx	African American/African Heritage
	Asian - East Asian Heritage
xxxxx/ xxxxxx	White - White/Caucasian/European Heritage
xxxxx/ xxxxxx	African American/African Heritage

Listing 9
Listing of Family History

Treatment = xxxxxx

Center/ Subject ID	A family history of premature coronary artery disease in women <65 yrs or men <55 years in first degree relatives only?
xxxxx/ xxxxxx	Yes
xxxxx/ xxxxxx	No

Listing 10
Listing of Medical Conditions

Treatment = xxxxxx

Center/ Subject ID	Category	Medical Condition	Status	NCI CTCAE Grade	Classification
xxxxx/ xxxxxx	Cardiovascular Risk Factors	ANGINA PECTORIS	Current		xxxxx
		DIABETES	Past		xxxxx
		HYPERTENSION	Current	x	
			Current		xxxxx
			Current		xxxxxxxxxxx
			Not assessed		
	Other medical condition	xxxxx	Current		xxxx
		xxxxxxx	Past		xxxx
		xxxxxxxxx	Current	x	xxxx

NCI-CTCAE version 4.03

Programming note: As coding is not done for medical conditions in SDTM MH, please display MHTERM as verbatim term as in other AE listings.

Listing 11
Listing of Disease Characteristics at Initial Diagnosis

Treatment = xxxxxx

Center/ Subject ID	Primary Tumor Type	Date of Diagnosis/ Time Since Diagnosis (Months)	Histology of Tumor	Histological Grade	Primary Tumor HPV Status
xxxx/ xxxxxx	Bladder	ddMMMyyyy/10.2	xxxx	Well differentiated	Negative
xxxx/ xxxxxx	Xxxx	ddMMMyyyy/xxx.x	xxxx	xxx	xxxxxxxx

Listing 12
Listing of Disease Characteristics at Screening

Treatment = xxxxxx

Center/ Subject ID	Measurable Disease	Non Target Lesions	Stage	Progress on Therapy?	Date of Last Recurrence/Time from Last Recurrence (Months)	Metastatic/ Unresectable Disease	Number of Previous Radiotherapy Regimens
xxxx/ xxxxxx	Yes	Yes	III	YES	ddMMMyyyy/xx.x	Yes	2
xxxx/ xxxxxx	..	..	IIIA	NO	ddMMMyyyy/x.x	XXX	1

Listing 13
Listing of Prior Anti-Cancer Therapy

Treatment = xxxxxx

Center/ Subject ID	ATC Level 1/ Preferred Term/ Verbatim Text	Regimen Sequence/ Type [1]	Intent	Start Date/ Study Day/ Stop Date/ Study Day	Duration of Therapy (Days)	Small Molecule Targeted Therapy Type
xxxx/ xxxxxx	Endocrine & metabolic/ Cytoxan/ CYTOXAN	1/ C	Neo-Adjuvant	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xxx	AKT Inhibitor
	xxxxxxxxxx/ xxxxxxxxxx/ XXXXXXXX	x/ H	Induction	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xxx	

[1]Therapy Type: C=Chemotherapy, H=Hormonal Therapy, I=Immunotherapy, B=Biologic Therapy.

Listing 14
Listing of Prior Anti-Cancer Radiotherapy

Treatment = xxxxxx

Center/ Subject ID	Body Site	Cumulative Dose (unit)/ Intent	Start Date/ Study Day/ Stop Date/ Study Day	Duration of Therapy (Days)
xxxxxx/ xxxxxx	RIGHT UPPER LOBE LUNG	xxx (xxxx)/ Local/Regional	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xxx
xxxxxx/ xxxxxx	CHEST	xxx (xxxx)/ Palliative	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xxx
xxxxxx/ xxxxxx	COLON	xxx (xxxx)/ Local/Regional	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xx
xxxxxx/ xxxxxx	COLON	xxx (xxxx)/ Local/Regional	ddMMMyyyy/ xxx/ ddMMMyyyy/ xxx	xx

Listing 15
Listing of Prior Cancer and Non-Cancer Related Surgical Procedures

Treatment = xxxxxx

Center	Subject	Classification	Date of Procedure	Study Day	Verbatim Term
xxxxx	xxxx	Cancer related	ddMMMyyyy	-xx	
		Cancer related	ddMMMyyyy	xx	
	xxxx	Cancer related	ddMMMyyyy	xx	
xxxxx	xxxx	Cancer related	ddMMMyyyy	-xx	
		Other general	ddMMMyyyy	xxx	Hysterectomy

