Hematology Drugs in the Pipeline

HEMONC TODAY presents the most recent information about hematology drugs in the pipeline. Drugs listed here are in phase 2 or phase 3 development for a variety of indications. Clinicians can use this chart as a quick reference to learn about the status of those drugs that may be clinically significant to their practice.

Generic name (Brand name, Manufacturer)	Indication(s)	Development status
abexinostat (Pharmacyclics)	follicular lymphoma, mantle cell lymphoma	phase 2
ABIO-0501 (Abiogen Pharma)	chronic myeloid leukemia	phase 2
Actimab-A (Actinium Pharmaceuticals)	acute myelogenous leukemia	phase 2
ACY-1215 (Acetylon Pharmaceuticals)	myeloma	phase 2
alisertib (MLN8237, Millennium Pharmaceuticals) **READ PERSPECTIVE** on this drug from Swaminathan Padmanabhan Iyer, MD, on page 88.	hematologic malignancies/relapsed/refractory peripheral T-cell lymphoma	phase 2/phase 3
AlloStim (Immunovative Therapies)	hematologic malignancies	phase 2
ALT-801 (Altor BioScience)	acute myelogenous leukemia, myeloma	phase 2
AME-133v (Mentrik Biotech)	non-Hodgkin's lymphoma	phase 2
aminopterin (Syntrix Biosystems)	pediatric acute lymphoblastic leukemia	phase 2
AMT-060 (uniQure)	hemophilia B	phase 2
anti-CD22 antibody drug conjugate (RG7593; Genentech, Seattle Genetics)	diffuse large B-cell lymphoma, non-Hodgkin's lymphoma	phase 2
anti-CD79b antibody drug conjugate (RG7596; Genentech, Seattle Genetics)	diffuse large B-cell lymphoma, non-Hodgkin's lymphoma	phase 2
AR-42 (Arno Therapeutics)	hematologic malignancies	phase 2
ARRY-520 (Array BioPharma)	myeloma	phase 2
ASC-101 (America Stem Cell)	myeloablation associated with hematologic malignancies	phase 2
AskBio009 (Asklepios BioPharmaceutical/Baxter International)	hemophilia B	phase 2
AT-101 (Ascenta Therapeutics)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase 2
AT7519 (Astex Pharmaceuticals)	myeloma	phase 2
AT9283 (Astex Pharmaceuticals)	myeloma	phase 2
AUY922 (Novartis)	myeloma	phase 2
bafetinib (CytRx)	chronic lymphocytic leukemia	phase 2
BAY 80-6946 (Bayer Healthcare)	non-Hodgkin's lymphoma	phase 2
B-cell lymphoma vaccine (BiovaxID, Biovest International)	mantle cell lymphoma/indolent follicular lymphoma	phase 2/phase 3
belinostat (Spectrum Pharmaceuticals)	peripheral B-cell lymphoma	phase 2
bendamustine (Treanda, Cephalon [Teva])	acute lymphoblastic leukemia, acute myelogenous leukemia, mantle cell lymphoma, myeloma	phase 2
beta-globin gene therapy (Bluebird Bio/Inserm)	beta-thalassemia, sickle cell anemia	phase 2
BHQ880 (Morphosys, Novartis)	myeloma	phase 2
BI-695500 (Boehringer Ingelheim)	non-Hodgkin's lymphoma	phase 3
BI-811283 (Boehringer Ingelheim)	acute myelogenous leukemia	phase 2
birinapant (TetraLogic Pharmaceuticals)	acute myelogenous leukemia	phase 2
BIW-8962 (BioWa/Kyowa Hakko Kirin)	myeloma	phase 2
BKM120 (Novartis)	relapsed/refractory non-Hodgkin's lymphoma	phase 2
blinatumomab (AMG 103, Amgen) **READ PERSPECTIVE** on this drug from Dan S. Kaufman, MD, PhD, on page 89.	acute lymphoblastic leukemia, non-Hodgkin's lymphoma	phase 2

