



## Sample Information

**Patient Name:** 蔡英玲

**Gender:** Female

**ID No.:** A203796266

**History No.:** 8980845

**Age:** 71

**Ordering Doctor:** DOC6266E 徐千富

**Ordering REQ.:** 0BXMWVP

**Signing in Date:** 2022/07/12

**Path No.:** S111-99747

**MP No.:** MY22019

**Assay:** Oncomine Myeloid Assay

**Sample Type:** Blood

**Date of blood drawing:** 2022/07/11

**Reporting Doctor:** DOC5466K 葉奕成 (Phone: 8#5466)

**Note:**

## Sample Cancer Type: Acute Lymphoblastic Leukemia

Table of Contents	Page	Report Highlights
Variants (Exclude variant in Taiwan BioBank with >1% allele frequency)	2	1 Relevant Biomarkers
Biomarker Descriptions	2	37 Therapies Available
Relevant Therapy Summary	3	1 Clinical Trials
Relevant Therapy Details	7	
Prognostic Details	38	
Diagnostic Details	39	
Clinical Trials Summary	39	
Alert Details	40	

## Relevant Biomarkers

Tier	Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
IA	<i>BCR-ABL1 fusion</i> BCR activator of RhoGEF and GTPase - ABL proto-oncogene 1, non-receptor tyrosine kinase	dasatinib <sup>1,2</sup> dasatinib + chemotherapy <sup>1,2</sup> imatinib* <sup>1,2</sup> imatinib* + chemotherapy <sup>2</sup> ponatinib <sup>1,2</sup> blinatumomab bosutinib bosutinib + chemotherapy bosutinib + inotuzumab ozogamicin	asciminib <sup>1</sup> bosutinib <sup>1,2</sup> dasatinib <sup>1,2</sup> dasatinib + chemotherapy <sup>1,2</sup> imatinib* <sup>1,2</sup> imatinib* + chemotherapy <sup>2</sup> interferon alpha-2b <sup>2</sup> nilotinib <sup>1,2</sup> allogeneic stem cells	1

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

\* Includes biosimilars

## Relevant Biomarkers (continued)

Tier	Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
		brexucabtagene autoleucel dasatinib + inotuzumab ozogamicin imatinib + inotuzumab ozogamicin inotuzumab ozogamicin inotuzumab ozogamicin + nilotinib inotuzumab ozogamicin + ponatinib nilotinib nilotinib + chemotherapy ponatinib + chemotherapy tisagenlecleucel-t	azacitidine cytarabine cytarabine + daunorubicin cytarabine + daunorubicin + etoposide cytarabine + etoposide + idarubicin cytarabine + fludarabine + idarubicin + filgrastim cytarabine + idarubicin cytarabine + mitoxantrone decitabine gemtuzumab ozogamicin + chemotherapy ponatinib venetoclax + chemotherapy	
	<b>Prognostic significance:</b> NCCN: Poor, ESMO: High <b>Diagnostic significance:</b> Acute Lymphoblastic Leukemia			

Public data sources included in relevant therapies: FDA<sup>1</sup>, NCCN, EMA<sup>2</sup>, ESMO

Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

\* Includes biosimilars

## Variants (Exclude variant in Taiwan BioBank with >1% allele frequency)

### Gene Fusions (RNA)

Genes	Variant ID	Locus	Read Count
BCR-ABL1	BCR-ABL1.B1A2	chr22:23524426 - chr9:133729451	19917

## Biomarker Descriptions

### ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase)

**Background:** The ABL1 proto-oncogene encodes the ABL1 non-receptor tyrosine kinase, a member of the ABL family which also includes ABL2<sup>1</sup>. Based on its cellular localization (cytoplasmic or nuclear), ABL1 regulates various cellular functions, including cell growth, adhesion, survival, invasion, or migration<sup>2,3</sup>. ABL1 is most extensively studied in hematological malignancies, where constitutive activation of the ABL1 gene is associated with Philadelphia chromosome (Ph+) leukemias. Ph+ (also denoted as t(9;22) (q34;q11)) is a translocation event involving rearrangement of the kinase domain of ABL1 on chromosome 9 with the promoter region of the partner gene BCR on chromosome 22<sup>2</sup>.