Listing 16
Listing of Concomitant Medications

Treatment = xxxxxx

Center/ Subject ID	ATC Level 1/ Ingredient/ Verbatim Text	Dose/ Units/ Freq/ Route	Date Started/ Study Day	Date Stopped/ Study Day	Medication Category	Reason For Medication
xxxxx/ xxxxxx	Fluticasone propionate/ FLIXOTIDE/ Asthma	xx/ MG/ 2XD/ IH	ddMMMyyyy/ xx	ddMMMyyyy/ xx	General Concomitant Medication	xxxxx
xxxxx/ xxxxxx	XXXXXXXXXX/ xxxxxxx	xxx/ xxx/ xxxx/ xx	ddMMMyyyy/ xx	ddMMMyyyy/ xx	Concomitant Medication of Interest /Suspected in causing SAE	xxxxx

Listing 17
Listing of Blood Products and Blood Supportive Care Products

Treatment = xxxxx

Center/ Subject ID	For SF, was it admin-istered?	Product	Product Type	Date	Quantity or Dose	Unit	Frequency
xxxxx/ xxxxxx	P	Blood products	Red Blood Cells	ddMMMyyyy	xxx		
			Platelets	ddMMMyyyy	xxx		
			Whole Blood	ddMMMyyyy	xxx		
			Plasma - FFP	ddMMMyyyy	xxx		
			Cryoprecipitate	ddMMMyyyy	xxx		
			White Blood Cells	ddMMMyyyy	xxx		
…			Other Blood Product, specify	ddMMMyyyy	xxx		
					xxx		
		Blood supportive care products	darbepoetin alfa (Aranesp)	ddMMMyyyy	xxx		
			eltrombopag (i.e. Promacta)	ddMMMyyyy	xxx		
			pegfilgrastim (NeulastaR)	ddMMMyyyy	xxx		
			romiplostim (i.e. NPlate)	ddMMMyyyy	xxx		

SF: stimulating Factor; P = Prophylactically; A = As treatment.

Listing 18
Listing of Follow-Up Anti-Cancer Therapy

Treatment = xxxxxx

Center/ Subject ID	Best Response	Time to Progression (Days)	ATC Level 1/ Preferred Term/ Verbatim Text	Start Date/ Study Day/ Stop Date/ Study Day	Duration of Therapy	Type of Therapy	Reason for Stopping Therapy
xxxx/ xxxxxx	Progressive disease	xxx	Endocrine & metabolic/ Cytoxan/ CYTOXAN	ddMMMyyyy/ xxx/ ddMMMyyyy/ -xxx	xxx d	Chemotherapy	xxxxx
			xxxxxxxx/ xxxxxxxxxx/ XXXXXXXXXX	ddMMMyyyy/ xxx/ ddMMMyyyy/ -xxx	xxx d	Hormonal	xxxxx
			xxxxxxxx/ xxxxxxxxxx/ XXXXXXXXXX	ddMMMyyyy/ xxx/ ddMMMyyyy/ -xxx	xxx d	Radiation	xxxxxxxxxxx

Note: Follow-up surgeries are listed separately.

Listing 19
Listing of Follow-Up Surgical Procedures

Treatment = xxxxxx

Center/ Subject ID	Classification	Date of Procedure	Study Day	Verbatim Term
xxxxxx/ xxxxxx	Cancer related	ddMMMyyyy	xx	
	Cancer related	ddMMMyyyy	xx	
xxxxxx/ xxxxxx	Cancer related	ddMMMyyyy	xx	
	Other surgical procedures	ddMMMyyyy	xxx	Hysterectomy

Listing 20
Listing of Exposure to GSK2820151

Treatment = xxxxxx

Center/ Subject ID	Average Daily Dose	Start Date/ Study Day	Stop Date/ Study Day	Dose (mg)	Cumulative Dose (mg)
xxxx/ xxxxxx	xxxx	ddMMMyyyy xx	xx/ xx	xx	xx

Average daily dose is defined as the cumulative dose divided by the duration of exposure for each subject in days.
The cumulative dose is the sum of the doses administered for a subject.

