

# ONCOLOGY TIMES

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## Exercise: Finding the Right Rx for Cancer Patients

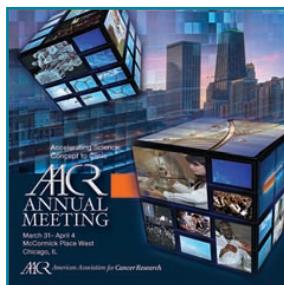
BY SARAH DIGIULIO

The question is no longer whether or not exercise is safe for cancer patients. Evidence shows it is not only not harmful, but can also relieve fatigue, protect bones, enhance cardiopulmonary functions, and help psychologically. Here's our roundup of recent findings, including a new study of the benefits of community-based, individually tailored group exercise programs for cancer survivors.

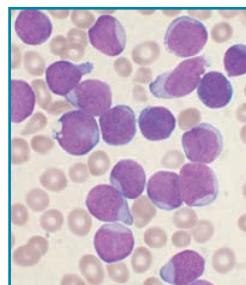
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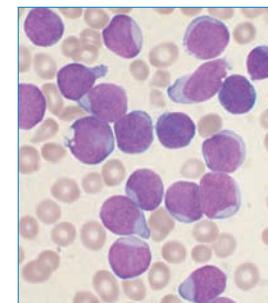
# Chemotherapy May Save Some Children with ALL Not Helped with Induction Therapy

BY SARAH DIGIULIO

For a subset of pediatric acute lymphoblastic leukemia (ALL) patients who do not have a clinical remission after induction therapy (typically intense chemotherapy), additional chemotherapy may be more effective than transplantation, which has been the standard second step, according to the

results of a large, international, retrospective study.

The study, published in the *New England Journal of Medicine* (2012;366:1371-1381),



reviewed 44,017 cases of pediatric ALL from 14 cancer care centers in the U.S., Europe, and Asia, making it the largest study ever of these pediatric ALL patients.

“We thought patients who fail chemotherapy would probably be refractory to all chemotherapy, and that you would therefore need to do transplantation, but that turned out to not be true for some types of leukemia,” said the corresponding author, Ching-Hon Pui, MD, Chair of the St. Jude Children’s Research Hospital Department of Oncology, in a telephone interview. Subsequent consolidation therapy with high-dose chemotherapy can save many children with precursor B-cell leukemia without other adverse features, he and his colleagues found.

Of the children with ALL in the study (first author was Martin Schrappe, MD), 1,041 had failed to respond to induction therapy and 32 percent of those patients survived for at least 10 years. But, the survival rate jumped to 72 percent for the subset of children with B-cell ALL who had

32 percent of the children reached 10-year survival—but the survival rate was 72 percent for the subset of patients with B-cell ALL treated with a second round of chemotherapy only.

received a second round of chemotherapy only. This subset represented about 25 percent of the patients for whom the initial chemotherapy had failed.

“These results tell us that induction failure should no longer be considered an automatic indication for a transplant,” Pui said.

Transplant is typically the next step after induction failure because it is the most aggressive treatment and includes a mild chemotherapy dose, Pui explained. But, two drugs not used during induction—methotrexate and mercaptopurine—are particularly effective for B-cell ALL patients, and are most effective for

## XALKORI® (crizotinib) capsules Brief Summary of Prescribing Information



### INDICATIONS AND USAGE

XALKORI is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. This indication is based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with XALKORI.

### DOSE AND ADMINISTRATION

**Recommended Dosing:** The recommended dose and schedule of XALKORI is 250 mg taken orally twice daily. Continue treatment as long as the patient is deriving clinical benefit from therapy. XALKORI may be taken with or without food. Swallow capsules whole. If a dose of XALKORI is missed, make up that dose unless the next dose is due within 6 hours. **Dose Modification:** Dosing interruption and/or dose reduction may be required based on individual safety and tolerability. If dose reduction is necessary, then reduce the dose of XALKORI to 200 mg taken orally twice daily. If further dose reduction is necessary, then reduce the dosage to 250 mg taken orally once daily based on individual safety and tolerability.

### CONTRAINDICATIONS

None.