**Alterations and prevalence:** BCR-ABL1 fusions are reported in more than 90% of chronic myeloid leukemia (CML) cases, 25-35% of adult acute lymphoblastic leukemia (ALL) cases, and 3-5% of childhood ALL cases<sup>4,5,6,7</sup>. Other known fusion partners in hematological cancers include NUP214, ETV6, and EML1<sup>2,5</sup>. Somatic missense mutations such as E255K/V, F317C/I/L/V, F359C/I/V, G250E, T315A/I, V299L, and Y253H are observed in the kinase domain of the BCR-ABL1 fusion, and are associated with resistance to first-generation tyrosine kinase inhibitors (TKI). In comparison to hematological cancer, ABL1 alterations (including somatic mutations and amplification) occur rarely in solid tumors<sup>2</sup>.

**Potential relevance:** The BCR-ABL1 fusion is a diagnostic marker for Ph+/BCR-ABL1 CML<sup>8</sup>. Secondary mutations in the kinase domain (KD) of the BCR-ABL1 fusion are associated with poor prognosis, as they confer resistance to various first- or second-line TKIs<sup>8</sup>. Several targeted TKIs are approved by the FDA for activated BCR-ABL1, primarily in hematological cancers. These include imatinib<sup>9</sup> (2001), dasatinib<sup>10</sup> (2006), and ponatinib<sup>11</sup> (2012) in CML and ALL, as well as nilotinib<sup>12</sup> (2007) and bosutinib<sup>13</sup> (2012) in CML. While imatinib is recommended as a first-line TKI for BCR-ABL1 fusion, variant-specific TKIs for KD mutations include nilotinib for T315I, Y253H, E255K/V, or F359V/C/I; dasatinib for F317C/I/L/V, T315I/A, or V299L; and bosutinib for T315I, V299L, G250E, or F317L CML<sup>8</sup>. Ponatinib is approved for T315I CML and ALL, as the mutation confers resistance to imatinib, dasatinib, nilotinib, and bosutinib<sup>8</sup>.













































































































## Biomarker Descriptions (continued)

The ABL myristoyl pocket (STAMP) inhibitor, asciminib, has also been approved (2021) for adults with BCR-ABL1 T315I mutated Philadelphia-chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase<sup>14</sup>.

## Relevant Therapy Summary

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### BCR-ABL1 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
dasatinib					
imatinib					
dasatinib + chemotherapy					
ponatinib					
bosutinib					
nilotinib					
asciminib					
imatinib + chemotherapy					
blinatumomab					
bosutinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone					
bosutinib + blinatumomab					
bosutinib + chemotherapy					
bosutinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone					
bosutinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone					
bosutinib + cytarabine + HyperCVAD					
bosutinib + cytarabine + HyperCVAD + methotrexate					
bosutinib + inotuzumab ozogamicin					
bosutinib + steroid					
bosutinib + vincristine + dexamethasone					
brexucabtagene autoleucel					
dasatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone					
dasatinib + blinatumomab					