Note: Average Daily Dose and Cumulative Dose are derived per subject. Please only display once for each subject.

Listing 21
Listing of Dose Interruptions

Treatment = xxxxxx

Center/ Subject ID	Dosing Date/ Study Day/ Dose (mg)	Primary Reason for Interruption/ Specify
xxxxx/ xxxxxx	PPD 42/ 0.80	xxxx/xxxxxxxxx

Listing 22
Listing of Dose Reductions

Treatment = xxxxxx

Center/ Subject ID	Dosing Date/ Study Day/ Dose (mg)	Primary Reason for Reduction/ Specify
xxxxx/ xxxxxx	ddMMMyyyy/ xx/ xx	xxxx/xxxxxxxxx

Listing 23
Listing of Adverse Events Profiles

Treatment = xxxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Preferred Term/ Verbatim Text	Outcome/ Onset Date/ Resolve Date/ Frequency/ Duration	Maximum Grade/ Serious/ Withdrawal from Study	Time since 1st Dose/ Last Dose	Action(s) taken with Treatment/ Relation to GSK2820151 Treatment	Dose Limiting Toxicity?
xxxxx/ xxxxxx	65/ Female/ White	Nausea/ NAUSEA	Resolved/ ddMMMyyyy/ ddMMMyyyy/ Single Episode/ xx d	Grade 4/ Yes/ Yes	xx d/ xx d	xxxxxxxxxxxxxx/ XXXX	Yes

Same format for:

Listing 24
Listing of Fatal Serious Adverse Events

Listing 25
Listing of Non-Fatal Serious Adverse Events

Listing 26
Listing of Adverse Events Leading to Discontinuations of GSK2820151 Treatment Profiles

Listing 27
Listing of Adverse Events Leading to Dose Interruptions

Listing 28
Listing of Adverse Events Leading to Dose Reductions

Listing 29
Listing of Adverse Events Recorded as Dose-Limiting Toxicities

Listing 30
Listing of Adverse Events of Special Interest

Programming Note: For Listing 30, Add the following footnote.
"Adverse Events of Special Interest are defined as any cardiovascular or death events."

Listing 31
Listing of Deaths

Treatment = xxxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Primary Cause of Death/ Secondary Cause of Death	Date of Death/ Study Day	Time From Last Dose	Last Dose (unit)
xxxxxx/ xxxxxx	62/ M/ White	xxxxxxxx/ xxxxxxxxxxxx	ddMMMyyyy/ xx	xx d	x/ xx
xxxxxx/ xxxxxx	45/ F/ Black	xxxxxxxx/ xxxxxxxxxxxx	ddMMMyyyy/ xx	xx d	x/ xx
xxxxxx/ xxxxxx	61/ M/ South Asian	xxxxxxxx/ xxxxxxxxxxxx	ddMMMyyyy/ xx	xx d	x/ xx
xxxxxx/ xxxxxx	52/ F/ White	xxxxxxxx/ xxxxxxxxxxxx	ddMMMyyyy/ xx	xx d	x/ xx

Listing 32
Listing of Subject Numbers for Specific Causes of Deaths

Primary Cause of Death	Secondary Cause of Death	Treatment	Number of Subjects	Subject Number
Cancer	xxxxxxxxxxxxxxxxxxx	xxxxx	2	xxxxxx, xxxxxx
		xxxxx	1	xxxxxx
Myocardial infarction	Haematologic Event	xxxxx	1	xxxxxx