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Generic name (Brand name, Manufacturer)	Indication(s)	Development status
BMS-911543 (Bristol-Myers Squibb)	myelofibrosis	phase 2
bortezomib (Velcade, Millennium Pharmaceuticals)	diffuse large B-cell lymphoma, steroid-refractory graft-versus-host disease/ first-line mantle cell lymphoma	phase 2/phase 3
bosutinib (Bosulif, Pfizer)	Philadelphia chromosome-positive chronic myeloid leukemia	phase 3
brentuximab vedotin (Adcetris; Millennium Pharmaceuticals, Seattle Genetics)	relapsed/refractory CD30+ non-Hodgkin's lymphoma, CD30+ lymphomas, Hodgkin's lymphoma in patients aged 60 years or older/Hodgkin's lymphoma, relapsed CD30+ cutaneous T-cell lymphoma, CD30+ mature T-cell lymphoma	phase 2/phase 3
BT-062 (Biotest Pharmaceuticals/ImmunoGen)	myeloma	phase 2
calaspargase pegol (Sigma-Tau Pharmaceuticals)	acute lymphoblastic leukemia in adolescents and children	phase 3
cancer vaccine (AlloStim, Immunovative Therapies)	hematologic malignancies	phase 2
carfilzomib (Kyprolis, Onyx Pharmaceuticals)	relapsed/refractory myeloma (monotherapy), relapsed myeloma (combination therapy)	phase 3
carlecortemcel-L (StemEx; Gamida Cell, Teva Pharmaceutical)	hematologic malignancies	phase 3
CC-486 (Celgene)	post-induction acute myelogenous leukemia maintenance, lower-risk myelodysplastic syndrome	phase 2
CLT-008 (Cellerant Therapeutics)	chemotherapy-related neutropenia	phase 2
CNDO-109 (Coronado Biosciences)	acute myelogenous leukemia	phase 2
crenolanib (CP-868-596, AROG Pharmaceuticals)	acute myelogenous leukemia	phase 2
CTL019 (Novartis)	chronic lymphocytic leukemia	phase 2
cytarabine/daunorubicin (CPX-351, Celator Pharmaceuticals)	acute myelogenous leukemia	phase 3
daratumumab (HuMax-CD38; Genmab, Janssen Biotech) **READ PERSPECTIVE** on this drug from Philip McCarthy, MD, on page 87. **READ PERSPECTIVE** on this drug from Swaminathan Padmanabhan Iyer, MD, on page 88.	myeloma	phase 2
darbepoetin alfa (Aranesp, Amgen)	myelodysplastic syndrome	phase 3
darinaparsin (ZIO-101, Ziopharm Oncology)	myeloma	phase 2
dasatinib (Sprycel, Bristol-Myers Squibb)	leukemia in children and adolescents	phase 2
dasiprotimut-T (BiovaxID, Biovest International)	mantle cell lymphoma/indolent follicular lymphoma	phase 2/phase 3
decitabine (Dacogen, Eisai)	pediatric acute myelogenous leukemia	phase 2
DCDS4501A (Genentech)	diffuse large B-cell lymphoma, non-Hodgkin's lymphoma	phase 2
DCDT2980S (Genentech)	diffuse large B-cell lymphoma, non-Hodgkin's lymphoma	phase 2
delanzomib (Cephalon [Teva])	myeloma	phase 2
dendritic cell vaccine (GRNVAC 1, Geron)	acute myelogenous leukemia	phase 2
DFP-10917 (Delta-Fly Pharma)	acute lymphoblastic leukemia, acute myelogenous leukemia	phase 2
dinaciclib (Merck)	chronic lymphocytic leukemia	phase 3
elotuzumab (AbbVie/Bristol-Myers Squibb)	myeloma	phase 3
eltrombopag (Promacta, GlaxoSmithKline)	acute myelogenous leukemia, myelodysplastic syndrome, chemotherapy-induced anemia	phase 2
entinostat (Syndax Pharmaceuticals)	leukemia, relapsed/refractory Hodgkin's lymphoma	phase 2
enzastaurin (Eli Lilly)	diffuse large B-cell lymphoma	phase 3
epoetin alfa biosimilar (Hospira)	anemia	phase 3

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Generic name (Brand name, Manufacturer)	Indication(s)	Development status
epratuzumab (Immunomedics)	non-Hodgkin's lymphoma	phase 2
epratuzumab Y-90 (IMMU-102, Immunomedics)	non-Hodgkin's lymphoma	phase 2
erythropoietin gene therapy (Medgenics)	anemia	phase 2
everolimus (Afinitor, Novartis)	diffuse large B-cell lymphoma	phase 3
ezatiostat (Telintra, Telik)	myelodysplastic syndrome	phase 2
Factor VIII/von Willebrand's factor (CSL Behring)	hemophilia A, von Willebrand's disease	phase 3
forodesine (BioCryst Pharmaceuticals)	chronic lymphocytic leukemia, cutaneous T-cell lymphoma	phase 2
fostamatinib (AstraZeneca/Rigel Pharmaceuticals)	hematologic malignancies	phase 2
GDC-0980/RG7422 (Genentech/Roche)	non-Hodgkin's lymphoma	phase 2
GL-0817 (Gliknik)	myeloma	phase 2
GVAX Leukemia (BioSante Pharmaceuticals)	acute myelogenous leukemia, chronic myeloid leukemia	phase 2
GVAX Multiple Myeloma (BioSante Pharmaceuticals)	multiple myeloma	phase 2
HCD122 (Novartis, XOMA)	lymphoma	phase 2
histamine dichloride (Ceplene, EpiCept)	acute myelogenous leukemia	phase 3
hTERT RNA vaccine (BioTime)	acute myelogenous leukemia	phase 2
human recombinant Factor VIII (Octapharma USA)	hemophilia A	phase 2
I-131 tositumomab (GlaxoSmithKline)	mantle cell lymphoma	phase 2
ibritumomab tiuxetan (Zevalin, Spectrum Pharmaceuticals)	mantle cell lymphoma, non-Hodgkin's lymphoma/diffuse large B-cell lymphoma	phase 2/phase 3
ibrutinib (PCI-32765; Janssen Biotech, Pharmacyclics) **READ PERSPECTIVE** on this drug from Fernando Cabanillas, MD, on page 87. **READ PERSPECTIVE** on this drug from Swaminathan Padmanabhan Iyer, MD, on page 88. **READ PERSPECTIVE** on this drug from Bruce D. Cheson, MD, FACP, FAAS, on page 89.	diffuse large B-cell lymphoma, myeloma/chronic lymphocytic leukemia, mantle cell lymphoma	phase 2/phase 3
idelalisib (GS-1101, Gilead) **READ PERSPECTIVE** on this drug from Bruce D. Cheson, MD, FACP, FAAS, on page 89.	chronic lymphocytic leukemia, indolent non-Hodgkin's lymphoma	phase 3
imetelstat (Geron)	myeloma, essential thrombocythemia	phase 2
Imprime PGG (Biothera)	chronic lymphocytic leukemia/first-line advanced indolent non-Hodgkin's lymphoma	phase 2/phase 3
INCB39110 (InCyte)	myelofibrosis	phase 2
indatuximab ravtansine (Biotest)	multiple myeloma	phase 2
inotuzumab ozogamicin (CMC-544, Pfizer)	acute lymphoblastic leukemia, aggressive non-Hodgkin's lymphoma	phase 3
interleukin-12 gene therapy (OncoSec Medical)	cutaneous T-cell lymphoma	phase 2
Iomab-B (Actinium Pharmaceuticals)	acute myelogenous leukemia	phase 2
ISF35 (Memben)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase 2
ISIS-FXI (Isis Pharmaceuticals)	clotting disorders	phase 2
ixazomib (MLN9708, Millennium Pharmaceuticals) **READ PERSPECTIVE** on this drug from Shaji K. Kumar, MD, on page 89.	relapsed/refractory myeloma	phase 3