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### BCR-ABL1 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
dasatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone	×	●	×	×	×
dasatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone	×	●	×	×	×
dasatinib + cytarabine + HyperCVAD	×	●	×	×	×
dasatinib + cytarabine + HyperCVAD + methotrexate	×	●	×	×	×
dasatinib + inotuzumab ozogamicin	×	●	×	×	×
dasatinib + steroid	×	●	×	×	×
dasatinib + vincristine + dexamethasone	×	●	×	×	×
imatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone	×	●	×	×	×
imatinib + blinatumomab	×	●	×	×	×
imatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone	×	●	×	×	×
imatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone	×	●	×	×	×
imatinib + cytarabine + HyperCVAD	×	●	×	×	×
imatinib + cytarabine + HyperCVAD + methotrexate	×	●	×	×	×
imatinib + inotuzumab ozogamicin	×	●	×	×	×
imatinib + steroid	×	●	×	×	×
imatinib + vincristine + dexamethasone	×	●	×	×	×
inotuzumab ozogamicin	×	●	×	×	×
inotuzumab ozogamicin + nilotinib	×	●	×	×	×
inotuzumab ozogamicin + ponatinib	×	●	×	×	×
nilotinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone	×	●	×	×	×
nilotinib + blinatumomab	×	●	×	×	×
nilotinib + chemotherapy	×	●	×	×	×
nilotinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone	×	●	×	×	×

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

 In this cancer type    
  In other cancer type    
  In this cancer type and other cancer types    
  No evidence

### BCR-ABL1 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
nilotinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone	×	●	×	×	×
nilotinib + cytarabine + HyperCVAD	×	●	×	×	×
nilotinib + cytarabine + HyperCVAD + methotrexate	×	●	×	×	×
nilotinib + steroid	×	●	×	×	×
nilotinib + vincristine + dexamethasone	×	●	×	×	×
ponatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone	×	●	×	×	×
ponatinib + blinatumomab	×	●	×	×	×
ponatinib + chemotherapy	×	●	×	×	×
ponatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone	×	●	×	×	×
ponatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone	×	●	×	×	×
ponatinib + cytarabine + HyperCVAD	×	●	×	×	×
ponatinib + cytarabine + HyperCVAD + methotrexate	×	●	×	×	×
ponatinib + steroid	×	●	×	×	×
ponatinib + vincristine + dexamethasone	×	●	×	×	×
tisagenlecleucel-t	×	●	×	×	×
Allogeneic hematopoietic stem cell transplantation	×	○	×	×	×
azacitidine	×	○	×	×	×
cytarabine	×	○	×	×	×
cytarabine + daunorubicin	×	○	×	×	×
cytarabine + daunorubicin + etoposide	×	○	×	×	×
cytarabine + etoposide + idarubicin	×	○	×	×	×
cytarabine + fludarabine + idarubicin + filgrastim	×	○	×	×	×
cytarabine + idarubicin	×	○	×	×	×
cytarabine + mitoxantrone	×	○	×	×	×
decitabine	×	○	×	×	×
gemtuzumab ozogamicin + cytarabine + daunorubicin	×	○	×	×	×

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Summary (continued)

● In this cancer type    
 ○ In other cancer type    
 ⓘ In this cancer type and other cancer types    
 × No evidence

### BCR-ABL1 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
venetoclax + azacitidine	×	○	×	×	×
venetoclax + cytarabine	×	○	×	×	×
venetoclax + decitabine	×	○	×	×	×
imatinib (Accord)	×	×	ⓘ	×	×
imatinib (Accord) + chemotherapy	×	×	ⓘ	×	×
imatinib (Koanaa)	×	×	ⓘ	×	×
imatinib (Koanaa) + chemotherapy	×	×	ⓘ	×	×
interferon alpha-2b	×	×	○	×	×
ponatinib, imatinib, chemotherapy	×	×	×	×	● (III)

\* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

## Relevant Therapy Details

### Current FDA Information

☒ In this cancer type    ☐ In other cancer type    ☒ In this cancer type and other cancer types

FDA information is current as of 2022-05-18. For the most up-to-date information, search [www.fda.gov](https://www.fda.gov).

