Confidence comes with ASPARLAS

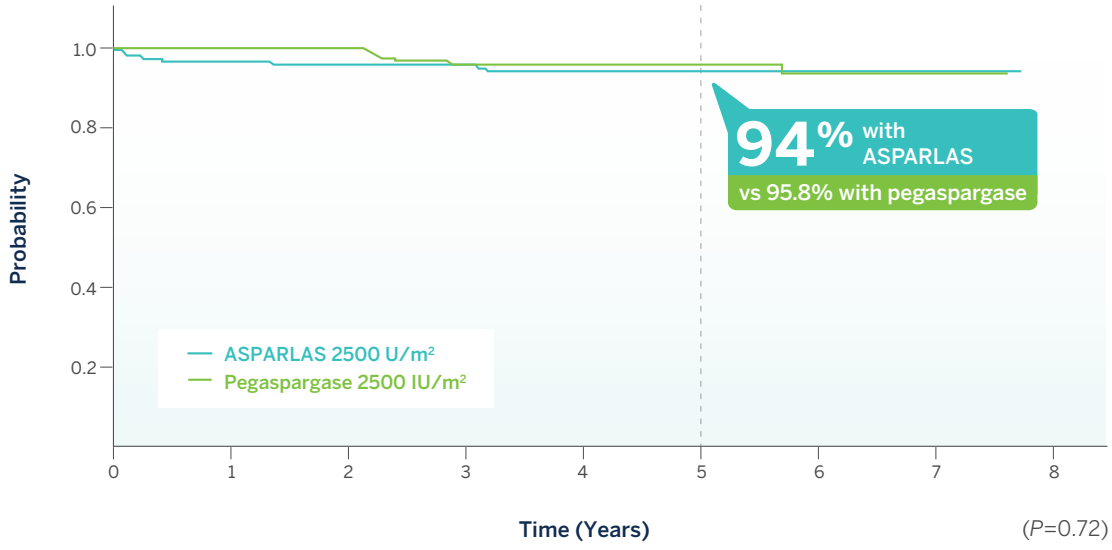
A recommended frontline asparaginase treatment that achieved and maintained the primary endpoint of nadir serum asparaginase activity (NSAA) above the level of 0.1 IU/mL with ASPARLAS 2500 IU/m^2 intravenously every 3 weeks[1]

ASPARLAS IS BUILT ON OVER 30 YEARS OF EXPERIENCE

#1 PRESCRIBED ASPARAGINASE TREATMENT FOR ALL REGIMENS[a]

ASPARLAS has proven 5-year overall survival (OS) for patients with acute lymphoblastic leukemia (ALL)[2]

5-year OS in the DFCI 11-001 study[2]



(*P*=0.72)

ASPARLAS	119	114	113	112	106	77	26	3
Pegaspargase	120	119	119	113	109	83	43	5

94% OS RATE FOR PATIENTS AT 5 YEARS WITH ASPARLAS WHEN ADMINISTERED FOR THE FULL DURATION AS PART OF A TREATMENT REGIMEN FOR ALL[2]

ASPARLAS kept the majority of patients free from relapse-related events through 5 years[2]

- 88.1% of patients achieved 5-year event-free survival (EFS) with ASPARLAS vs 84.9% with pegaspargase when administered for the full duration as part of a treatment regimen for ALL (*P*=0.65)[2]

ASPARLAS IS INDICATED AS A COMPONENT OF A MULTI-AGENT CHEMOTHERAPEUTIC REGIMEN FOR THE TREATMENT OF ALL IN PEDIATRIC AND YOUNG ADULT PATIENTS AGE 1 MONTH TO 21 YEARS[1]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of serious hypersensitivity reactions to pegylated L-asparaginase
- History of serious thrombosis during L-asparaginase therapy
- History of serious pancreatitis during previous L-asparaginase treatment
- History of serious hemorrhagic events during previous L-asparaginase therapy
- Severe hepatic impairment

[a]As of [November 2024].[3]

DFCI, Dana-Farber Cancer Institute; IU, international units.

