Click here for the BESPONSA SmPC

*Results from phase 3 INO-VATE study comparing BESPONSA and SC in adult patients with R/R B-cell ALL (n=218).[1]
†Results from pooled data from INO-VATE and the earlier phase 1/2 Study 1010 of patients who received HSCT after treatment (n=101 for BESPONSA, n=31 for SC).[3]
AE=adverse event; ALL=acute lymphoblastic leukemia; CR=complete response; CRi=complete response without complete blood count recovery; HSCT=hematopoietic stem cell transplantation; MRD=minimal residual disease; OS=overall survival; R/R=relapsed or refractory; SC=standard chemotherapy.

PP-INO-GLB-0135. May 2021.

BESPONSA® ▼
inotuzumab ozogamicin SOLUTION FOR INFUSION

IN RELAPSED OR REFRACTORY B-CELL ALL

MAKE YOUR FIRST SHOT COUNT **AND AIM TO INCREASE LONG-TERM SURVIVAL**

BESPONSA achieved:

80.7%
CR/CRi rate[1]* (88/109)

78%
MRD-negativity rate in patients who achieved CR/CRi[1]* (69/88)

UP TO 51%
Post-transplant OS at 2 years[2Ü]

▼ **This medicinal product is subject to additional monitoring.**

Indication: BESPONSA is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome-positive (Ph+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI).

Aim to Increase Long-term Survival Rates

BESPONSA more than doubled the rate of CR/CRi and achieved higher rates of MRD-negativity among responders vs SC[1]*

- Of patients receiving BESPONSA, 80.7% (95% CI, 72.1-87.7) achieved CR/CRi, vs 29.4% (95% CI, 21.0-38.8) with SC, a difference of 51.3 percentage points ($P<0.001$)[1]
  - BESPONSA was associated with higher remission rates when used for first salvage: 87.7% CR/CRi (95% CI, 77.9-94.2) vs 28.8% for SC (95% CI, 18.8-40.6)[1]
- Of responding patients, 78.4% (95% CI, 68.4-86.5) achieved MRD-negativity with BESPONSA vs 28.1%
  (95% CI, 13.7-46.7) with SC[1]

BESPONSA demonstrated a median OS benefit of 7.7 months (95% CI, 6.0-9.2) vs 6.2 months (95% CI, 4.7-8.3) with SC (HR 0.75 [97.5% CI, 0.57-0.99] $P=0.0105$)[2*†]

- The primary endpoint of OS was not met in the INO-VATE ALL study[1,2]
- BESPONSA improved 2-year OS vs SC (22.8% [95% CI, 16.7-29.6] vs 10.0% [95% CI, 5.7-15.5)[2]

*Results from phase 3 INO-VATE study comparing BESPONSA and SC in adult patients with R/R B-cell ALL (n=218).[1]
ÜOne-sided *P*-value using log-rank test. Surviving patients followed for a minimum of 2 years. The median follow-up duration for patients who completed the study or were censored for OS was 29.6 months (range 1.7-49.7 months).[2]
ALL=acute lymphoblastic leukemia; CI=confidence interval; CR=complete response; CRi=complete response without complete blood count recovery; HR=hazard ratio; MRD=minimal residual disease; OS=overall survival; SC=standard chemotherapy.

