For adult patients with CML failing at least one 2G TKI or who have the T315I mutation[1]

# ICLUSIG® (PONATINIB) COMBINES EXPERIENCE AND DATA THAT MAY HELP IMPROVE THEIR FUTURE[2,3]


## WE'VE COME A LONG WAY IN CML TREATMENT, BUT WE STILL HAVE WORK TO DO

We know that treatment failure in CML can be devastating for the 1 in 3 patients who experience failure in the 1L setting (on imatinib or a 2G TKI).[4-6]

Failure of the first 2G TKI is still a problem today: 30–40% of patients experience 2G TKI failure by 5 years in the 1L setting, and there is a low likelihood of response to an alternative 2G TKI (regardless of treatment line).[7]

Read on to learn more about why you should consider switching to ICLUSIG after one 2G TKI, for eligible patients.

## ICLUSIG HAS BEEN WITH YOU SINCE 2013!

## TOGETHER, WE'VE BUILT EXPERIENCE AND CONFIDENCE WITH ICLUSIG IN PATIENTS WITH CML[1–3]

**Over the last decade, ICLUSIG has proudly demonstrated responses that are:**

### Fast

Median time to MCyR in CP-CML patients who achieved MCyR in PACE: **2.8 months** (range: 1.6 to 11.3 months)[1]

Median time to MMR in CP-CML patients who achieved MMR in PACE: **5.5 months** (range: 1.8 to 55.5 months)[1]

### Deep

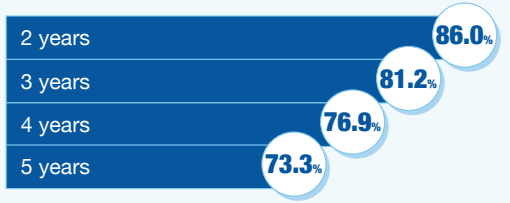
MMR rate in CP-CML patients in PACE at **5-year follow-up**:[2]

**40%** of patients

### Durable

Among CP-CML patients in PACE, at **5 years**:
**59%** of patients who achieved MMR at any time maintained their response[2]
**82%** of patients who achieved MCyR by 12 months maintained their response (Kaplan-Meier estimates)[2]

For patients with CP-CML, the probability of overall survival from PACE is estimated at:[1]




## Data from the OPTIC trial affirmed efficacy outcomes, demonstrating clinical benefit in patients with CP-CML

The **primary endpoint** (≤1% BCR::ABL1$^{IS}$ at 12 months) was achieved by **44.1%** of patients.[3] Data shown below were secondary endpoints of the OPTIC trial:


with a response-based dose-reduction from 45 mg or 30 mg to 15 mg **maintained response**.[3*]

**MR2 (≤1% BCR::ABL1$^{IS}$) by 24 months:[3]**


45 mg → 15 mg regimen

**Estimated 24-month OS[3]**


45 mg → 15 mg regimen

**Estimated 24-month PFS[3]**


45 mg → 15 mg regimen

## The OPTIC trial now provides clear evidence to induce, reduce and maintain ICLUSIG dose to manage your patients with CP-CML[3]

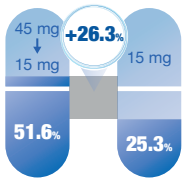
**Induce**
with 45 mg orally, once daily

**Reduce**
to 15 mg orally, once daily, upon achievement of ≤1% BCR::ABL1[IS]*

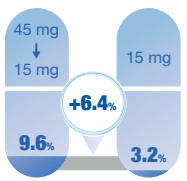
**Maintain**
with 15 mg dose*

The results from the OPTIC trial support an ICLUSIG regimen of a starting dose of 45 mg reduced to 15 mg upon response, to maximise response while minimising toxicity[3]