### WARNINGS AND PRECAUTIONS

**Hepatotoxicity:** Drug-induced hepatotoxicity with fatal outcome has occurred. These cases have occurred during XALKORI treatment in <1% of patients in clinical trials. Concurrent elevations in ALT >3 times the upper limit of normal and total bilirubin >2 times the upper limit of normal, with normal alkaline phosphatase, occurred in <1% of patients in clinical trials. Elevation in ALT >5 times the upper limit of normal occurred in 7% of patients in Study A and in 4% of patients in Study B. These laboratory findings were generally asymptomatic and reversible upon dosing interruption. Patients usually resumed treatment at a lower dose without recurrence; however, 3 patients from Study A (2%) and 1 patient from Study B (<1%) required permanent discontinuation from treatment. Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin in patients who develop transaminase elevations. **Pneumonitis:** XALKORI has been associated with severe, life-threatening, or fatal treatment-related pneumonitis in clinical trials with a frequency of 4 in 255 (1.6%) patients across Studies A and B. All of these cases occurred within 2 months after the initiation of treatment. Monitor patients for pulmonary symptoms indicative of pneumonitis. Exclude other causes of pneumonitis, and permanently discontinue XALKORI in patients diagnosed with treatment-related pneumonitis. **QT Interval Prolongation:** QTc prolongation has been observed. Avoid use of XALKORI in patients with congenital long QT syndrome. Consider periodic monitoring with electrocardiograms (ECGs) and electrolytes in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QT interval. Permanently discontinue XALKORI in patients who develop Grade 4 QTc prolongation. Withhold XALKORI in patients who develop Grade 3 QTc prolongation until recovery to ≤ Grade 1, then resume XALKORI at 200 mg twice daily. In case of recurrence of Grade 3 QTc prolongation, withhold XALKORI until recovery to ≤ Grade 1, then resume XALKORI at 250 mg once daily. Permanently discontinue XALKORI if Grade 3 QTc prolongation recurs. **ALK Testing:** Detection of ALK-positive NSCLC using an FDA-approved test, indicated for this use, is necessary for selection of patients for treatment with XALKORI. Assessment for ALK-positive NSCLC should be performed by laboratories with demonstrated proficiency in the specific technology being utilized. Improper assay performance can lead to unreliable test results. Refer to an FDA-approved test’s package insert for instructions on the identification of patients eligible for treatment with XALKORI. **Pregnancy:** XALKORI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. There are no adequate and well-controlled studies in pregnant women using XALKORI. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus.

### ADVERSE REACTIONS

Safety of XALKORI was evaluated in 255 patients with locally advanced or metastatic ALK-positive NSCLC in 2 single-arm clinical trials (Studies A and B). Among the 255 patients for whom data on Grade 1-4 adverse reactions are available, median exposure to study drug was 5.1 months in Study A and 7.8 months in Study B. Dosing interruptions occurred in 36% and 45% of patients in Studies A and B, and lasted >2 weeks in 13% and 19% of all patients. Dose reductions occurred in 44% and 29% of patients. The rates of treatment-related adverse events resulting in permanent discontinuation were 6% in Study A and 3% in Study B. The most common adverse reactions (≥25%) across both studies were vision disorder, nausea, diarrhea, vomiting, edema, and constipation. Grade 3-4 adverse reactions in ≥4% of patients in both studies included ALT increased and neutropenia. Among the 397 patients for whom information on deaths and serious adverse reactions is available, deaths within 28 days of the last dose of study drug occurred in 45 patients. Ten (2.5%) patients died within 28 days of their first dose of study drug. Causes of death included disease progression (32 patients), respiratory events (9), and other (4). Respiratory causes of death included pneumonia (2), hypoxia (2), ARDS (1), dyspnea (1), pneumonitis (1), emphysema (1), and pulmonary hemorrhage (1). Other causes of death included septic shock, DIC, cardiovascular event, and death due to unknown cause (1 each). Serious adverse events in ≥2% of patients included pneumonia, dyspnea, and pulmonary embolism. Table 3 lists the common adverse reactions on Studies A and B in patients receiving XALKORI.

