# BGB-3111-206

# BGB-3111-206 Trial Design

**Phase 2**

**Study Identifier:**
BGB-3111-206, NCT03206970

**Primary Endpoint:** ORR assessed by IRC using PET-based imaging per the Lugano criteria[3]
**Key Secondary Endpoints:** PFS, DoR, OS, safety

**Eligibility criteria**

- R/R MCL
- Prior treatment regimen(s) for MCL
- Progressive disease or lack of response on most recent treatment
- ECOG PS 0-2

**Treatment**

**Up to 3 years**

**Zanubrutinib 160 mg PO BID (N=86)**

Treatment until unacceptable toxicity, disease progression or end of study

BID=twice daily, DoR=duration of response, ECOG PS=Eastern Cooperative Oncology Group performance status, IRC=independent review committee, MCL=mantle cell lymphoma, ORR=objective response rate, OS=overall survival, PET=positron emission tomography, PFS=progression-free survival, PO=per oral, R/R=relapsed/refractory.

1. Song Y et al. Blood. 2022. 139 (21): 3148–3158; 2. ClinicalTrials.gov. https://www.clinicaltrials.gov/ct2/show/NCT03206970. Accessed October 9, 2025. 3. Cheson BD et al. J Clin Oncol. 2014;32(27):3059–3067.

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# Patient and Disease Characteristics

| Characteristic | Total (N=86) |
|---|---|
| **Age** | |
| Median (range), years | 61 (34-75) |
| ≥65 years, n (%) | 22 (25.6%) |
| **Race, n (%)** | |
| Chinese | 86 (100.0%) |
| **Sex, n (%)** | |
| Male | 67 (77.9%) |
| Female | 19 (22.1%) |
| **ECOG PS, n (%)** | |
| 0/1 | 82 (95.3%) |
| 2 | 4 (4.7%) |
| **Extranodal disease, n (%)** | 61 (70.9%) |
| Bone marrow involvement | 39 (45.3%) |
| Gastrointestinal involvement | 15 (17.4%) |
| **Refractory disease[a]** | 45 (52.3%) |
| ***TP53*-mutated (N=54)[b]** | 15 (27.8%) |
| **Bulky disease, n (%)** | |
| >5 cm tumor mass | 37 (43.0%) |

| Characteristic | Total (N=86) |
|---|---|
| **Blastoid variant of MCL, n (%)** | 12 (14.0%) |
| **Patients with prior lines of therapy, n (%)** | 86 (100.0%) |
| Median (range) number of prior therapies | 2 (1–4) |
| ≥3 prior therapies, n (%) | 29 (33.7%) |
| **Prior regimens,[c] n (%)** | |
| Patients with ≥1 rituximab-containing regimen | 64 (74.4%) |
| R-CHOP, R-CHOP-like | 46 (53.5%) |
| CHOP, CHOP-like | 31 (36.0%) |
| High-dose cytarabine-containing regimen[d] | 33 (38.4%) |
| (R) hyper-CVAD (A)/EPOCH | 23 (26.7%) |
| Lenalidomide | 12 (14.0%) |
| Bortezomib | 7 (8.1%) |
| Stem cell transplant | 3 (3.5%) |
| **MIPI-b, n (%)[e]** | |
| Low-risk | 12 (14.0%) |
| Intermediate-risk | 39 (45.3%) |
| High-risk | 33 (38.4%) |
| Missing | 2 (2.3%) |

Data cutoff: September 8, 2020.
[a]Refractory disease was defined as the lack of at least a partial response to the last therapy before study entry, as assessed by the investigator. [b]54 patients had baseline sequencing. For the remaining patients, 21 did not provide consent, nine lacked adequate tumor tissue, and for two, the assay failed at the library preparation step [c]Categories are not mutually exclusive as patients may be included under multiple regimens. [d]High-dose cytarabine-containing regimens included dexamethasone, cytarabine, and cisplatin (DHAP); etoposide, methylprednisolone, cytarabine, cisplatin (ESHAP); methotrexate and cytarabine (hyperCVAD B); cyclophosphamide, etoposide, cytarabine, methylprednisolone, vincristine, nedaplatin (CDEADP) [e]MIPI-b score was derived with the use of four baseline clinical prognostic factors (age, ECOG performance status, lactate dehydrogenase level, and white blood cell count) plus percent Ki-67 expression in tumor cells, and its range depends on the range of these characteristics.. The index classifies patients as having low-, intermediate-, or high-risk disease, as defined by scores of <5.7, ≥5.7 to <6.5 and ≥6.5, respectively. CHOP=cyclophosphamide, doxorubicin, vincristine, and prednisone, ECOG PS=Eastern Cooperative Oncology Group performance status, EPOCH=etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin, hyper-CVAD=cyclophosphamide, vincristine, doxorubicin, and dexamethasone, MCL=mantle cell lymphoma, MIPI-b=Biologic Mantle Cell Lymphoma International Prognostic Index, R=rituximab. TP53=tumor protein 53 gene.
Song Y et al. *Blood*. 2022. 139;(21):3148-3158..