**Improvement in response rate (by 12 months)**



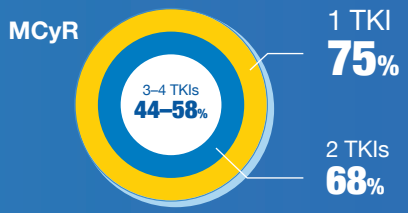

**AOE rate (by 12 months)**




# UNDERSTANDING OF HOW TO OPTIMISE USE OF CURRENT TKIs TO IMPROVE PATIENT OUTCOMES CONTINUES TO GROW

**Early use of ICLUSIG leads to the deepest responses[1]**

The **deepest response with ICLUSIG** was achieved when used after 1 or 2 TKIs compared to after 3 or 4.[1]



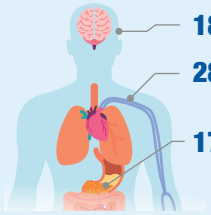

In the PACE trial, patients with CP-CML who received **fewer prior TKIs** attained **higher cytogenetic, haematological and molecular responses**.[1]

10 years

## With a decade of ICLUSIG experience, the safety profile is well characterised and tolerability is manageable[1]

## ICLUSIG had a manageable safety profile in the OPTIC trial, with no new safety signals[3]

The most common non-haematological TEAEs for all cohorts combined in the OPTIC trial were:[3]



**18%** Headache
**28%** Arterial Hypertension
**17%** Lipase Increase

## AOEs have occurred in:[1]

Iclusig-treated patients

**25% PACE** (≥64 mo follow up) including arterial cardiovascular **(13%)**, cerebrovascular **(9%)** and peripheral vascular occlusive **(11%)** adverse reactions

**10% OPTIC** (45 mg cohort, median follow up: 31.1 mo) including arterial cardiovascular **(4%)**, cerebrovascular **(2%)** and peripheral vascular occlusive **(3%)** adverse reactions

## Common AEs

- AEs occurring in ≥10% of CML and Ph+ ALL patients in PACE:[1]

Upper respiratory tract infection, anaemia, platelet count decreased, neutrophil count decreased, decreased appetite, insomnia, headache, dizziness, hypertension, dyspnoea, cough, abdominal pain, diarrhoea, vomiting, constipation, nausea, lipase increased, alanine aminotransferase increased, aspartate aminotransferase increased, rash, dry skin, pruritus, bone pain, arthralgia, myalgia, pain in extremity, back pain, muscle spasm, fatigue, asthenia, oedema peripheral, pyrexia, pain.

- A full list of ADRs can be found in the SmPC[1]

## ICLUSIG combines experience and data to improve patients' futures – consider early switch to ICLUSIG after just one 2G TKI


### A decade of building patients' futures

More than **15,000 patients** have been treated with ICLUSIG over the past 10 years in Europe.[8]

Incyte

**For more information contact:**

John Eriksson
jeriksson@incyte.com
+46 73 440 88 12

Sophia Björkdahl
sbjorkdahl@incyte.com
+46 704 66 31 05

ICLUSIG is indicated in adult patients with CP-, AP- or BP-CML who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. ICLUSIG is also indicated in patients with Ph+ ALL who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. The recommended starting dose of ICLUSIG is 45 mg once daily.

*Patients with loss of response can re-escalate the dose of ICLUSIG to a previously tolerated dosage of 30 mg or 45 mg orally once daily. Continue ICLUSIG until loss of response at the re-escalated dose or unacceptable toxicity. Consider discontinuing ICLUSIG if a complete haematological response has not occurred by 3 months.[1]

1L, first-line; 2G, second-generation; ADR, adverse drug reaction; AE, adverse event; AOE, arterial occlusive event; AP, accelerated phase; BP, blast phase; CML, chronic myeloid leukaemia; CP, chronic phase; IS, International Scale; MCyR, major cytogenetic response; MMR, major molecular response; mo, months; MR, molecular response; OPTIC, Optimizing Ponatinib Treatment In CP-CML; OS, overall survival; PACE, Ponatinib Ph+ ALL and CML Evaluation; PFS, progression-free survival; Ph+ ALL, Philadelphia chromosome–positive acute lymphoblastic leukaemia; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor.