#### BCR-ABL1 fusion

#### ☒ dasatinib, dasatinib + chemotherapy

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2021-06-29

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

#### Indications and usage:

SPRYCEL® is a kinase inhibitor indicated for the treatment of

- newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
- adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.
- pediatric patients 1 year of age and older with Ph+ CML in chronic phase.
- pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

#### Reference:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/021986s025lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021986s025lbl.pdf)

## BCR-ABL1 fusion (continued)

## ① imatinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2022-03-24

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Indications and usage:**

GLEEVEC® is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
- Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/021588s060lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021588s060lbl.pdf)

## ● ponatinib

**Cancer type:** Acute Lymphoblastic Leukemia **Label as of:** 2022-02-15

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Indications and usage:**

ICLUSIG® is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
- Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated.
- T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

**Limitations of Use:** ICLUSIG® is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/203469s035lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/203469s035lbl.pdf)



## BCR-ABL1 fusion (continued)

### ○ asciminib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia **Label as of:** 2021-10-29

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Indications and usage:**

SCEMBLIX® is a kinase inhibitor indicated for the treatment of adult patients with:

- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). This indication is approved under accelerated approval based on major molecular response (MMR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Ph+ CML in CP with the T315I mutation.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/215358s000Orig2lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig2lbl.pdf)

### ○ bosutinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia **Label as of:** 2021-05-14

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Indications and usage:**

BOSULIF® is a kinase inhibitor indicated for the treatment of adult patients with

- Newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML).
- Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/203341s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203341s020lbl.pdf)

### ○ nilotinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia **Label as of:** 2021-09-23

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Indications and usage:**

TASIGNA® is a kinase inhibitor indicated for the treatment of:

- Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.
- Pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

**Reference:**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/022068s035s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022068s035s036lbl.pdf)

## Current NCCN Information

- ☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

NCCN information is current as of 2022-05-02. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BCR-ABL1 fusion

#### ● blinatumomab

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

#### ● bosutinib

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

#### ● bosutinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

#### ● bosutinib + blinatumomab

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● bosutinib + chemotherapy

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Refractory, Relapsed (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + cytarabine + HyperCVAD

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● bosutinib + cytarabine + HyperCVAD + methotrexate

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + inotuzumab ozogamicin

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + steroid

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● bosutinib + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● brexucabtagene autoleucel

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + blinatumomab

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● dasatinib + chemotherapy

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Refractory, Relapsed (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + cytarabine + HyperCVAD

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● dasatinib + cytarabine + HyperCVAD + methotrexate

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + inotuzumab ozogamicin

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + steroid

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● dasatinib + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● imatinib

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● imatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● imatinib + blinatumomab

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● imatinib + chemotherapy

Cancer type: Acute Lymphoblastic Leukemia Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]



**BCR-ABL1 fusion (continued)****● imatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Refractory, Relapsed (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● imatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● imatinib + cytarabine + HyperCVAD**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● imatinib + cytarabine + HyperCVAD + methotrexate**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● imatinib + inotuzumab ozogamicin

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● imatinib + steroid

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● imatinib + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● inotuzumab ozogamicin

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● inotuzumab ozogamicin + nilotinib

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● inotuzumab ozogamicin + ponatinib

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● nilotinib

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● nilotinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**BCR-ABL1 fusion (continued)****● nilotinib + blinatumomab**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● nilotinib + chemotherapy**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● nilotinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Refractory, Relapsed (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

**● nilotinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone**

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● nilotinib + cytarabine + HyperCVAD

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● nilotinib + cytarabine + HyperCVAD + methotrexate

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● nilotinib + steroid

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● nilotinib + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● ponatinib

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + asparaginase + cytarabine + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + blinatumomab

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + chemotherapy

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● ponatinib + cyclophosphamide + cytarabine + daunorubicin + methotrexate + PEG-L-asparaginase + vincristine + dexamethasone + prednisone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Refractory, Relapsed (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + cytarabine + daunorubicin + etoposide + methotrexate + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + cytarabine + HyperCVAD

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + cytarabine + HyperCVAD + methotrexate

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ● ponatinib + steroid

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● ponatinib + vincristine + dexamethasone