Hematology Drugs in the Pipeline

Generic name (Brand name, Manufacturer)	Indication(s)	Development status
JNJ-26481585 (Janssen)	cutaneous T-cell lymphoma	phase 2
JNJ-40346527 (Janssen)	Hodgkin's lymphoma	phase 2
KW-2478 (Kyowa Hakko Kirin)	myeloma	phase 2
lenalidomide (Revlimid, Celgene)	relapsed/refractory diffuse large B-cell lymphoma/chronic lymphocytic leukemia, relapsed/refractory mantle cell lymphoma, diffuse large B-cell lymphoma (maintenance), follicular lymphoma maintenance, myelodysplastic syndrome (non-deletion 5q), myeloma (newly diagnosed and maintenance)	phase 2/phase 3
lenalidomide (Revlimid, Celgene) and azacitidine injection (Vidaza, Celgene)	acute myelogenous leukemia	phase 2
lestaurtinib (CEP-701, Cephalon [Teva])	acute myelogenous leukemia, essential thrombocytosis, polycythemia vera	phase 2
leukemia DNA vaccine (WT1; Inovio Pharmaceuticals, University of Southampton)	acute myelogenous leukemia, chronic myeloid leukemia	phase 2
lintuzumab Ac-225 (Actimab-A, Actinium Pharmaceuticals)	acute myelogenous leukemia	phase 2
lintuzumab Bi-213 (Bismab-A, Actinium Pharmaceuticals)	acute myelogenous leukemia	phase 2
lirilumab (Bristol-Myers Squibb)	acute myelogenous leukemia	phase 2
LOR-2040 (Lorus Therapeutics)	acute myelogenous leukemia	phase 2
LY2090314 (Eli Lilly)	acute myelogenous leukemia, acute promyelocytic leukemia	phase 2
LY2784544 (Eli Lilly)	myeloproliferative disorders	phase 2
mapatumumab (HGS-ETR1, GlaxoSmithKline)	myeloma	phase 2
MEDI-551 (AstraZeneca/MedImmune)	hematologic malignancies	phase 2
melphalan intravenous (Ligand Pharmaceuticals/Spectrum Pharmaceuticals)	myeloma	phase 3
mesenchymal precursor cell product (Mesoblast)	bone marrow regeneration in patients who undergo bone marrow transplantation	phase 3
milatuzumab (Immunomedics)	chronic lymphocytic leukemia	phase 2
milatuzumab-doxorubicin conjugate (Immunomedics)	myeloma	phase 2
mocetinostat (MGCD0103, MethylGene)	diffuse large B-cell lymphoma, follicular lymphoma	phase 2
mogamulizumab (Poteligeo; Kyowa Hakko Kirin)	adult T-cell leukemia, adult T-cell lymphoma, peripheral T-cell lymphoma/cutaneous T-cell lymphoma	phase 2/phase 3
momelotinib (CYT-387, Gilead Sciences) **READ PERSPECTIVE** on this drug from Ruben A. Mesa, MD, on page 89.	myelofibrosis	phase 2
MSC1936369B (EMD Serono)	hematologic malignancies	phase 2
NAV Therapeutic (ReGenX Biosciences)	hemophilia B	phase 2
navitoclax (ABT-263, AbbVie)	chronic lymphocytic leukemia	phase 2
nilotinib (Tasigna, Novartis)	acute lymphoblastic leukemia in children and adolescents, chronic myeloid leukemia in children and adolescents	phase 2
NS-018 (Nippon Shinyaku)	myelofibrosis	phase 2
obinutuzumab (Biogen Idec/Genentech/Roche)	chronic lymphocytic leukemia, diffuse large B-cell lymphoma, first-line and refractory indolent non-Hodgkin's lymphoma	phase 3
ocaratuzumab (Mentrik Biotech)	non-Hodgkin's lymphoma	phase 2
ofatumumab (Arzerra, GlaxoSmithKline)	chronic lymphocytic leukemia, diffuse large B-cell lymphoma, relapsed/refractory follicular lymphoma	phase 3
pacritinib (SB1518, Cell Therapeutics) **READ PERSPECTIVE** on this drug from Ruben A. Mesa, MD, on page 89.	relapsed lymphoma/myelofibrosis	phase 2/phase 3
palbociclib (PD-0332991, Pfizer)	myeloma	phase 2
panobinostat (LBH589, Novartis)	myeloma	phase 3