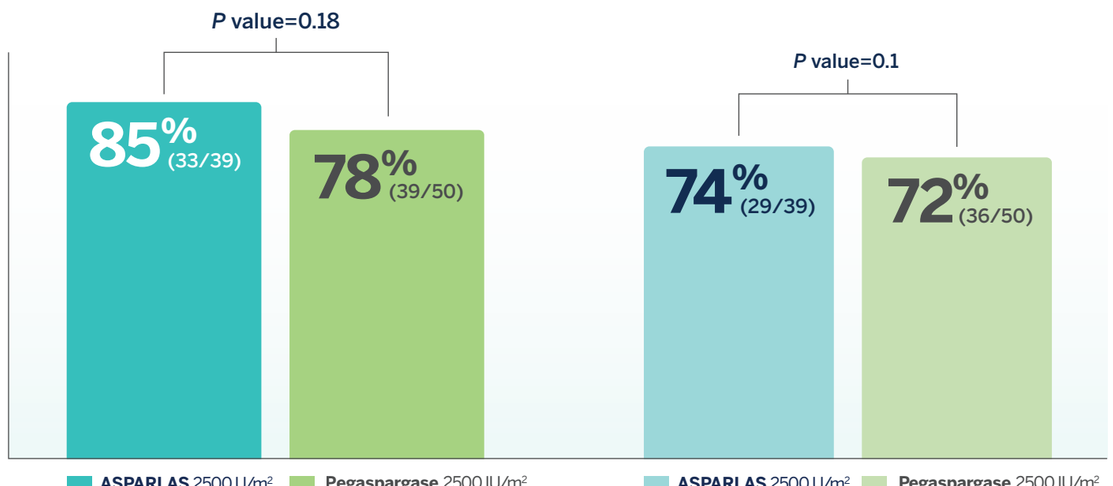
Please see Important Safety Information throughout and Full Prescribing Information accompanying this document or at AsparlasHCP.com.

ASPARLAS®
(calaspargase pegol-mknl)
750 units/mL injection

Think beyond complete remission with ASPARLAS

The majority of patients on a regimen containing ASPARLAS were able to achieve minimal residual disease (MRD) negativity, the strongest prognostic indicator in pediatric ALL[4,5]

Percentage of high-risk patients achieving MRD negativity after induction in the COG AALL07P4 study[4]



- All eligible patients in COG AALL07P4 had newly diagnosed NCI-designated high-risk B-cell ALL (aged ≥10 years and/or initial white blood cell count ≥50,000/mL)[4]

A THE MAJORITY OF PATIENTS IN EACH COHORT ACHIEVED MRD NEGATIVITY (<0.01%) BY THE END OF INDUCTION AT DAY 29[4]