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell (Induction therapy); Other recommended intervention
- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ● tisagenlecleucel-t

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- B-cell; Relapsed, Refractory (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### ○ bosutinib

Cancer type: Chronic Phase Chronic Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (First-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]



## BCR-ABL1 fusion (continued)

### ○ cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + idarubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ dasatinib

Cancer type: Chronic Phase Chronic Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 1

Population segment (Line of therapy):

- (First-line therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

## BCR-ABL1 fusion (continued)

### ○ imatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

### ○ nilotinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 1

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

### ○ Allogeneic hematopoietic stem cell transplantation

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Consolidation therapy)

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ bosutinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

## BCR-ABL1 fusion (continued)

### ☐ cytarabine

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ☐ cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ☐ cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ☐ cytarabine + idarubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ☐ cytarabine + mitoxantrone

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ○ dasatinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia      **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

### ○ decitabine

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Induction therapy)

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ gemtuzumab ozogamicin + cytarabine + daunorubicin

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Induction therapy); Other recommended intervention

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ imatinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia      **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (First-line therapy); Other recommended intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

## BCR-ABL1 fusion (continued)

### ○ nilotinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia      **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

### ○ ponatinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia      **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (First-line therapy); Preferred intervention

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

### ○ venetoclax + azacitidine

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Induction therapy)

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ venetoclax + cytarabine

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Induction therapy)

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ venetoclax + decitabine

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- (Induction therapy)

**Reference:** NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ○ azacitidine

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- (Induction therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ cytarabine + fludarabine + idarubicin + filgrastim

Cancer type: Acute Myeloid Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2B

Population segment (Line of therapy):

- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 1.2022]

### ○ bosutinib

Cancer type: Myeloid/Lymphoid Neoplasms with Eosinophilia

Variant class: ABL1 fusion

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Chronic Phase, Blast Phase (Line of therapy not specified); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [Version 1.2022]

## BCR-ABL1 fusion (continued)

### ☐ imatinib

**Cancer type:** Myeloid/Lymphoid Neoplasms with Eosinophilia     **Variant class:** ABL1 fusion

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- Chronic Phase, Blast Phase (Line of therapy not specified); Other recommended intervention

**Reference:** NCCN Guidelines® - NCCN-Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [Version 1.2022]

### ☐ ponatinib

**Cancer type:** Myeloid/Lymphoid Neoplasms with Eosinophilia     **Variant class:** ABL1 fusion

**NCCN Recommendation category:** 2A

**Population segment (Line of therapy):**

- Chronic Phase, Blast Phase (Line of therapy not specified); Other recommended intervention

**Reference:** NCCN Guidelines® - NCCN-Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [Version 1.2022]

## Current EMA Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

EMA information is current as of 2022-05-18. For the most up-to-date information, search [www.ema.europa.eu/ema](http://www.ema.europa.eu/ema).

### BCR-ABL1 fusion

#### ☒ dasatinib, dasatinib + chemotherapy

**Cancer type:** Acute Lymphoblastic Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2022-04-21

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/sprycel-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/sprycel-epar-product-information_en.pdf)

#### ☒ imatinib (Accord), imatinib (Accord) + chemotherapy

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2022-01-10

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/imatinib-accord-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/imatinib-accord-epar-product-information_en.pdf)

#### ☒ imatinib (Koanaa), imatinib (Koanaa) + chemotherapy

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2021-10-01

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/imatinib-koanaa-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/imatinib-koanaa-epar-product-information_en.pdf)

#### ☒ imatinib, imatinib + chemotherapy

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2021-11-10

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/imatinib-teva-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/imatinib-teva-epar-product-information_en.pdf)



## BCR-ABL1 fusion (continued)

### ① imatinib, imatinib + chemotherapy

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2022-04-05

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/glivec-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/glivec-epar-product-information_en.pdf)