Listing 33
Listing of Clinical Chemistry Data

Treatment =xxxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Lab Test (units)	Planned Time	Collection Date	Study Day	Converted Data		NR Flag [1]	Grade [2]
						Result	Low-High		
xxxxxx/	63/	Alk Phos (xxx)	Screening	ddMMMyyyy	-x	xx.xx	xx.x- xx.x		x
xxxxxx	Male/		Week 1 Day 1	ddMMMyyyy	xx	xx.xx	xx.x- xx.x		x
	White		Week x Day x	ddMMMyyyy	xx	xx.xx	xx.x- xx.x		x
			…	ddMMMyyyy	xx	xx.xx	xx.x- xx.x	H	x
		ALT (xxx)	Screening	ddMMMyyyy	-x	xx.xx	xx.x- xx.x		x
			Week 1 Day 1	ddMMMyyyy	xx	xx.xx	xx.x- xx.x	H	x
			Week x Day x	ddMMMyyyy	xx	xx.xx	xx.x- xx.x	H	x
			…	ddMMMyyyy	xx	xx.xx	xx.x- xx.x	H	x
		Hemoglobin (xxx)	Screening	ddMMMyyyy	-x	xx.x	x.x- xx.x		x
			Week 1 Day 1	ddMMMyyyy	xx	xx.x	x.x- xx.x		x
			Week x Day x	ddMMMyyyy	xx	xx.x	x.x- xx.x		x
			…	ddMMMyyyy	xx	xx.x	x.x- xx.x		x
		Platelets (xxxx)	Screening	ddMMMyyyy	-x	xxx.x	xxx.x-xxx.x		x
			…	ddMMMyyyy	xx	xxx.x	xxx.x-xxx.x		x

[1] NR for Normal Range flag; H=Above range, L=Below range, N=Normal range.
[2] NCI-CTCAE version 4.03

Same format for:

Listing 34
Listing of Hematology Data

Listing 35
Listing of Thyroid Function Test Data

Listing 36
Listing of Urinalysis Data

Listing 37
Listing of Coagulation Data

Listing 38
Listing of Pancreatic Markers Data

Listing 39
Listing of Lipid Panel Data

Listing 40
Listing of Serum Data

Programming note: for listing 35, please include lab tests as available in SDTM: Thyrotropin (xxx), Thyroxine, Free (pxxx), and Triiodothyronine, Free (xxx).

Programming note for listing 36, please include qualitative urinalysis data (AVALC is populated) per RAP section 11.7. High, Low, NR Flag will be left blank.

Listing 41
Listing of Vital Signs

Treatment = xxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time	Study Day	Actual Date/Time Reading		Systolic Blood Pressure (mmHg)/ Grade	Diastolic Blood Pressure (mmHg)/ Grade	Heart Rate (bests /min)	Respiratory Rate (breaths/min)	Temperature (C)	Weight (kg)
xxx/ xxxxxx	23/ Male/ White	Screening Week 1 Day 2	-xx	ddMMMyyyy /hh:mm	1	xx/ Grade 0	xx/ Grade 0	xx H	xx	xx	xx
				ddMMMyyyy /hh:mm	2	xxx/ Grade 1	xxx/ Grade 1	xx			
				ddMMMyyyy /hh:mm	3	xxx/ Grade 2	xxx/ Grade 2	Xx			
				ddMMMyyyy Average /hh:mm		xxx/ Grade 3	xxx/ Grade 3				
		Week x Day x	1	ddMMMyyyy /hh:mm		xxx/ Grade 3	xxx/ Grade 3	xx H	xx	xx H	xx
				ddMMMyyyy /hh:mm		xxx/ Grade 0	xxx/ Grade 0	xx H	xx	xx H	xx
				ddMMMyyyy /hh:mm		xxx/ Grade 2	xxx/ Grade 2	xx L	xx	xx L	xx
		…									

Note: L = Low, H = High.
Systolic BP (mmHg): Grade 0 (<120), Grade 1 (>=120-<140), Grade 2 (>=140-<160) and Grade 3 (>=160), only applies to post-baseline records with increase from baseline.
Diastolic BP (mmHg): Grade 0 (<80), Grade 1 (>=80-<90), Grade 2 (>=90-<100), and Grade 3 (>=100), only applies to post-baseline records with increase from baseline.
Heart Rate (beats/min): L (<60), H (>100), only applies to post-baseline records.
Temperature (C): L (<=35), H (>=38), only applies to post-baseline records.

Programming note: repeated readings are only applicable for BP measurements and Heart Rate for some assessments, e.g. Week 1 Day 2.

Listing 42
Listing of ECOG Performance Status Scale

Treatment = xxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time	Study Day	Actual Date	ECOG Performance Status *	Change from Baseline
xxx/ xxxxxx	23/ Male/ White	Screening	-xx	ddMMMyyyy	1	
		Week x Day x	xx	ddMMMyyyy	0	x
		Week x Day x				

*0 = Fully active, able to carry on all pre-disease performance without restriction;
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work;
2 = Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours;
3 = Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours;
4 = Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair;
5 = Dead.