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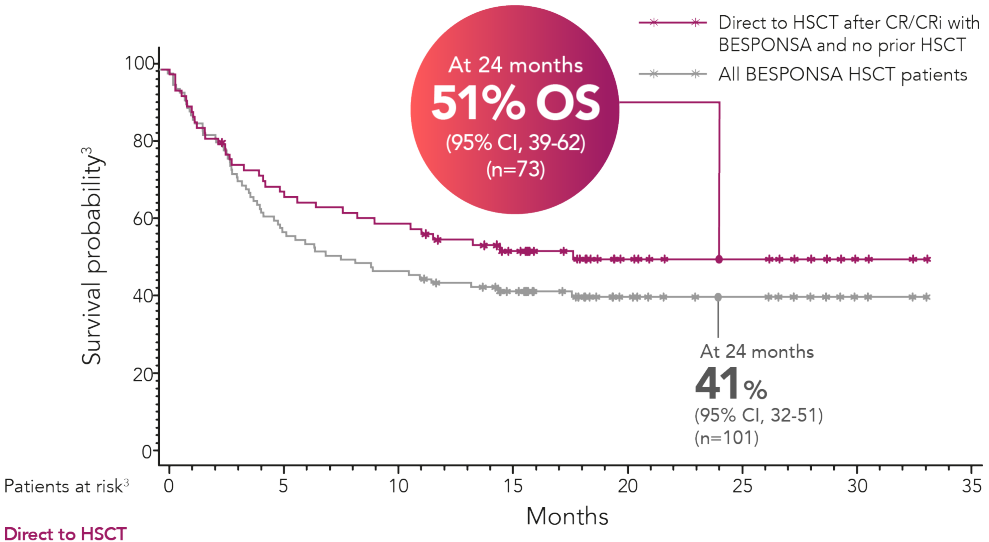
Higher Post-transplant OS Results Were Achieved After CR/CRi with BESPONSA Led Directly to a First HSCT[3]*

OS based on timing of HSCT (pooled analysis of 2 trials)



- **Higher frequency of early death post HSCT:** There was a higher frequency of early death post HSCT (at Day 100) in the BESPONSA arm; however, there was evidence of a late survival benefit for BESPONSA
- Monitor closely for toxicities post HSCT, including signs and symptoms of infection and VOD[4]

*Results from pooled data from INO-VATE and the earlier phase 1/2 Study 1010 of patients who received HSCT after treatment (n=101 for BESPONSA, n=31 for SC).[3]

CI=confidence interval; CR=complete response; CRi=complete response without complete blood count recovery; HSCT=hematopoietic stem cell transplantation; OS=overall survival; VOD=veno-occlusive disease

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BESPONSA Safety Profile

Incidence and Management of VOD Risks

- Of 79 BESPONSA-treated patients who underwent HSCT, 18 (22.3%) developed VOD/SOS[2]*
- Patient selection and therapy management should be a key focus to avoid VOD[2]
- Several risk factors were associated with increased risk for post-HSCT VOD[2]
  - Dual-alkylator conditioning regimens
  - Bilirubin ≥ULN before conditioning therapy
  - Bilirubin ≥ULN before follow-up HSCT
  - Prior HSCT
  - Age ≥55 years[†]
  - Number of treatment cycles received[†]

Other Adverse Events

- The most frequent grade ≥3 AEs in the BESPONSA arm were neutropenia (47%), thrombocytopenia (41%), leukopenia (27%), and febrile neutropenia (27%)[2]

For more information on AEs, see the BESPONSA SmPC

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[Ü]Additional VOD/SOS risk factors that were significant in a univariate analysis but not in multivariate analysis.

AE=adverse event; HSCT=hematopoietic stem cell transplantation; SOS=sinusoidal obstruction syndrome; ULN=upper limit of normal; VOD=veno-occlusive disease.

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References

1. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard care for acute lymphoblastic leukemia. *N Engl J Med.* 2016;375(8):740-753.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard of care in relapsed or refractory acute lymphoblastic leukemia: final report and long-term survival follow-up from the randomized, phase 3 INO-VATE study. *Cancer*. 2019;125(14):2474-2487.
3. Marks DI, Kebriaei P, Stelljes M, et al. Outcomes of allogeneic stem cell transplantation after inotuzumab ozogamicin treatment for relapsed or refractory acute lymphoblastic leukemia. *Biol Blood Marrow Transplant.* 2019;25(9):1720-1729.
4. BESPONSA [summary of product characteristics]. Pfizer; 2020.

Before prescribing Besponsa, please refer to the full Summary of Product Characteristics (SmPC).

Please refer to your local authorities concerning reimbursement status. Medicinal product subject to medical prescription.

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