ASPARLAS is proven in the treatment of ALL

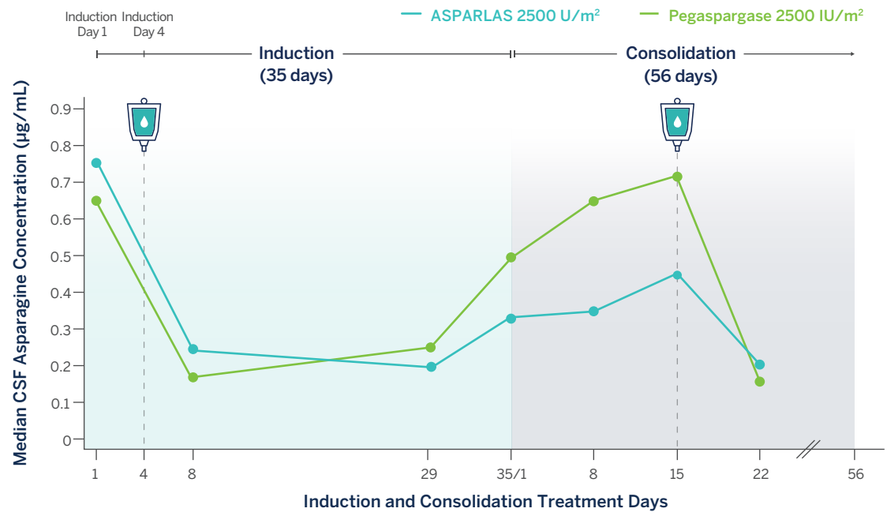
- Efficacy was based on the achievement and maintenance of NSAA above the level of 0.1 U/mL using ASPARLAS 2500 U/m² intravenously every 3 weeks[1]
- Serum asparaginase activity level is the best and most reliable measure of asparaginase efficacy[6]
- 99% of patients treated with ASPARLAS achieved and maintained NSAA >0.1[1]
- Efficacy was demonstrated in a population pharmacokinetic (PK) model using evaluable PK data from clinical trials DFCI 11-001 (n=13) and COG AALL07P4 (n=111)[7]
- Rates of complete remission measured as part of the safety evaluation and not as an efficacy end point in the DFCI 11-001 study showed 98% complete remission in a subgroup of patients with B-cell ALL treated with ASPARLAS vs 99% in patients receiving pegaspargase[1]

COG, Children's Oncology Group.

Please see Important Safety Information throughout and Full Prescribing Information accompanying this document or at AsparlasHCP.com.

ASPARLAS offers long-lasting CSF asparagine depletion to control leukemic lymphoblasts and potentially prevent CNS relapse[3,4]

Mean CSF asparagine concentrations over time after ASPARLAS and pegaspargase administration in the COG AALL07P4 study[4]



- Asparagine concentrations in plasma (n=41) were maintained below the assay limit of quantification for more than 18 days following a single dose of ASPARLAS or pegaspargase during the induction phase[1]
- Mean CSF asparagine levels returned to prebaseline levels by the time of the consolidation dose on Day 15 in pegaspargase-treated patients, which was earlier than occurred for patients treated with ASPARLAS[4]

A SINGLE DOSE OF ASPARLAS IN THE INDUCTION PHASE MAINTAINED ASPARAGINE DEPLETION THROUGH DAY 25[1]

TO LEARN MORE ABOUT ASPARLAS,
SCAN OR VISIT AsparlasHCP.com

CNS, central nervous system; CSF, cerebrospinal fluid.

ASPARLAS®
(calaspargase pegol-mknl)
750 units/mL injection

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity: Grade 3 and 4 hypersensitivity reactions including anaphylaxis have been reported in clinical trials with ASPARLAS with an incidence of 7% to 21%. Because of the risk of serious allergic reactions, administer ASPARLAS in a clinical setting with resuscitation equipment and other agents necessary to treat anaphylaxis. Premedicate patients 30-60 minutes prior to administration of ASPARLAS. Observe patients for 1 hour after administration. Discontinue ASPARLAS in patients with serious hypersensitivity reactions.

Pancreatitis: Cases of pancreatitis have been reported in clinical trials with ASPARLAS with an incidence of 12% to 16%. Inform patients of the signs and symptoms of pancreatitis, which, if left untreated, could be fatal. Assess serum amylase and/or lipase levels to identify early signs of pancreatic inflammation. Discontinue ASPARLAS in case of suspicion of pancreatitis. If pancreatitis is confirmed, do not resume ASPARLAS.

Thrombosis: Serious thrombotic events, including sagittal sinus thrombosis, have been reported in clinical trials with ASPARLAS with an incidence of 9% to 12%. Discontinue ASPARLAS in patients experiencing serious thrombotic events.

Hemorrhage: Hemorrhage associated with increased prothrombin time (PT), increased partial thromboplastin time (PTT), and hypofibrinogenemia have been reported. Evaluate patients with signs and symptoms of hemorrhage with coagulation parameters including PT, PTT, and fibrinogen. Consider appropriate replacement therapy in patients with severe or symptomatic coagulopathy.

