# A Post Approval Commitment Study on Tabrecta® (Capmatinib) in South Korea

Last Update: Jan 14, 2025
A Post Approval Commitment Study on Tabrecta® (Capmatinib) in South Korea; Open Label, Prospective, Multicenter, Post Approval Surveillance
ClinicalTrials.gov Identifier:
NCT05703516
Novartis Reference Number:CINC280AKR01
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

## Study Description

This is an open label, prospective, multicenter, non-comparative study to assess the safety and effectiveness of Tabrecta® (Capmatinib) in real world setting. Also, this study is to fulfill the regulatory requirements as part of the RMP (Risk Management Plan) for Tabrecta® (Capmatinib), as requested by Korea Health Authority, MFDS (Ministry of Food and Drug Safety). The study is a post approval surveillance so there will be no comparator arm/drug nor blinding process.

Dose/regimen should follow locally approved label and it could be adjusted as per the decision from treating physician during treatment period, under their routine clinical practice. Treatment duration is deemed to the decision from treating physician under their routine clinical practice, since this study is a post approval surveillance and to look for safety profiles happening under real world practice. There will be no intervention from Novartis regarding dose/regimen and treatment duration.

This study will be completed after data collection of the last subject during the follow up period. The follow up period is recommended for up to 24 weeks after enrollment or up to the time of discontinuation of study drug (in case of early discontinuation) as per linical judgement of treating physician.

Condition
Non-Small-Cell Lung Carcinoma
Overall Status
Recruiting
Number of Participants
250
Start Date
Jun 12, 2023
Completion Date
Oct 31, 2026
Gender
All
Age(s)

18 Years - 100 Years (Adult, Older Adult)

# Interventions

Other

### Capmatinib

There is no treatment allocation. Capmatinib will be prescribed by the physician as per locally approved label. Treatment duration depends on the decision of treating physician. No drug will be dispensed from Novartis

# Eligibility Criteria

Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study.
* Subject who are diagnosed as exon 14 skipping mutated NSCLC from tissue or plasma(ctDNA) sample analysis by treating physician (i.e. Any kind of diagnostic methods the institution currently has. Diagnostic modalities for research purpose would be also allowable.)
* Subject who plan to receive Tabrecta® (Capmatinib) as per locally approved label

Exclusion Criteria:

* Subject with contraindication according to the locally approved label
* Subject whose medical record is not accessible
* Subject who are not willing to provide informed consent

**Korea, Republic of**

**Novartis Investigative Site**

Recruiting

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# Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com