Table 3: Adverse Reactions in ≥ 10% of Patients with Locally Advanced or Metastatic ALK-Positive NSCLC on Studies A and B<sup>1</sup>

Adverse Event	Treatment Emergent (N=255)		Treatment Related (N=255)	
	All Grades n (%)	Grades 3/4 n (%)	All Grades n (%)	Grades 3/4 n (%)
<b>EYE DISORDERS</b>				
Vision Disorder <sup>2</sup>	163 (64%)	0 (0)	159 (62%)	0 (0)
<b>GASTROINTESTINAL DISORDERS</b>				
Nausea	145 (57%)	2 (<1%)	136 (53%)	0
Diarrhea	124 (49%)	1 (<1%)	109 (43%)	0
Vomiting	116 (45%)	3 (1%)	101 (40%)	0
Constipation	98 (38%)	2 (<1%)	69 (27%)	1 (<1%)
Esophageal Disorder <sup>2</sup>	51 (20%)	3 (1%)	29 (11%)	0
Abdominal Pain <sup>4</sup>	40 (16%)	1 (<1%)	20 (8%)	0
Stomatitis <sup>5</sup>	27 (11%)	1 (<1%)	15 (6%)	1 (<1%)
<b>GENERAL DISORDERS</b>				
Edema <sup>3</sup>	97 (38%)	2 (<1%)	72 (28%)	0
Fatigue	80 (31%)	6 (2%)	51 (20%)	4 (2%)
Chest Pain/Discomfort <sup>7</sup>	30 (12%)	1 (<1%)	3 (1%)	0
Fever	30 (12%)	1 (<1%)	2 (<1%)	0
<b>INFECTIONS AND INFESTATIONS</b>				
Upper Respiratory Infection <sup>8</sup>	50 (20%)	1 (<1%)	4 (2%)	0
<b>INVESTIGATIONS</b>				
Alanine Aminotransferase Increased	38 (15%)	17 (7%)	34 (13%)	14 (5%)
Aspartate Aminotransferase Increased	29 (11%)	7 (3%)	24 (9%)	5 (2%)
<b>METABOLISM AND NUTRITION</b>				
Decreased Appetite	69 (27%)	3 (1%)	49 (19%)	0
<b>MUSCULOSKELETAL</b>				
Arthralgia	29 (11%)	3 (1%)	4 (2%)	0
Back Pain	28 (11%)	0	2 (<1%)	0
<b>NERVOUS SYSTEM DISORDERS</b>				
Dizziness <sup>9</sup>	60 (24%)	0	42 (16%)	0
Neuropathy <sup>10</sup>	58 (23%)	1 (<1%)	34 (13%)	1 (<1%)
Headache	34 (13%)	1 (<1%)	10 (4%)	0
Dysgeusia	33 (13%)	0	30 (12%)	0
<b>PSYCHIATRIC DISORDERS</b>				
Insomnia	30 (12%)	0	8 (3%)	0
<b>RESPIRATORY DISORDERS</b>				
Dyspnea	57 (22%)	16 (6%)	5 (2%)	3 (1%)
Cough	54 (21%)	3 (1%)	9 (4%)	0
<b>SKIN DISORDERS</b>				
Rash	41 (16%)	0	25 (10%)	0

<sup>1</sup>Study A used CTCAE v4.0, and Study B used CTCAE v3.0.

<sup>2</sup>Includes diplopia, photopsia, photophobia, vision blurred, visual field defect, visual impairment, vitreous floaters, visual brightness, and visual acuity reduced.

<sup>3</sup>Includes dyspepsia, dysphagia, epigastric discomfort/pain/burning, esophagitis, esophageal obstruction/pain/spasm/ulcer, gastroesophageal reflux, odyphagia, and reflux esophagitis.

<sup>4</sup>Includes abdominal discomfort, abdominal pain, abdominal pain upper, and abdominal tenderness.

<sup>5</sup>Includes mouth ulceration, glossodynia, glossitis, cheilitis, mucosal inflammation, oropharyngeal pain/discomfort, oral pain, and stomatitis.

<sup>6</sup>Includes edema, edema localized, and peripheral edema.

<sup>7</sup>Includes chest pain, chest discomfort, and musculoskeletal chest pain.

<sup>8</sup>Includes nasopharyngitis, rhinitis, pharyngitis, and upper respiratory tract infection.