### ● dasatinib, dasatinib + chemotherapy

**Cancer type:** Acute Lymphoblastic Leukemia

**Label as of:** 2022-03-30

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/dasatinib-accord-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/dasatinib-accord-epar-product-information_en.pdf)

### ● ponatinib

**Cancer type:** Acute Lymphoblastic Leukemia

**Label as of:** 2022-05-11

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/clusig-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/clusig-epar-product-information_en.pdf)

### ○ bosutinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia, Blast Phase Chronic Myeloid Leukemia, Chronic Phase Chronic Myeloid Leukemia

**Label as of:** 2022-05-03

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/bosulif-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/bosulif-epar-product-information_en.pdf)

### ○ interferon alpha-2b

**Cancer type:** Chronic Myeloid Leukemia

**Label as of:** 2021-07-06

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/introna-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/introna-epar-product-information_en.pdf)

## BCR-ABL1 fusion (continued)

### ○ nilotinib

**Cancer type:** Accelerated Phase Chronic  
Myeloid Leukemia, Chronic Phase Chronic  
Myeloid Leukemia

**Label as of:** 2021-07-21

**Variant class:** BCR-ABL1 fusion [t(9;22)  
(q34;q11)]

**Reference:**

[https://www.ema.europa.eu/en/documents/product-information/tasigna-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/tasigna-epar-product-information_en.pdf)

## Current ESMO Information

☒ In this cancer type
 ☐ In other cancer type
 ☒ In this cancer type and other cancer types

ESMO information is current as of 2022-05-02. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

### BCR-ABL1 fusion

#### ☐ dasatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- (First-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

#### ☐ imatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- (First-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

#### ☐ nilotinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** I / A

**Population segment (Line of therapy):**

- (First-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

#### ☐ dasatinib

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** II / A

**Population segment (Line of therapy):**

- (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

## BCR-ABL1 fusion (continued)

### ○ imatinib

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** II / A

**Population segment (Line of therapy):**

- (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

### ○ nilotinib

**Cancer type:** Acute Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** II / A

**Population segment (Line of therapy):**

- (Line of therapy not specified)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

### ○ bosutinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** V / A

**Population segment (Line of therapy):**

- Resistant, Refractory (Second-line therapy, Third-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

### ○ dasatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** V / A

**Population segment (Line of therapy):**

- Resistant, Refractory (Second-line therapy, Third-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

## BCR-ABL1 fusion (continued)

### ○ imatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** V / A

**Population segment (Line of therapy):**

- Resistant, Refractory (Second-line therapy, Third-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

### ○ nilotinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

**ESMO Level of Evidence/Grade of Recommendation:** V / A

**Population segment (Line of therapy):**

- Resistant, Refractory (Second-line therapy, Third-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

### ○ dasatinib

**Cancer type:** Chronic Phase Chronic Myeloid Leukemia

**Variant class:** t(9;22)(q34;q11.2)

**ESMO Level of Evidence/Grade of Recommendation:** V / A

**Population segment (Line of therapy):**

- Resistant, Refractory (Second-line therapy, Third-line therapy)

**Reference:** ESMO Clinical Practice Guidelines - ESMO-Chronic Myeloid Leukemia [Ann Oncol (2017) 28 (suppl 4): iv41–iv51. (Corrigendum: 03 October 2018)]

## Prognostic Details

### Current NCCN Information

NCCN information is current as of 2022-05-02. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

#### BCR-ABL1 fusion

#### Prognostic significance: NCCN: Poor

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

#### Summary:

- Cytogenetics risk groups for B-ALL

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### Current ESMO Information

ESMO information is current as of 2022-05-02. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

#### BCR-ABL1 fusion

#### Prognostic significance: ESMO: High

Cancer type: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Lymphoblastic Leukaemia [Ann Oncol (2016) 27 (suppl 5): v69-v82.]