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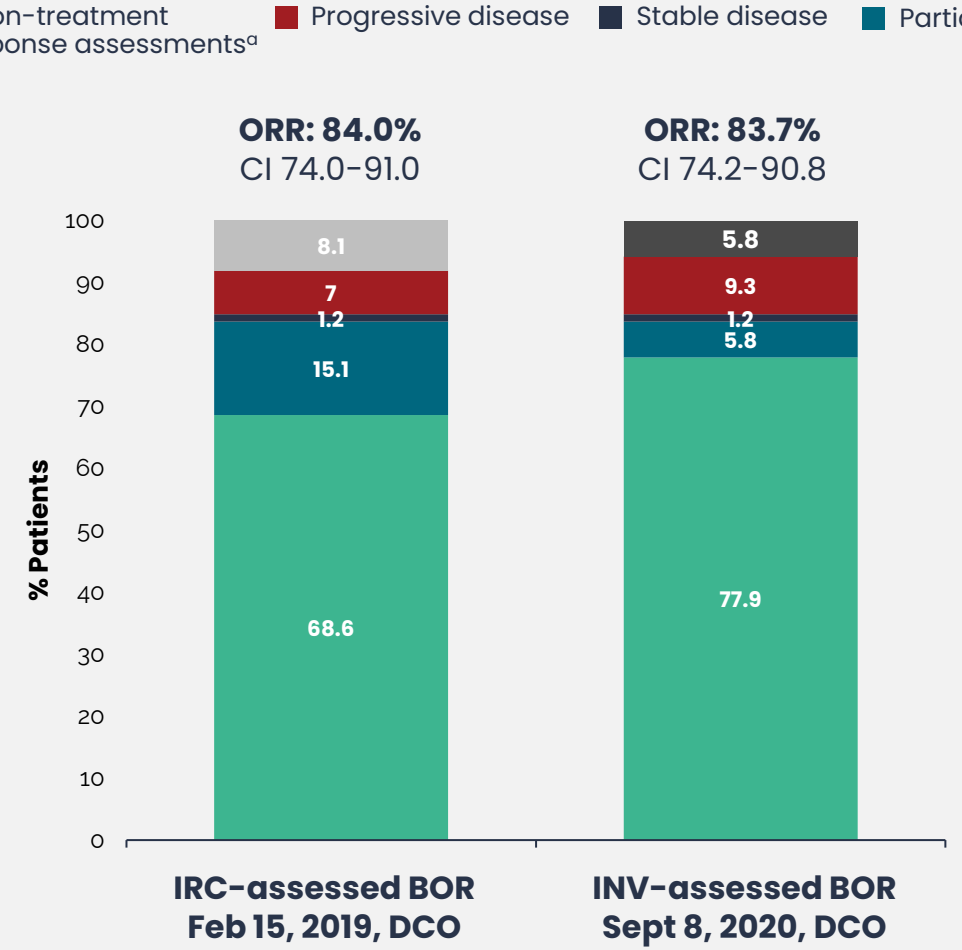
# Best Overall Response: Primary Endpoint

| IRC-Assessed Efficacy Variable[1] | N=86 |
|---|---|
| Median TTR, months (range) | 2.7 (2.5-16.6) |
| Median DoR, months (95% CI) | 19.5 (0.9-19.5) |
| Event at risk-free rate at 12 months, % (95% CI) | 78.3 (67.0-86.0) |




| Investigator-Assessed Efficacy Variable[2] | N=86 |
|---|---|
| Median TTR, months (range) | 2.7 (2.5-3.0) |
| Median time to CR, months (range) | 2.8 (2.5-16.7) |
| Median DoR, months (95% CI) | NE (24.9-NE) |
| Event-at risk free rate at 30 months, % (95% CI) | 57.3 (44.9-67.9) |

Median follow-up: 35.3 months

[a]Includes one patient with no evidence of disease at baseline.
BID=twice daily, BOR=best overall response, CI=confidence interval, CR=complete response, DCO=data cutoff, DoR=duration of response, INV=investigator, IRC=independent review committee, NE=not estimable, ORR=overall response rate, PO=orally, TTR=time to response.
1. Song Y et al. *Clin Cancer Res.* 2020;26(16):4216-4224 2. Song Y et al. *Blood.* 2022;139:3148-3158.