<sup>9</sup>Includes balance disorder, dizziness, and presyncope.

<sup>10</sup>Includes burning sensation, dysesthesia, hyperesthesia, hypoesthesia, neuralgia, paresthesia, peripheral neuropathy, peripheral motor neuropathy, and peripheral sensory neuropathy.

Vision disorders including visual impairment, photopsia, vision blurred, vitreous floaters, photophobia, and diplopia, were reported in 159 (62%) patients in clinical trials. These events generally started within two weeks of drug administration. Consider ophthalmological evaluation, particularly if patients experience photopsia or experience new or increased vitreous floaters. Severe or worsening vitreous floaters and/or photopsia could also be signs of a retinal hole or pending retinal detachment. Advise patients to exercise caution when driving or operating machinery due to the risk of developing a vision disorder. Neuropathy as defined in Table 3 and attributed to study drug by the investigator was reported in 34 (13%) patients. While most events were Grade 1, Grade 2 motor neuropathy and Grade 3 peripheral neuropathy were reported in 1 patient each. Dizziness and dysgeusia were also very commonly reported in these studies, but were all Grade 1 or 2 in severity. Bradycardia occurred in 12 (5%) patients treated with XALKORI. All of these cases were Grade 1 or 2 in severity. Complex renal cysts occurred in 2 (1%) patients treated with XALKORI. There were no reports of abnormal urinalyses or renal impairment in these cases. **Laboratory Abnormalities:** Grade 3 or 4 neutropenia, thrombocytopenia, and lymphopenia occurred in 5.2%, 0.4%, and 11.4% of patients, respectively.

### DRUG INTERACTIONS

**Drugs That May Increase Crizotinib Plasma Concentrations:** Coadministration of crizotinib with strong CYP3A inhibitors increases crizotinib plasma concentrations. Avoid concomitant use of strong CYP3A inhibitors, including but not limited to atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nefinavir, ritonavir, saquinavir, telithromycin, troleanomycin, and voriconazole. Avoid grapefruit or grapefruit juice which may also increase plasma concentrations of crizotinib. Exercise caution with concomitant use of moderate CYP3A inhibitors. **Drugs That May Decrease Crizotinib Plasma Concentrations:** Coadministration of crizotinib with strong CYP3A inducers decreases crizotinib plasma concentrations. Avoid concurrent use of strong CYP3A inducers, including but not limited to carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, and St. John’s Wort. **Drugs Whose Plasma Concentrations May Be Altered By Crizotinib:** Dose reduction may be needed for coadministered drugs that are predominantly metabolized by CYP3A. Avoid coadministration of crizotinib with CYP3A substrates with narrow therapeutic indices, including but not limited to alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, piroxicam, quinidine, sirolimus, and tacrolimus.

### USE IN SPECIFIC POPULATIONS

**Pregnancy Category D:** XALKORI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. There are no adequate and well-controlled studies of XALKORI in pregnant women. Advise women of childbearing potential to avoid becoming pregnant while receiving XALKORI. Women of childbearing potential who are receiving this drug, or partners of women of childbearing potential receiving this drug, should use adequate contraceptive methods during therapy and for ≥90 days after completing therapy. If this drug is used during pregnancy, or if the patient or their partner becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus. **Nursing Mothers:** It is not known whether XALKORI is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from XALKORI, consider whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** The safety and efficacy of XALKORI in pediatric patients has not been established. Decreased bone formation in growing long bones was observed in immature rats at 150 mg/kg/day following once daily dosing for 28 days (approximately 10 times the AUC in adult patients at the recommended human dose). Other toxicities of potential concern to pediatric patients have not been evaluated in juvenile animals. **Geriatric Use:** Clinical studies of XALKORI did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger patients. Of the 136 patients in Study A, 19 (14%) were ≥65 years. Of the 119 patients in Study B, 16 (13%) were ≥65 years. **Hepatic Impairment:** XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma crizotinib concentrations. Clinical studies excluded patients with AST or ALT >2.5 x ULN, or >5 x ULN, if due to liver metastases. Patients with total bilirubin >1.5 x ULN were also excluded. Therefore, use caution in patients with hepatic impairment. **Renal Impairment:** No starting dose adjustment is needed for patients with mild (creatinine clearance [ClCr] 60 to 90 mL/min) and moderate renal impairment (ClCr 30 to 60 mL/min), as steady-state trough concentrations in these two groups were similar to those in patients with normal renal function (ClCr >90 mL/min) in Study B. The potential need for starting dose adjustment in patients with severe renal impairment cannot be determined, as clinical and pharmacokinetic data were available for only one patient. In addition, no data are available for patients with end-stage renal disease. Therefore, use caution in patients with severe renal impairment (ClCr <30 mL/min) or patients with end-stage renal disease.