**1.** ICLUSIG® (ponatinib). Summary of Product Characteristics. Incyte Biosciences Distribution B.V. 2022; **2.** Cortes JE, et al. *Blood*. 2018;132:393–404; **3.** Cortes JE, et al. *Blood*. 2021;138:2042–50; **4.** Miller GD, et al. *Biologics*. 2014;8:243–54; **5.** Leukaemia Care. https://media.leukaemiacare.org.uk/wp-content/uploads/Living-with-Leukaemia-2018-Full-Report-Web-Version.pdf (accessed June 2023); **6.** Borghi L, et al. *Front Psychol*. 2019;10:329; **7.** Cortes J, Lang F. *J Hematol Oncol*. 2021;14:44; **8.** Incyte, data on file.

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**Iclusig (ponatinib) 15 mg, 30 mg och 45 mg filmdragerade tabletter.** Rx. 15 mg: F, 30 mg/45 mg: $F_f$. ATC-kod: L01EA05. Antineoplastiska medel, proteinkinashämmare. **Indicerat** för vuxna patienter med kronisk myeloisk leukemi (KML) i kronisk fas, accelererad fas eller blastkris som är resistenta mot dasatinib eller nilotinib; som är intoleranta mot dasatinib eller nilotinib och för vilka påföljande behandling med imatinib inte är kliniskt lämplig; eller som har T315I-mutation; samt för vuxna patienter med Philadelphia-kromosompositiv akut lymfatisk leukemi (Ph+ ALL) som är resistenta mot dasatinib; som är intoleranta mot dasatinib och för vilka påföljande behandling med imatinib inte är kliniskt lämplig; eller som har T315I-mutation. **Varningar & försiktighet**: Ska sättas in av läkare med erfarenhet av diagnosticering och behandling av patienter med leukemi. Innan behandling med ponatinib inleds ska patientens kardiovaskulära status bedömas, inklusive sjukdomshistoria och kroppsundersökning och de kardiovaskulära riskfaktorerna ska hanteras aktivt. Kardiovaskulär status ska övervakas kontinuerligt och medicinsk och understödjande behandling som används för sjukdomstillstånd med en kardiovaskulär risk ska optimeras under behandling med ponatinib. Utsättning av behandlingen ska övervägas om ett fullständigt hematologiskt svar inte har uppnåtts efter 3 månader. Under behandling ska blodtrycket övervakas och hanteras vid varje besök på kliniken och hypertoni ska behandlas till normalvärdet. Behandlingen med Iclusig ska avbrytas temporärt om inte hypertonin är under kontroll med läkemedel Användningen av VEGF-hämmare till patienter med eller utan hypertoni kan främja bildningen av aneurysmer och/eller arteriella dissektioner. Denna risk ska noga övervägas innan Iclusig sätts in hos patienter med riskfaktorer såsom hypertoni eller tidigare aneurysm. Patienter ska övervakas avseende tecken och symtom på hjärtsvikt och behandlas så som är kliniskt indicerat, inklusive avbrytande av behandling med Iclusig. Komplett blodstatus, kardiovaskulär status, leverfunktion och serumlipas bör kontrolleras och hanteras enligt SPC. Patienter med myokardinfarkt, tidigare revaskularisering eller stroke i anamnesen bör inte behandlas med ponatinib. Inclusig associeras med svår myelosuppression, kardiovaskulära biverkningar, pankreatit, levertoxicitet, hemorragi och reaktivering av hepatit B. Patienter ska testas för HBV-infektion innan behandling och bärare ska övervakas under och efter behandling. Fall av posterior reversibel encefalopatisyndrom (PRES) har rapporterats. Försiktighet bör iakttas om Iclusig används samtidigt med måttliga och starka CYP3A-hämmare och måttliga och starka CYP3A-inducerare. Fertila kvinnor som behandlas med Iclusig ska informeras om att inte bli gravida och män som behandlas med Iclusig ska informeras om att inte avla barn under behandlingen. Amning ska avbrytas under behandling med Iclusig. Försiktighet rekommenderas vid bilkörning och användning av maskiner. **MAH:** Incyte Biosciences Distribution B.V., Paasheuvelweg 25, 1105 BP Amsterdam, Nederländerna. Produktresumén uppdaterad 2022-03-24. Besök www.fass.se för ytterligare information och pris.