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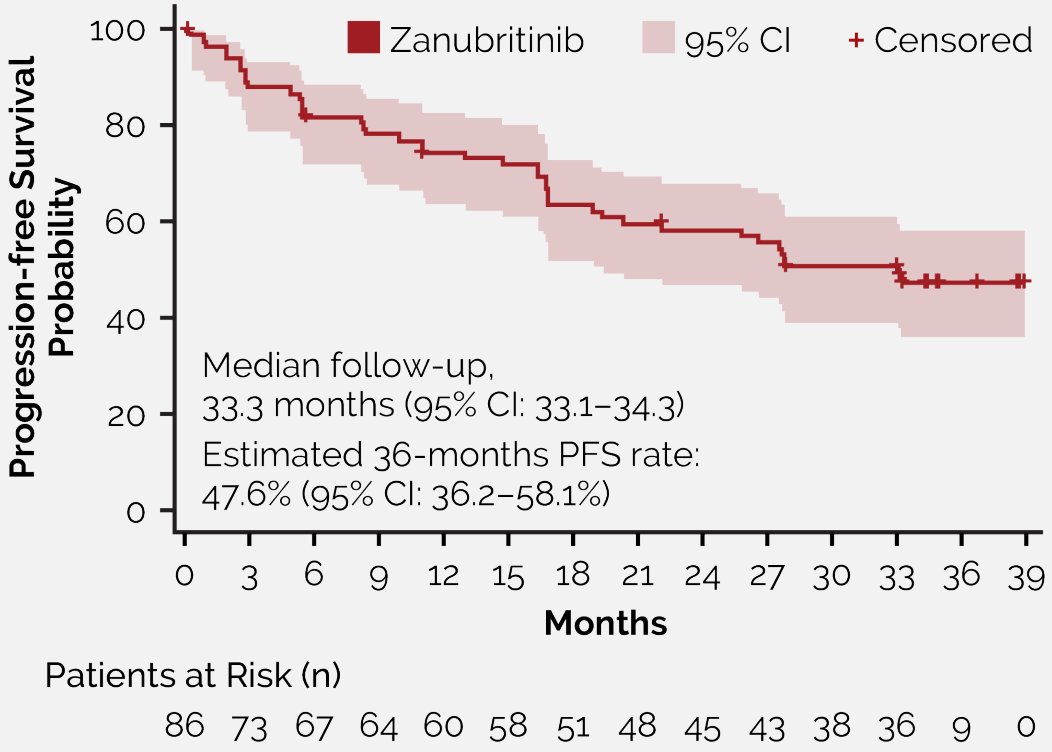
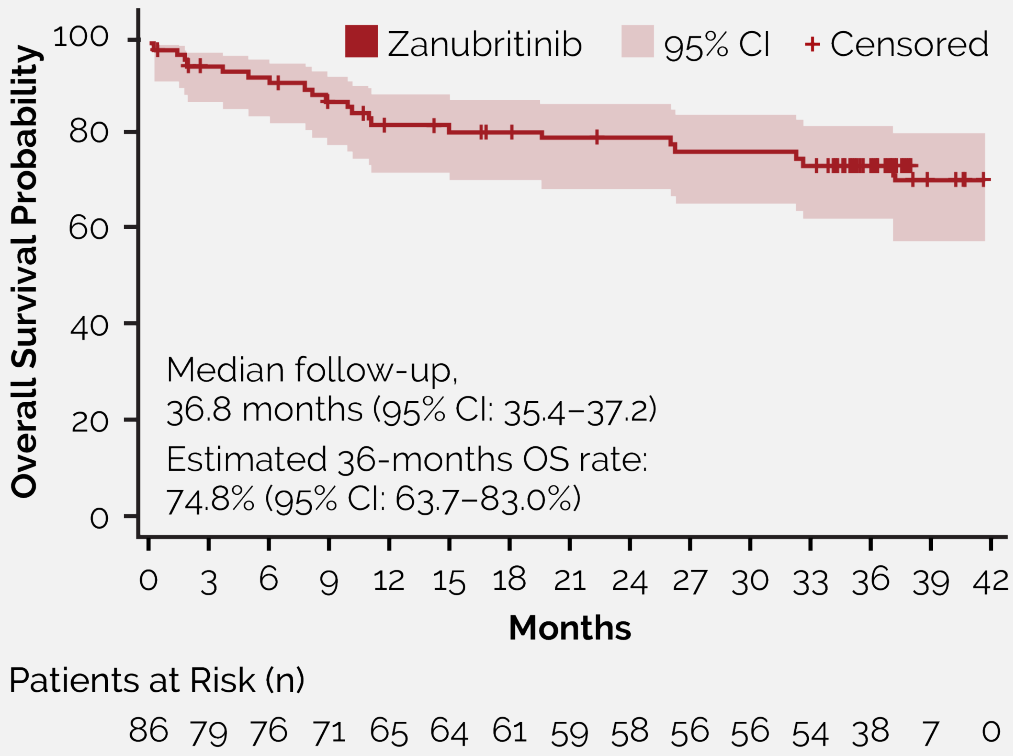
# PFS and OS by Investigator