## Diagnostic Details

### Current NCCN Information

NCCN information is current as of 2022-05-02. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

#### BCR-ABL1 fusion

#### Diagnostic significance: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

NCCN Recommendation category: 2A

#### Diagnostic notes:

- B-cell Lymphoblastic Leukemia/Lymphoma subtype based on molecular characterization

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 1.2022]

### Current ESMO Information

ESMO information is current as of 2022-05-02. For the most up-to-date information, search [www.esmo.org](http://www.esmo.org).

#### BCR-ABL1 fusion

#### Diagnostic significance: Acute Lymphoblastic Leukemia

Variant class: BCR-ABL1 fusion [t(9;22)(q34;q11)]

#### Diagnostic notes:

- ALL with adverse clinico-biological features (Mandatory)

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Lymphoblastic Leukaemia [Ann Oncol (2016) 27 (suppl 5): v69-v82.]


## Clinical Trials Summary


#### BCR-ABL1 fusion

NCT ID	Title	Phase
NCT03589326	A Phase III, Randomized, Open-label, Multicenter Study Comparing Ponatinib Versus Imatinib, Administered in Combination With Reduced-Intensity Chemotherapy, in Patients With Newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL)	III


## Alerts Informed By Public Data Sources


### Current NCCN Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

NCCN information is current as of 2022-05-02. For the most up-to-date information, search [www.nccn.org](http://www.nccn.org).  
For NCCN International Adaptations & Translations, search [www.nccn.org/global/international\\_adaptations.aspx](http://www.nccn.org/global/international_adaptations.aspx).

### BCR-ABL1 fusion

#### imatinib

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia    **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "Imatinib is not recommended for patients with disease progression on prior TKI therapy."

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]

#### omacetaxine

**Cancer type:** Accelerated Phase Chronic Myeloid Leukemia    **Variant class:** BCR-ABL1 fusion [t(9;22)(q34;q11)]

##### Summary:

NCCN Guidelines® include the following supporting statement(s):

- "Omacetaxine is not a treatment option for patients who present with accelerated phase CML."

**Reference:** NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]



## Signatures

Testing Personnel:

Laboratory Supervisor:

Pathologist:

## References

1. Pendergast. The Abl family kinases: mechanisms of regulation and signaling. *Adv. Cancer Res.* 2002;85:51-100. PMID: 12374288
2. Greuber et al. Role of ABL family kinases in cancer: from leukaemia to solid tumours. *Nat. Rev. Cancer.* 2013 Aug;13(8):559-71. PMID: 23842646
3. Colicelli. ABL tyrosine kinases: evolution of function, regulation, and specificity. *Sci Signal.* 2010 Sep 14;3(139):re6. PMID: 20841568
4. Achkar et al. A rare chronic myeloid leukemia case with Philadelphia chromosome, BCR-ABL e13a3 transcript and complex translocation involving four different chromosomes. *Oncol Lett.* 2010 Sep;1(5):797-800. PMID: 22966382
5. De et al. ABL1 fusion genes in hematological malignancies: a review. *Eur. J. Haematol.* 2011 May;86(5):361-71. PMID: 21435002
6. De et al. Cytogenetics in pre-B and B-cell acute lymphoblastic leukemia: a study of 208 patients diagnosed between 1981 and 2008. *Cancer Genet. Cytogenet.* 2010 Jul 1;200(1):8-15. PMID: 20513528
7. Leoni et al. Tyrosine kinase inhibitors in BCR-ABL positive acute lymphoblastic leukemia. *Haematologica.* 2015 Mar;100(3):295-9. PMID: 25740105
8. NCCN Guidelines® - NCCN-Chronic Myeloid Leukemia [Version 3.2022]
9. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/021588s060lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021588s060lbl.pdf)
10. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/021986s025lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021986s025lbl.pdf)
11. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/203469s035lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/203469s035lbl.pdf)
12. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/022068s035s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022068s035s036lbl.pdf)
13. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/203341s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203341s020lbl.pdf)
14. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/215358s000Orig2lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig2lbl.pdf)