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Generic name (Brand name, Manufacturer)	Indication(s)	Development status
perifosine (Aeterna Zentaris)	chronic lymphocytic leukemia	phase 2
pidilizumab (CT-011, CureTech)	acute myelogenous leukemia, diffuse large B-cell lymphoma, follicular lymphoma	phase 2
pixantrone (Pixuvri, Cell Therapeutics)	diffuse large B-cell lymphoma, follicular lymphoma	phase 3
PKC412 (Novartis)	aggressive systemic mastocytosis/acute myelogenous leukemia	phase 2/phase 3
plitidepsin (Aplidin, PharmaMar)	myeloma	phase 3
PLX3397 (Plexxikon)	acute myelogenous leukemia, Hodgkin's lymphoma	phase 2
PNT2258 (ProNAi Therapeutics)	B-cell lymphoma	phase 2
pomalidomide (Pomalyst, Celgene)	myelofibrosis	phase 3
ponatinib (Iclusig, Ariad)	acute myelogenous leukemia/chronic myeloid leukemia	phase 2/phase 3
PR104 (Proacta)	acute myelogenous leukemia	phase 2
pracinostat (MEI Pharma) **READ PERSPECTIVE** on this drug from Aaron T. Gerds, MD, MS, on page 87.	myelodysplastic syndrome, myelofibrosis	phase 2
PRI-724 (Prism Pharma)	acute myelogenous leukemia, chronic myeloid leukemia	phase 2
PRLX-93936 (Prolexsys Pharmaceuticals)	myeloma	phase 2
PVX-410 (OncoPep)	myeloma	phase 2
quizartinib (Ambit Biosciences)	relapsed/refractory acute myelogenous leukemia	phase 2
recombinant CD40 ligand immunotherapy (ISF35, Memgen)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase 2
recombinant Factor VIIa (BAX-817, Baxter International)	hemophilia A, hemophilia B	phase 2
recombinant Factor VIIa (BAY 86-6150, Bayer Healthcare)	hemophilia A, hemophilia B	phase 3
recombinant Factor VIII (BAY 94-9027, Bayer Healthcare)	hemophilia A	phase 3
recombinant Factor VIII-Fc (Biogen Idec)	hemophilia A	phase 3
recombinant Factor VIII glycopegylated (NN7088, Novo Nordisk)	hemophilia A	phase 3
recombinant Factor IX-FP (CSL-654, CSL Behring)	hemophilia B	phase 3
recombinant Factor IX-Fc (Biogen Idec)	hemophilia B in children	phase 3
recombinant Factor IX glycopegylated (NN7999, Novo Nordisk)	hemophilia B	phase 3
recombinant porcine Factor VIII (OBI-1; Inspiration Biopharmaceuticals, Ipsen)	hemophilia A	phase 3
recombinant von Willebrand's Factor (BAX-111, Baxter International)	von Willebrand's disease	phase 3
remestemcel-L (Prochymal, Osiris Therapeutics)	graft-versus-host disease	phase 3
RGI-2001 (REGiMMUNE)	graft-versus-host disease	phase 2
rigosertib (Onconova Therapeutics)	myelodysplastic syndrome	phase 3
rituximab (Rituxan; Genentech, Biogen Idec)	diffuse large B-cell lymphoma	phase 3
romidepsin (Istodax, Celgene)	newly diagnosed peripheral T-cell lymphoma	phase 3
romiplostim (Nplate, Amgen)	chemotherapy-induced thrombocytopenia	phase 2
ruxolitinib (Jakafi, Incyte)	hematologic malignancies, essential thrombocythemia/polycythemia vera	phase 2/phase 3
sapacitabine (Cyclacel Pharmaceuticals)	chronic lymphocytic leukemia, myelodysplastic syndrome/ acute myelogenous leukemia	phase 2/phase 3
SAR245409 (XL765; Exelixis, Sanofi)	non-Hodgkin's lymphoma	phase 2