Listing 43
Listing of Abnormal ECG Findings

Treatment = xxxxxx
Vendor = ERT

Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time/ Date/Time/ Study Day	Triplicate	Result	Clinically Significant ?
xxx/ xxxxxx	65/ White/ Female	Week x Day X Pre-dose/ ddMMMyyyy hh:mm/ x	1	Abnormal	No
			2	Abnormal	No
			3	Abnormal	No
xxx/ xxxxxx	58 White/ Male	Week x Day x 15m/ ddMMMyyyy hh:mm/ x	X	Abnormal	Yes

Programming note: ECG labs are collected by both local and central labs. Please display separately.

Listing 44
Listing of ECG Values

Treatment = xxxxxx
Vendor = ERT

Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time/ Date/Time/ Study Day	Triplicate	Heart Rate (beats/min.)	PR Interval (msec)	QRS Duration (msec)	QT Interval (msec)	QTc (Fridericia) (msec)
xxx/ xxxxxx	23/ Male/ White	Screening	1	xx	xxx	xxx	xxx	xxx
			2	xx	xxx	xxx	xxx	xxx
			3	xx	xxx	xxx	xxx	xxx
			Average	xx	xxx	xxx	xxx	xxx
		Week X Day X Pre-dose	xx	xx	xxx	xxx	xxx	xxx

Programming note: ECG labs are collected by both local and central labs. Please display separately.

Listing 45
Listing of Change from Baseline ECG Values

Treatment = xxxxxx
Vendor = ERT

			Change from Baseline				
Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time/ Date/Time/ Study Day	Heart Rate (beats/min.)	PR Interval (msec)	QRS Duration (msec)	QT Interval (msec)	QTc (Fridericia) (msec)
xxx/ xxxxxx	23/ Male/ White	Screening	xx	xxx	xxx	xxx	xxx
		Week X Day X Pre-dose	xx	xxx	xxx	xxx	xxx

Note: Average values of each visit were used to calculate baseline and post-baseline values.

Listing 46
Listing of Left Ventricular Ejection Fraction (LVEF) ECHO Results

Treatment = xxxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Planned Time	Study Day	Scan Date	Vendor	LVEF (%)	Absolute Change From Baseline	Scan Results
xxx/ xxxxxx	23/ Male/ White	Screening	-x	ddMMMyyyy	VIRTUALSCOPICS	xxx		Normal
				ddMMMyyyy	WAYNE STATE UNIVERSITY PHYSICIAN GROUP	xxx	xxx	Abnormal, Not Clinically Significant
		Week X Day X		ddMMMyyyy		xxx	xxx	xxx

Listing 47
Listing of Investigator-Assessed Response (RECIST 1.1)

Treatment = xxxxxx

Center/ Subject ID	Measurable Disease at baseline	Planned Time	Date	Resp. Day	Target Lesion Response	Non-Target Lesion Response	New Lesion	Response [1]	If PD, Method of Assessment/ Date [2]
xxxx/ xxxxxx	Yes	Screening	ddMMMyyyy	xx					
		xxxxxxxx	ddMMMyyyy	xx	SD	SD	No	SD	
		..	ddMMMyyyy	xx	PR	SD	No	PR	
			ddMMMyyyy	xx	PR	SD	No	PR	
		..	ddMMMyyyy	xx	PR	SD	No	PD	Radiological

[1] Response: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluable, NA=Not Applicable.
[2] Date provided of non-radiological assessment.

Listing 48
Listing of Investigator-Assessed Target Lesions (RECIST 1.1)

Treatment = xxxxxx

Center/ Subject ID	Planned Time	Sum LD (mm)/ Sum Non Lymph Node LD (mm)/ Sum Nadir (mm)	Percent Change in Sum LD From Baseline	Percent Change Nadir/ Absolute Change Nadir(mm)	Target Lesion Response	Lesion Number	Organ/ Location	Method/ Slice Thickness/ Date/ Lesion Assessment Day	LD(mm)[1]/ Target Lesion Status/ Specify the reason
xxxxx/ xxxxxx	Screening	xx				1	Lung/ RIGHT UPPER QUADRANT	CT scan/ xx/ ddMMMyyyy/ xx	xx
						2	Lymph nodes/ RIGHT AXILLA	CT scan/ xx/ ddMMMyyyy/ xx	xx
	xxxxxxxx	xx/ xx	xx%	xx%/ xx	SD	1	Lung/ RIGHT UPPER QUADRANT	CT scan/ / ddMMMyyyy/ xx	xx/ Lesion split or divided
						2	Liver/ Abdomen	CT scam Xx/ ddMMyyy/ xx	Xx/ Not done/ Scan not performed

[1] LD = Lesion diameter

Programming note: Sum of Non Lymph Node LD, Sum of Nadir, and Lesion Status are only collected at post-baseline assessments. For slice thickness, it is only collected at baseline, please retain for post-baseline visits.