### OVERDOSAGE

There have been no known cases of XALKORI overdose. Treatment of overdose with XALKORI should consist of general supportive measures. There is no antidote for XALKORI.

### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Carcinogenicity studies with crizotinib have not been conducted. Crizotinib was genotoxic in an in vitro micronucleus assay in Chinese Hamster Ovary cultures, in an in vitro human lymphocyte chromosome aberration assay, and in an in vivo rat bone marrow micronucleus assays. Crizotinib was not mutagenic in vitro in the bacterial reverse mutation (Ames) assay. No specific studies with crizotinib have been conducted in animals to evaluate the effect on fertility; however, crizotinib is considered to have the potential to impair reproductive function and fertility in humans based on findings in repeat-dose toxicity studies in the rat. Findings observed in the male reproductive tract included testicular pachytene spermatocyte degeneration in rats given ≥50 mg/kg/day for 28 days (>3 times the AUC at the recommended human dose). Findings observed in the female reproductive tract included single-cell necrosis of ovarian follicles of a rat given 500 mg/kg/day (approximately 10 times the recommended human daily dose on a mg/m<sup>2</sup> basis) for 3 days.

### PATIENT COUNSELING INFORMATION

**Hepatotoxicity:** Inform patients that symptoms of weakness, fatigue, anorexia, nausea, vomiting, abdominal pain (especially RUQ abdominal pain), jaundice, dark urine, generalized pruritus, and bleeding diathesis, especially in combination with fever and rash, should be reported immediately. **Gastrointestinal Effects:** Inform patients that nausea, diarrhea, vomiting, and constipation are the most commonly reported gastrointestinal adverse events occurring in patients who received XALKORI. Supportive care for gastrointestinal adverse events requiring treatment may include standard anti-emetic and/or anti-diarrheal or laxative medications. **Visual Effects:** Inform patients that visual changes such as perceived flashes of light, blurry vision, light sensitivity, and floaters are commonly reported adverse events. These events began most commonly during the first two weeks of treatment. Advise patients to report flashes or floaters to their physicians. **Effects on Ability to Drive and Use Machines:** No studies on the effect of XALKORI on the ability to drive and use machines have been performed. However, advise patients to exercise caution when driving or operating machinery due to the risk of developing a vision disorder, dizziness, or fatigue while taking XALKORI. **Concomitant Medications:** Advise patients to inform their health care providers of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products. **Instructions for Taking XALKORI:** Advise patients to take XALKORI exactly as prescribed, not to change their dose or to stop taking XALKORI unless they are told to do so by their doctor. Take XALKORI with or without food. Swallow XALKORI capsules whole. Advise patients to keep XALKORI in the original container. Do not crush, dissolve, or open capsules. Inform patients to avoid grapefruit or grapefruit juice while taking XALKORI. If a patient misses a dose, advise the patient to take it as soon as remembered unless it is less than 6 hours until the next dose, in which case, advise the patient not to take the missed dose. Advise patients not to take two doses at the same time to make up for a missed dose. **Pregnancy and Nursing:** Inform patients of childbearing potential to use adequate contraceptive methods during therapy and for ≥90 days after completing therapy. Advise patients to inform their doctor if they or their partners are pregnant or think they may be pregnant. Also advise patients not to breastfeed while taking XALKORI.

### Rx Only

April 2012



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→CHEMO ALL

continued from page 17



CHING-HON PUI, MD: “We thought patients who fail chemotherapy would probably be refractory to all chemotherapy, and that you would therefore need to do transplantation. But that turned out to not be true for some types of leukemia.”

those between age 1 and 6, and those with high hyperdiploidy, the study found.