Hematology Drugs in the Pipeline

Generic name (Brand name, Manufacturer)	Indication(s)	Development status
SAR302503 (Sanofi)	polycythemia vera, myelofibrosis (combination therapy)/myelofibrosis	phase 2/phase 3
SAR3419 (ImmunoGen/Sanofi)	acute lymphoblastic leukemia, non-Hodgkin's lymphoma	phase 2
sargramostim (Leukine, Bayer Healthcare)	chronic lymphocytic leukemia	phase 2
sepantronium bromide (YM155, Astellas Pharma)	non-Hodgkin's lymphoma	phase 2
SGI110 (Astex Pharmaceuticals)	acute myelogenous leukemia, myelodysplastic syndrome	phase 2
siltuximab (CNTO-328, Janssen Biotech)	myeloma, myelodysplastic syndrome	phase 2
simtuzumab (Gilead Sciences)	myelofibrosis	phase 2
SL-401 (Stemline Therapeutics)	relapsed/refractory acute myelogenous leukemia, relapsed/refractory blastic plasmacytoid dendritic cell neoplasm, myelodysplastic syndrome	phase 2
SNS01-T (Senesco Technologies)	diffuse large B-cell lymphoma, mantle cell lymphoma, myeloma	phase 2
sotatercept (ACE-011, Acceleron Pharma)	anemia in myelodysplastic syndrome, anemia in end-stage renal disease/ chemotherapy-induced anemia	phase 2/phase 3
tabalumab (Eli Lilly)	myeloma	phase 3
tamibarotene (CytRx)	acute promyelocytic leukemia	phase 2
T-cell replacement therapy (CaspaCIDe DLI, Bellicum Pharmaceuticals)	graft-versus-host disease in patients with late-stage cancer who undergo bone marrow transplantation	phase 2
temozolomide (Temodar, Merck)	acute myelogenous leukemia	phase 2
tetradecanoylphorbol acetate (PD-616, Biosuccess Biotech)	acute myelogenous leukemia	phase 2
TH-302 (EMD Serono/Threshold Pharmaceuticals)	myeloma	phase 2
TH-9402 (Kiadis Pharma)	graft-versus-host disease	phase 2
TKI258 (Novartis)	myeloma	phase 2
tosedostat (Cell Therapeutics/Chroma Therapeutics)	acute myelogenous leukemia	phase 2
trametinib (GSK1120212, GlaxoSmithKline)	lymphoma	phase 2
TRU-016 (Emergent BioSolutions)	chronic lymphocytic leukemia	phase 2
TXA127 (Tarix Pharmaceuticals)	chemotherapy-induced thrombocytopenia	phase 2
ublituximab (TG-1101, TG Therapeutics)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase 2
umbilical cord blood stem cell therapy (NiCord, Gamida Cell)	sickle cell anemia, hematologic malignancies	phase 2
veltuzumab (IMMU-106, Immunomedics)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase 2
vemurafenib (Roche)	BRAF V600 mutation-positive myeloma	phase 2
vincristine sulfate liposome injection (Marqibo, Talon Therapeutics)	acute lymphoblastic leukemia in the elderly	phase 3
volasertib (Boehringer Ingelheim)	acute myelogenous leukemia	phase 3
vorinostat (Zolinza, Merck)	myeloma	phase 3
vosaroxin (Sunesis Pharmaceuticals)	acute myelogenous leukemia	phase 3
WT1 antigen-specific cancer immunotherapeutic (GlaxoSmithKline)	acute myelogenous leukemia	phase 2
zanolimumab (Emergent BioSolutions)	peripheral T-cell lymphoma	phase 2

Information in this chart was compiled from the Pharmaceutical Research and Manufacturers of America, NIH (www.clinicaltrials.gov), corporate websites and the databases of HEMONC TODAY. The publisher or editors do not assume responsibility for any errors or omissions.

Hematology Drugs in the Pipeline

HEMONC TODAY asked key opinion leaders to offer perspective about hematology drugs in the pipeline they believe have the potential to change practice.

PERSPECTIVE: IBRUTINIB


Fernando Cabanillas

Without doubt, one of the most promising new agents under development for lymphoma is the Bruton's tyrosine kinase (BTK) inhibitor known as ibrutinib (PCI-32765; Janssen, Pharmacyclics).

BTK plays a critical role in B-cell receptor signaling, essential for normal development of B cells (Niiro H. *Nat Rev Immunol*. 2002;2:945-956).

A phase 2 trial designed for patients with relapsed or refractory mantle cell lymphoma who were either bortezomib (Velcade, Millennium) naive or previously exposed has been published as a preliminary study (Wang ML. *N Engl J Med*. 2013;369:507-516). This trial used a daily dose of 560 mg of ibrutinib given orally and repeated until disease progression. The trial included 111 heavily pretreated patients (median age, 68 years; median three prior therapies). The prognostic factors were unfavorable, as 86% of patients had intermediate-risk or high-risk mantle cell lymphoma.

Researchers observed a 68% response rate (n=75), with a complete response rate of 21% and a partial response rate of 47%. Interestingly, prior treatment with bortezomib had no effect on the response rate. With a median follow-up of 15.3 months, the estimated median response duration was 17.5 months and median PFS was 13.9 months. Median OS has not been reached.

The most common toxic effects were mild or moderate diarrhea, fatigue and nausea. Grade 3 or higher hematologic events were infrequent. They included neutropenia (16%), thrombocytopenia (11%) and anemia (10%).

Ibrutinib was shown in this study to have impressive single-agent activity in the relapse/refractory setting, with long duration of response and a very acceptable toxicity profile. This agent has also shown preliminary activity in chronic lymphocytic leukemia, diffuse large B-cell lymphoma and low-grade B-cell lymphomas. This agent also has shown very promising activity in Waldenstrom's macroglobulinemia (Advani RH. *J Clin Oncol*. 2013;31:88-94).

The FDA has invited the pharmaceutical company that manufactures this drug to apply for approval as a breakthrough treatment in mantle cell lymphoma and Waldenstrom's macroglobulinemia.

— Fernando Cabanillas, MD

HEMONC TODAY Editorial Board member

Disclosure: Cabanillas reports no relevant financial disclosures.

PERSPECTIVE: DARATUMUMAB


Philip McCarthy

Daratumumab (HuMax-CD38; Genmab, Janssen) is a monoclonal antibody that is directed against CD38. This antibody reacts against cells expressing CD38, such as malignant plasma cells. Interestingly, it does not appear to have major effects on T cells or endothelial cells, which can express CD38.

