Historically, MTD has not been reached with either BID or QD schedule in ~30 patients. Furthermore, TRAEs are typically limited by kinetics associated with inhibition of wild-type EGFR.10

BI 1810631 is a novel TKI that covalently and selectively binds to the TKD of HER2, and is under investigation as an oral treatment for NSCLC tumours harbouring HER2 TKI mutations, excluding exon20 mutations (NCT01989604).

**HER2 mutation frequencies in solid tumours**

- **Ovarian cancer (4-6%)**
- **Lung cancer (2-4%)**
- **Pancreatic cancer (1-2%)**
- **Breast cancer (4-6%)**
- **Colorectal cancer (5-6%)**
- **Cervical cancer (3-5%)**
- **Prostate cancer (1%)**

**Key points and conclusions**

- As of 23 January 2023, 36 patients had been treated; median number of cycles: 4 (range 1–14).
- MTD has not been reached with either BID or QD schedule.
- Only three DLTs have been observed to date: grade 3 anaemia, grade 3 ALT increased, and grade 2 elevation of blood alanine aminotransferase.
- BI 1810631 was well tolerated; 25 patients (69%) experienced TRAEs (mostly grade 1 or 2). The most common TRAE was diarrhoea (n=10; 28%).
- BI 1810631 has demonstrated encouraging preliminary antitumour activity in various cancers with HER2 aberrations, including NSCLC.
- Patients are planned to be recruited from 18 countries, across Europe, the Middle East, Australia, Asia, and North America.

**References**


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**Key findings and conclusions**

Mechanism of action of BI 1810631, a novel TKI

**BI 1810631 binds to the TKD of HER2 receptors, inhibiting wild-type and mutant HER2, including ex20Dins**

- Avoids toxicity associated with inhibition of wild-type EGFR.
- Possible better safety and efficacy than TKIs that bind to both HER2 and EGFR receptors.

**Efficacy**

- Overall: 9 patients of 26 patients (35%) with ND
treated with BI 1810631 had objective response.
- Median duration of objective response: 3 (range 1–20) months.

**Planned countries for Phase Ib**

- **Europe and Middle East**
  - **Europe**: Austria, Belgium, Canada, France, Germany, Hungary, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom.
  - **Middle East**: United Arab Emirates, Bahrain, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen.

**Germany**