While that subset of children did not seem to benefit from allogeneic transplantation, the researchers did conclude that transplant therapy was still most effective for the subset of patients with T-cell ALL, and was more effective than further chemotherapy alone.

“This is an important implication,” said Pui, who will receive ASCO’s Pediatric Oncology Award at this year’s Annual Meeting. “When a doctor fails a patient with induction therapy, they need to know other features before they determine whether they should recommend transplantation.”

**Key Implications**

Asked for his opinion of the study for this article, Peter Adamson, MD, Director of Experimental Therapeutics in Oncology at Children’s Hospital of Philadelphia,



PETER ADAMSON, MD: “Some of our assumptions so far of which patients relapse are going to turn out not to be correct.”

pointed out that one of the most important takeaways from this research is realizing that the most effective means of curing ALL patients is likely personalizing therapies to various subsets of patients—however small those populations are. Induction failure occurs in just two to three percent of children with ALL, and the subset of patients with precursor B-cell ALL accounts for only about 25 percent of those patients.

“I think the main lesson is that in making future advances in curing ALL—because the subsets of populations that we need to study are getting smaller, including the subsets where induction therapy fails—we will need to collaborate, and collaborate on a large scale. And, secondly, we learned that some of our assumptions so far turned out to be incorrect,” Adamson said in a phone interview. He is also Chief of the Division of Clinical Pharmacology and Therapeutics at the hospital and Professor of Pediatrics at the Perelman

Even though the percentage of children with ALL who do not respond to induction therapy is very small, it is one of the most likely predictors of overall failure and is indicative of the highest risk of a negative disease outcome.

School of Medicine at the University of Pennsylvania.

**‘Practice Changing’**

And *OT*’s Clinical Advisory Editor for Hematology/Oncology, Mikkael Sekeres, MD, MS, Director of the Leukemia Program and Chair of the Hematology/Oncology Pharmacy & Therapeutics Committee at the Cleveland Clinic Taussig Cancer Institute, predicted that for this small subset of patients, the evidence from this study may change the paradigm of treatment

“Those with precursor B-cell ALL without other adverse features may actually have at least as good if not a better outcome with subsequent chemotherapy, as compared with hematopoietic stem cell transplantation, which in itself may redefine whether or not these patients were truly induction ‘failures,’ or whether our traditional assessment of failure in pediatric ALL may be premature,” he said.

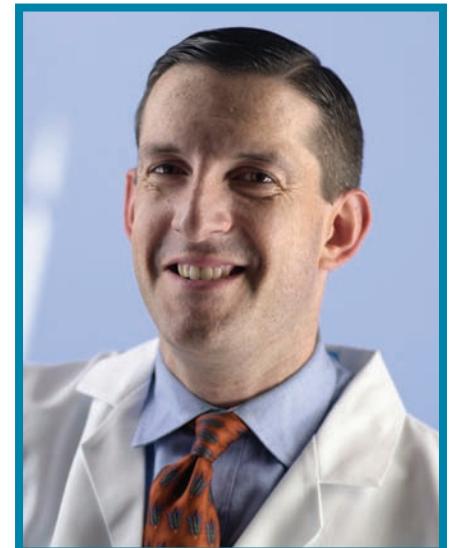
Adamson noted that future research needs to look at individual subsets of

patients and what makes them unique. “We need to understand the heterogeneity—what are the features in the leukemia in these children that are go-

“Induction failure should no longer be considered an automatic indication for a transplant.”

ing to predispose them to this outcome,” he said.

Sekeres said that future research is also needed to see if the findings are consistent



MIKKAEL SEKERES, MD, MS: “The findings may redefine whether or not these patients were truly induction ‘failures,’ or whether our traditional assessment of failure in pediatric ALL may be premature.”

**Researchers Dedicated the Study to James Nachman**

The researchers dedicated the study to James B. Nachman, MD, who died last year of a suspected heart attack while on a rafting trip in the Grand Canyon.

“He contributed, with a truly global view and outstanding personal dedication, to this and many other important scientific papers in the field of pediatric leukemia,” the authors wrote.

for different age groups. “Whether these results can be translated to the treatments of adults with ALL remains to be seen,” he said. ■