Median PFS was 33.0 months (95% CI: 19.4-NE)[1]




Median OS was not reached[1]




**February 15, 2019, data cutoff**: Median PFS was 22.1 months (95% CI: 17.4-NE)[2]

Data cutoff: September 8, 2020.
CI=confidence interval. NE=not estimable, OS=overall survival, PFS=progression-free survival.
1. Song Y et al. *Blood.* 2022;139:3148-3158; 2. Song Y et al. *Clin Cancer Res.* 2020;26(16):4216–42247.

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# Safety Summary and AEs of Special Interest

The safety profile with median 35.3 months' follow-up was largely unchanged from that in the previously reported 18.4 months' follow-up

| n (%) | All Patients (N=86) | |
|---|---|---|
| | 18.4 Months Follow-Up n (%)[1] | 35.3 Months Follow-Up n (%)[2,3] |
| Grade ≥3 TEAEs[a] | 36 (41.9) | 43 (50.0) |
| Serious TEAEs | 21 (24.4) | 25 (29.1) |
| TEAEs leading to study drug discontinuation | 8 (9.3) | 8 (9.3) |
| TEAEs leading to study drug interruption | 13 (15.1) | 16 (18.6) |
| TEAEs leading to study drug reduction | 2 (2.3) | 2 (2.3) |
| Death due to TEAE[b] | 6 (7.0) | 6 (7.0) |

| AEI Category Preferred Term[3] n (%) | Patients (N=86) | |
|---|---|---|
| | Any Grade | Grade ≥3 |
| Patients with at least one AEI | 76 (88.4) | 34 (39.5) |
| Infections[c] | 56 (65.1) | 16 (18.6) |
| Neutropenia | 43 (50.0)[d] | 17 (19.8)[b] |
| Thrombocytopenia | 34 (39.5) | 6 (7.0) |
| Hemorrhage (inc. minor bleeds involving mucous membranes & skin)[e] | 31 (36.0) | 1 (1.2) |
| Anemia | 15 (17.4) | 5 (5.8) |
| Hypertension | 14 (16.3) | 3 (3.5) |
| Major hemorrhage | 3 (3.5) | 1 (1.2) |

**Most AEs occurred during early-stage zanubrutinib treatment, and no new safety signals were observed after extended follow-up**

Data cutoff: September 8, 2020.
[a]Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE, version 4.03). [b]Death within 30 days of the last dose of zanubrutinib. [c]The "Infections" AEI category is summarized under the Infections and Infestations SOC. [d]Included one patient with febrile neutropenia. [e]The "Haemorrhage" AEI category is summarized under the Haemorrhage terms (excluding laboratory terms) SMQN.
AE=adverse event, AEI=adverse event of interest, TEAE=treatment-emergent adverse event.
1. Song Y et al. *Clin Cancer Res*. 2020;26(16):4216-4224; 2. Song Y et al. Poster presented at: EHA 2021;Abstract No. EP789; 3. Song Y et al. *Blood*. 2022;139:3148-3158.