The clinical trial results using this antibody alone have been quite exciting. At the 2012 ASH Annual Meeting and Exposition, there was a very nice clinical study that demonstrated this antibody has clinical activity in patients with heavily pretreated multiple myeloma.

What made this very exciting is that this is the first antibody to work as a single agent in patients with multiple myeloma. In other words, it did not require chemotherapy to make it work, and it had anti-myeloma activity when given to patients with relapsed and refractory multiple myeloma. There will be an update of the clinical trial at the 2013 ASH Annual Meeting, and it will be important to determine there are no unusual effects of the therapy.

This could be the rituximab equivalent — the anti-CD20 antibody used for non-Hodgkin's lymphoma therapy — for multiple myeloma.

— Philip McCarthy, MD

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Disclosure: McCarthy reports no relevant financial disclosures.

PERSPECTIVE: CAR-T CELLS


Matt Kalaycio

We have known for decades that T cells have powerful anticancer effects. These effects are most clearly demonstrated following allogeneic stem cell transplant, where infusions of T cells can induce remissions in some patients who have relapsed. This observation has led to the recent adoption of reduced-intensity transplant, which depends largely on T-cell mediated graft-versus-malignancy effects. Unfortunately, we have had difficulty separating the beneficial anticancer effects of T cells from their side effect of graft-versus-host disease (GVHD). The ability to capture the graft-versus-malignancy effect without inducing GVHD is the focus of much research in the transplant field.

One way to avoid GVHD is to employ autologous T cells as anticancer effector cells. Sipuleucel-T (Provenge, Dendreon) for prostate cancer is one such treatment with modest survival benefits. More recently, though, breakthroughs have been made in the manufacture of chimeric antigen receptor T cells (CAR-T cells). These T cells are engineered to express antibodies on their surface to target cells of interest. The best example of such cells are those engineered to express anti-CD19, thus targeting CD19-positive B cells. The problem historically has been to overcome immunologic rejection of the CAR-T cells by the patient. This problem has recently been addressed by inserting a lentiviral vector into the cells, resulting in resistance to immunologic attack.

The results with the latest iterations of CAR-T cells have been spectacular. Complete and sustained remissions have been reported in patients with advanced CD19-positive chronic lymphocytic leukemia and acute lymphoblastic leukemia. This exciting, but nascent, adoptive immunotherapy requires additional effort to scale up production and scale down costs, but promises to delay — if not replace — allogeneic stem transplant for CD19-positive B-cell lymphoproliferative disorders in the future.

— Matt Kalaycio, MD

Department chair

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Disclosure: Kalaycio reports no relevant financial disclosures.

PERSPECTIVE: PRACINOSTAT


Aaron T. Gerds

Discovery of recurrent mutations in DNMT3A, TET2, ASXL1 and others critical in DNA methylation and posttranslational modification of histones reinforces the essential role of epigenetic regulation in the leukemogenesis of myelodysplastic syndrome (MDS), leading to the utilization of the so-called hypomethylating therapy with azacitidine (Vidaza, Celgene) and decitabine (Dacogen, Eisai) in patients harboring these abnormalities (Traina F. *Leukemia*. 2013;doi:10.1038/leu.2013.269). Nonetheless, in the single-agent setting, current literature describes a modest response rate (about 15%, including complete responses and partial responses) and survival benefit (about 9 months for azacitidine only).

Although inhibitors of histone deacetylases (HDAC) have yielded unexceptional results in the single-agent setting, the prospect of an additive or synergistic effect with combined epigenetic therapy is the nidus for current clinical trials. Pracinostat (MEI Pharma) is a rationally designed, potent, oral, pan-HDAC that has demonstrated synergistic interactions with azacitidine in preclinical studies. In a pilot study of nine patients with advanced MDS, pracinostat in combination with azacitidine yielded an 89% overall response rate (seven achieved complete response or complete response with incomplete peripheral blood count recovery) with minimal observed toxicity (Quintas-Cardama A. Abstract #3821. Presented at: ASH Annual Meeting; Dec. 8-11, 2012; Atlanta). Furthermore, five (56%) patients achieved a complete cytogenetic response and five patients were bridged to allogeneic hematopoietic cell transplantation. Invigorated by these results, we now eagerly await the results of a randomized, placebo-controlled phase 2 trial of the combination (clinicaltrials.gov identifier: NCT01873703) currently enrolling patients through the MDS Clinical Research Consortium.

— Aaron T. Gerds, MD, MS

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Disclosure: Gerds reports no relevant financial disclosures.

Hematology Drugs in the Pipeline

PERSPECTIVE: ABT-199, ANTIBODY-DRUG CONJUGATES

Mitchell R. Smith

Enhancing death of cancer cells through apoptosis has been a longstanding research goal. Lymphoid malignancies that overexpress the anti-apoptotic BCL-2 protein are logical targets for such treatment. Anti-sense oligonucleotides that downregulate BCL-2, such as oblimersen (Genasense, Genta) had activity in chronic lymphocytic leukemia and follicular lymphoma but were cumbersome as drugs. Apoptotic threshold is controlled not only by BCL-2, but by a complex balance of pro- and anti-apoptotic members of the BCL-2 family of proteins. These interact through a common BH3 protein domain, so that small molecules designed to mimic this BH3 domain can be pro-apoptotic.