Hepatotoxicity: Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of hepatic veno-occlusive disease (VOD), have been observed in patients treated with ASPARLAS in combination with standard chemotherapy, including during the induction phase of multiphase chemotherapy. Do not administer ASPARLAS to patients with severe hepatic impairment. Evaluate bilirubin and transaminases prior to each dose of ASPARLAS and at least weekly, during cycles of treatment that include ASPARLAS, through 6 weeks after the last dose of ASPARLAS. Monitor frequently for signs and symptoms of hepatic VOD, which may include rapid weight gain, fluid retention with ascites, hepatomegaly (which may be painful), and rapid increase of bilirubin. For patients who develop abnormal liver tests after ASPARLAS, more frequent monitoring for liver test abnormalities and clinical signs and symptoms of VOD is recommended. In the event of serious liver toxicity, including VOD, discontinue treatment with ASPARLAS and provide supportive care.

ADVERSE REACTIONS

The most common grade 3 and above adverse reactions (incidence ≥10%) for patients receiving ASPARLAS with multiagent chemotherapy observed in the DFCI clinical trial were elevated transaminase (52%), increased bilirubin (20%), pancreatitis (18%) and abnormal clotting studies (14%). There was 1 fatal adverse reaction (multi-organ failure in the setting of chronic pancreatitis associated with a pancreatic pseudocyst). Not all grade 1 and 2 adverse reactions were collected prospectively.

References: 1. Asparlas. Package insert. Servier Pharmaceuticals LLC; 2023. **2.** Vrooman LM, Blonquist TM, Stevenson KE, et al. Efficacy and toxicity of pegaspargase and calaspargase pegol in childhood acute lymphoblastic leukemia: results of DFCI 11-001. *J Clin Oncol*. 2021;39(31):3496-3505. doi:10.1200/JCO.20.03692 **3.** Data on file. Servier Pharmaceuticals LLC. **4.** Angiolillo AL, Schore RJ, Devidas M, et al. Pharmacokinetic and pharmacodynamic properties of calaspargase pegol Escherichia coli L-asparaginase in the treatment of patients with acute lymphoblastic leukemia: results from Children's Oncology Group study AALL07P4. *J Clin Oncol*. 2014;32(34):3874-3882. doi:10.1200/JCO.2014.55.5763 **5.** Borowitz MJ, Devidas M, Hunger SP, et al. Clinical significance of minimal residual disease in childhood acute lymphoblastic leukemia and its relationship to other prognostic factors: a Children's Oncology Group study. *Blood*. 2008;111(12):5477-85. doi:10.1182/blood-2008-01-132837 **6.** van der Sluis IM, Vrooman LM, Pieters R, et al. Consensus expert recommendations for identification and management of asparaginase hypersensitivity and silent inactivation. *Haematologica*. 2016;101(3):279-85. doi:10.3324/haematol.2015.137380 **7.** Li R-J, Jin R, Liu C, et al. FDA approval summary: calaspargase pegol-mknl for treatment of acute lymphoblastic leukemia in children and young adults. *Clin Cancer Res*. 2020;26(2):328-331. doi:10.1158/1078-0432.CCR-19-1255

Please see Important Safety Information throughout and Full Prescribing Information accompanying this document or at AsparlasHCP.com.

© 2025 Servier Pharmaceuticals LLC, Boston, MA 02210. All rights reserved. Customer Service: 1-800-807-6124. Servier and the Servier logo are trademarks of LES LABORATOIRES SERVIER. ASPARLAS is a registered trademark of Servier IP UK Ltd, a wholly owned indirect subsidiary of LES LABORATOIRES SERVIER.

US-03486 05/2025

SERVIER

ASPARLAS® (calaspargase pegol-mknl)
750 units/mL injection