nature portfolio

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Last updated by author(s): Apr 28, 2025

Reporting Summary

Nature Portfolio wishes to improve the reproducibility of the work that we publish. This form provides structure for consistency and transparency in reporting. For further information on Nature Portfolio policies, see our Editorial Policies and the Editorial Policy Checklist.

Statistics

For all statistical analyses, confirm that the following items are present in the figure legend, table legend, main text, or Methods section.

n/a	Confirmed
☐	☒ The exact sample size (*n*) for each experimental group/condition, given as a discrete number and unit of measurement
☐	☒ A statement on whether measurements were taken from distinct samples or whether the same sample was measured repeatedly
☒	☐ The statistical test(s) used AND whether they are one- or two-sided *Only common tests should be described solely by name; describe more complex techniques in the Methods section.*
☒	☐ A description of all covariates tested
☒	☐ A description of any assumptions or corrections, such as tests of normality and adjustment for multiple comparisons
☐	☒ A full description of the statistical parameters including central tendency (e.g. means) or other basic estimates (e.g. regression coefficient) AND variation (e.g. standard deviation) or associated estimates of uncertainty (e.g. confidence intervals)
☒	☐ For null hypothesis testing, the test statistic (e.g. *F*, *t*, *r*) with confidence intervals, effect sizes, degrees of freedom and *P* value noted *Give P values as exact values whenever suitable.*
☒	☐ For Bayesian analysis, information on the choice of priors and Markov chain Monte Carlo settings
☒	☐ For hierarchical and complex designs, identification of the appropriate level for tests and full reporting of outcomes
☒	☐ Estimates of effect sizes (e.g. Cohen's *d*, Pearson's *r*), indicating how they were calculated

Our web collection on statistics for biologists contains articles on many of the points above.

Software and code

Policy information about availability of computer code

Data collection	TrialMaster V5.0
Data analysis	Statistical analyses were carried out using SAS version 9.4.

For manuscripts utilizing custom algorithms or software that are central to the research but not yet described in published literature, software must be made available to editors and reviewers. We strongly encourage code deposition in a community repository (e.g. GitHub). See the Nature Portfolio guidelines for submitting code & software for further information.

Data

Policy information about availability of data

All manuscripts must include a data availability statement. This statement should provide the following information, where applicable:

- Accession codes, unique identifiers, or web links for publicly available datasets
- A description of any restrictions on data availability
- For clinical datasets or third party data, please ensure that the statement adheres to our policy

Data supporting the findings of this trial are available within the manuscript and the supplementary materials. Reasonable requests for additional data sharing should be directed to the corresponding author and will be evaluated in accordance with the data access and sharing policy of Human Genetic Resource Administration of China.

Research involving human participants, their data, or biological material

Policy information about studies with human participants or human data. See also policy information about sex, gender (identity/presentation), and sexual orientation and race, ethnicity and racism.

Reporting on sex and gender	Sex (Male & Female) was described as baseline characteristics of the patients in results-patients and treatments, Table 1 and Supplementary Table S1. Sex was also used in subgroup analysis of ORR as shown in Supplementary Figure S3.
Reporting on race, ethnicity, or other socially relevant groupings	Race (East Asian & Caucasian) was described as baseline characteristics of the patients in results-patients and treatments, Table 1 and Supplementary Table S1.
Population characteristics	Baseline characteristics of the patients were described in results-patients and treatments, Table 1 and Supplementary Table S1.
Recruitment	Patients were evaluated by the investigators or staff at the study sites. Recruitment was limited to locations or regions where the study being conducted. Written informed consent was obtained prior to patient enrollment.
Ethics oversight	The study protocol received approval from the institutional review board and ethics committee at all participating sites.

Note that full information on the approval of the study protocol must also be provided in the manuscript.

Field-specific reporting

Please select the one below that is the best fit for your research. If you are not sure, read the appropriate sections before making your selection.

☒ Life sciences ☐ Behavioural & social sciences ☐ Ecological, evolutionary & environmental sciences

For a reference copy of the document with all sections, see nature.com/documents/nr-reporting-summary-flat.pdf

Life sciences study design

All studies must disclose on these points even when the disclosure is negative.

Sample size	The sample size was based on the typical 3+3 design as well as clinical considerations for safety and efficacy as detailed in the study protocol.
Data exclusions	Patients excluded for this study were presented in the CONSORT diagram (Figure 1). Exclusion criteria are detailed in the study protocol.
Replication	All relevant experiments in lab and statistical analyses reported in this study can be replicated.
Randomization	not applicable for this single-arm study
Blinding	not applicable for this open-label study

Reporting for specific materials, systems and methods

We require information from authors about some types of materials, experimental systems and methods used in many studies. Here, indicate whether each material, system or method listed is relevant to your study. If you are not sure if a list item applies to your research, read the appropriate section before selecting a response.

Materials & experimental systems

n/a	Involved in the study
☒	☐ Antibodies
☒	☐ Eukaryotic cell lines
☒	☐ Palaeontology and archaeology
☒	☐ Animals and other organisms
☐	☒ Clinical data
☒	☐ Dual use research of concern
☒	☐ Plants

Methods

n/a	Involved in the study
☒	☐ ChIP-seq
☒	☐ Flow cytometry
☒	☐ MRI-based neuroimaging

Clinical data

Policy information about clinical studies

All manuscripts should comply with the ICMJE guidelines for publication of clinical research and a completed CONSORT checklist must be included with all submissions.

Clinical trial registration	NCT05458219
Study protocol	Study protocol is available in supplementary materials
Data collection	Patients were enrolled in China and Australia. The first patient was enrolled on October 26th, 2022 and the study is ongoing. As of June 30th, 2024, a total of 540 patients were screened and 211 patients were enrolled to receive IBI343 monotherapy. This report includes 19 patients from the dose escalation phase and 108 patients with G/GEJ adenocarcinoma from the dose expansion phase (Figure 1).
Outcomes	The primary endpoints of this phase 1 study included the safety and tolerability of IBI343 and the maximum tolerated dose (MTD) as well as the recommended Phase 2 dose (RP2D) of IBI343. The secondary endpoints included the preliminary efficacy of IBI343, assessed through objective response rate (ORR), disease control rate (DCR), duration of response (DoR), progression-free survival (PFS) as evaluated by the investigator, and overall survival (OS).

Plants

Seed stocks	*Report on the source of all seed stocks or other plant material used. If applicable, state the seed stock centre and catalogue number. If plant specimens were collected from the field, describe the collection location, date and sampling procedures.*
Novel plant genotypes	*Describe the methods by which all novel plant genotypes were produced. This includes those generated by transgenic approaches, gene editing, chemical/radiation-based mutagenesis and hybridization. For transgenic lines, describe the transformation method, the number of independent lines analyzed and the generation upon which experiments were performed. For gene-edited lines, describe the editor used, the endogenous sequence targeted for editing, the targeting guide RNA sequence (if applicable) and how the editor was applied.*
Authentication	*Describe any authentication procedures for each seed stock used or novel genotype generated. Describe any experiments used to assess the effect of a mutation and, where applicable, how potential secondary effects (e.g. second site T-DNA insertions, mosiacism, off-target gene editing) were examined.*