Navitoclax, (ABT-263, AbbVie) — an oral pro-drug of the parent compound ABT-737, with demonstrated activity against CLL and B-cell lymphoma — was in late stage clinical development. One of its targets, however, is the BCL-2 family member BCL-XL, which is critical to platelet survival. Thus, an on-target effect is thrombocytopenia, making chemotherapy combinations problematic.

Rational drug modification led to ABT-199 (AbbVie, Genentech), a variant that does not inhibit BCL-XL. ABT-199 is proceeding through trials in both CLL and lymphoma. The early data, updated at ASCO this year, are promising. Impressive single-agent activity (85% response rate) was observed even during phase 1 development in patients with heavily pretreated CLL, including in patients with deletion 17p (Seymour JF. Abstract #7018. Presented at: ASCO Annual Meeting; May 31-June 4, 2013; Chicago). In fact, tumor lysis syndrome — a marker of activity — has been observed, requiring cautious intrapatient dose escalation, which has slowed development somewhat. In a smaller number of heavily pretreated patients with a variety of lymphoma subtypes, the response rate was 55% (Davids MS. Abstract #8520. Presented at: ASCO Annual Meeting; May 31-June 4, 2013; Chicago).

It is certainly logical to consider pairing an antiproliferative agent with a pro-apoptotic approach. ABT-199 is proceeding in clinical development alone, and in combination with chemotherapy, rituximab (Rituxan; Genentech, Biogen Idec) and B-cell receptor signal pathway inhibitors. We still need to optimize such combinations, determine which diseases are most sensitive to this strategy of enhancing apoptosis and define biomarkers of activity, but it is clear that this will be an important addition to therapy of lymphoid malignancies.

Antibody-drug conjugates (ADC) are a rapidly expanding class of therapeutic agents, led by the approval of brentuximab vedotin (Adcetris, Seattle Genetics) for CD30-positive Hodgkin's lymphoma and anaplastic large-cell lymphoma. ADC are complexes comprised of an antibody that can be varied to target a particular disease coupled via a linker to a cytotoxic agent. Based on the success of brentuximab vedotin, the same cytotoxic anti-tubulin agent MMAE has been conjugated to target B cells via CD22 (DCDT2980S) and CD79b (DCDS4501A).

Data from phase 1 studies of safety and preliminary efficacy of each of these ADC, with or without rituximab, in heavily pretreated patients with B-cell lymphoma were presented at the International Conference on Malignant Lymphoma in June, as well as at ASH last year (Palanca-Wessels M. Abstract #56. Presented at: ASH Annual Meeting; Dec. 8-11, 2012; Atlanta. Advani R. Abstract #59. Presented at: ASH Annual Meeting; Dec. 8-11, 2012; Atlanta). The overall response rate for the CD22-targeted agent was 30% alone and 33% in combination with rituximab, and overall response rate for the CD79b-targeted agent was 57% alone and 78% with rituximab, with a complete remission rate of 12% and 22%, respectively. Toxicities are primarily neutropenia, common to several ADC, and peripheral neuropathy related to MMAE.

Phase 2 trials are ongoing. Similar in concept is the CD22-targeted ADC inotuzumab ozogamicin (CMC-544, Pfizer), which targets the same cytotoxic agent as in gemtuzumab ozogamicin (Mylotarg, Pfizer), in this case to B cells via CD22. This agent, currently in phase 3 trials, has demonstrated single-agent activity in lymphoma and ALL, and it is being investigated in combination with rituximab and with R-CVP (Ogura M. Presented at: International Conference on Malignant Lymphoma; June 19-22, 2013; Lugano, Switzerland).

The "Trojan Horse" approach of using monoclonal antibodies to target therapeutic antibodies into cells is not new, but with new linker technology and following the approval of brentuximab vedotin, we can expect rapid expansion of the number of active targeted therapeutics based on this strategy.

— Mitchell R. Smith, MD, PhD

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Disclosure: Smith reports research funding from AbbVie. He was a clinical investigator for ABT-263 and inotuzumab ozogamicin. He also was a co-author on the Ogura abstract.

PERSPECTIVE: IBRUTINIB, ALISERTIB, DARATUMUMAB

Swaminathan Padmanabhan Iyer

Ibrutinib (PCI-32765; Janssen Biotech, Pharmacyclics) — an oral, small-molecule inhibitor of Bruton's tyrosine kinase — is on the cusp of FDA approval for chronic lymphocytic leukemia and mantle cell lymphoma.

Mantle cell lymphoma is an aggressive lymphoma that initially responds to treatment but invariably becomes resistant. We have pushed the bar for this poor-prognostic disease to maybe 4 or 5 years with chemotherapy, transplant and rituximab (Rituxan, Genentech/Biogen Idec Pharmaceuticals). With ibrutinib, the response rate is about 70% (Wang ML. *N Engl J Med*. 2013;369:507-516), and some have continued for many years with 20% complete responses.

It has shown tremendous benefit in patients heavily pretreated with chemotherapy. Also, the median age of diagnosis of mantle cell lymphoma is 65 years. Because ibrutinib is an oral drug, it will help older patients, many of whom cannot undergo chemotherapy because of comorbidities.