Listing 49
Listing of Investigator-Assessed Non-Target Lesions (RECIST 1.1)

Treatment = xxxxxx

Center/ Subject ID	Planned Time	Non-target Lesion Response	Lesion Number	Organ/ Location	Method/ Date/ Lesion Assessment Day	Non-target Lesion Status/ Specify the reason
xxxx/ xxxxxx	Screening	CR	1	Bone/ LUMBAR SPINE	MRI/ ddMMMyyyy/ xx	Present
			2	Bone/ THORACIC SPINE	MRI/ ddMMMyyyy/ xx	Present
			3	Lymph nodes/ RIGHT AXILLA	Direct Measure by Physical Exam/ ddMMMyyyy/ xx	Present
	Week x Day x		1	Xxx	Xxx	Not assessable - xxxx

Listing 50
Listing of Investigator -Assessed New Lesions

Treatment = xxxxxx

Center/ Subject ID	Planned Time	Lesion Number	Organ/ Location	Method/ Date/ Lesion Assessment Day	Lesion Status
PPD	Week 12, Day 85	1	Lung/ RIGHT UPPER QUADRANT	CT scan/ PPD 172	Unequivocal
		2	Lymph nodes/ RIGHT AXILLA	Direct Measure by Physical Exam/ PPD 174	Unequivocal
	Week 12, Day 85	1	Lung/ RIGHT UPPER QUADRANT	CT scan/ PPD 181	Equivocal
	Week 24, Day	1	Lung/ RIGHT UPPER QUADRANT	CT scan/ PPD 231	Unequivocal

Listing 51
Listing of Progression Free Survival (RECIST 1.1)

Treatment = xxxxxx

Center/ Subject ID	Age(Years)/ Sex/ Race	Treatment Start Date/ Event or Censoring Date	Endpoint Description for PFS	PFS (weeks)	New Anti-cancer Therapy Start Date
xxxxx/ xxxxxx	Female/ xx	ddMMMyyyy/ ddMMMyyyy	Event: Died xx	xx.x	ddMMMyyyy
xxxxx/ xxxxxx	Male/ xx	ddMMMyyyy/ ddMMMyyyy	Censor: xxxxxxxxxxxx	xx.x	

Listing 52
Listing of GSK2820151 Pharmacokinetic Concentration-Time Data

Treatment = xxxxxx

Center/ Subject ID	Planned Schedule	Planned Time	Date/Actual Time	Time Deviation (Hours)	Actual Relative Time (Hours)	Concentration (ng/mL)
xxx/ xxxxxx	Week 1 Day 1	Pre-dose	ddMMMyyyy/hh:mm	x.xxx	x.xx	NQ
		15Min post Dose	ddMMMyyyy/hh:mm			xxxx.XXX
		30 Min post Dose	ddMMMyyyy/hh:mm			x.xxx
		1Hour post Dose	ddMMMyyyy/hh:mm			xxxx.xxx
		2Hour post Dose	ddMMMyyyy/hh:mm			xxxx.xxx
		4 Hour post Dose	ddMMMyyyy/hh:mm			xxxx.xxx
. . .						

NQ = Non-quantifiable.

Listing 53
Listing of Derived GSK2820151 Pharmacokinetic Parameters

Treatment = xxxxx

Center/ Subject ID	Cmax (ng/mL)	tmax (h)	AUC(0-t) (h*ng/mL)	AUC(0-tau) (unit)	AUC(0-inf) (h*ng/mL)	t1/2 (h)	C tau (unit)	Ro [1]	CL/F (mL/h)	Vz/F (mL)
xxx/ xxxxxx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

[1] Ratio of AUC(0-tau): AUC(0-tau) on Week 3 Day 4/AUC(0-tau) on Week 1 Day 1