In addition, the toxicity is very minimal, so you have a very targeted therapy with tremendous efficacy and few side effects. That is the goal of cancer treatment, and it's game-changing for mantle cell lymphoma.

I'm also very optimistic that ibrutinib will improve outcomes for patients with CLL (Byrd JC. *N Engl J Med*. 2013;369:1278-1279). The data we have seen so far are from single-agent studies. In reality, we'll be looking at combining it with drugs already approved — particularly less toxic ones, such as rituximab, bendamustine (Treanda, Cephalon) and ofatumumab (Arzerra, GlaxoSmithKline). So we're on the verge of a paradigm shift, moving away from heavy chemotherapy to realizing our goal of targeted therapy.

The phase 1 data for alisertib (MLN8237, Millennium Pharmaceuticals), an aurora A kinase inhibitor, looked very promising in several fast-growing diseases, including Burkitt's lymphoma, T-cell lymphoma, diffuse large B-cell lymphoma and even some solid tumors. A phase 2 study by Friedberg and colleagues (Friedberg JW. *J Clin Oncol*. 2013;doi:10.1200/JCO.2012.46.8793) found a 57% response rate in T-cell lymphoma. That is one of the highest we have seen for T-cell lymphomas.

Millennium is enrolling for a phase 3 trial that will include 350 patients with peripheral T-cell lymphoma to compare alisertib with other standard agents. Based on the results we saw in phase 1 and phase 2 studies, the data that will come from this study could be a game-changer for T-cell lymphoma. If it eventually is approved, we could combine it with other agents in hopes of pushing the envelope to increase responses.

Daratumumab (Janssen Biotech/Genmab) targets CD38, which is present in almost every multiple myeloma. For the first time, we have a monoclonal antibody approach in multiple myeloma.

The responses we have seen so far are phenomenal, close to 95%. We have to keep in mind these data are phase 1 and phase 2, but it appears very promising as both a single-agent therapy and in combination with other agents.

Overall, we are at a tipping point. For some time, we thought we could cure every hematologic cancer with transplant. Now we realize we have options beyond transplant, but they require a three-pronged approach.

First, we have to try to understand the biology. Hematologic cancer is a genomic disease. A deeper understanding of genes gives us essential diagnostic and prognostic information. Second, based on what we learn from the genes, we can identify smart ways to develop drugs. Third, we understand — even within the same malignancies — each patient has a unique disease signature.

So we are going beyond transplants, which may not be ideal for everyone. We have learned to use the genomic approach and smarter drugs to personalize treatments, and that is the way of the future.

— Swaminathan Padmanabhan Iyer, MD

Leader, early drug development

Co-director, Malignant Hematology Program

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Disclosure: Iyer reports no relevant financial disclosures.

Hematology Drugs in the Pipeline

PERSPECTIVE: IXAZOMIB


Shaji K. Kumar

Proteasome inhibition is an effective treatment strategy for many malignancies, especially for myeloma and mantle cell lymphoma.

Bortezomib (Velcade, Millennium Pharmaceuticals) was the first proteasome inhibitor successfully evaluated in the clinic and has since become an integral part of myeloma therapy, alone and in combination regimens (Richardson PG. *N Engl J Med*. 2003;348:2609-2617. Kumar S. *Blood*. 2008;112:2177-2178). The main drawback with bortezomib has been the risk of peripheral neuropathy, mitigated to a great extent by subcutaneous administration and reduced administration frequency.

Ixazomib (MLN9708, Millenium) represents a potential paradigm shift in proteasome inhibition strategy, offering an orally bioavailable option with reduced toxicity (Chauhan D. *Clin Cancer Res*. 2011;17:5311-5321. Lee EC. *Clin Cancer Res*. 2011;17:7313-7323). Ixazomib is the precursor of the active moiety MLN2238, a peptide boronic acid analogue similar in structure to bortezomib, binding in a reversible fashion to the 20s proteasome subunit but with a faster dissociation than bortezomib, leading to better tissue distribution. Ixazomib has been studied in a once-a-week schedule, given on days 1, 8 and 15 of a 28-day cycle, as well as a twice-a-week schedule similar to bortezomib, in which it is given on days 1, 4, 8 and 11 of a 3-week cycle.

In phase 1 studies of single-agent ixazomib, both schedules induced responses and were well tolerated (Kumar S. Abstract #8514. Presented at: ASCO Annual Meeting; May 31-June 4, 2013; Chicago. Kumar SK. Abstract #332. Presented at: ASH Annual Meeting; Dec. 8-11, 2012; Atlanta. Lonial S. Abstract #8017. Presented at: ASCO Annual Meeting; June 1-5; Chicago. Merlini G. Abstract #731. Presented at: ASH Annual Meeting; Dec. 8-11, 2012; Atlanta). The major side effects have been gastrointestinal (nausea, vomiting and diarrhea), thrombocytopenia and fatigue. Peripheral neuropathy has been conspicuous by its low rate and lack of severity.

Ixazomib has been combined with lenalidomide (Revlimid, Celgene) and dexamethasone in newly diagnosed myeloma with high response rates, and it offers a completely oral option for an effective induction regimen (Kumar SK. Abstract #332. Presented at: ASH Annual Meeting; Dec. 8-11, 2012). Ongoing studies are comparing this combination in both upfront and relapsed settings, the results of which could result in its approval.

— Shaji K. Kumar, MD

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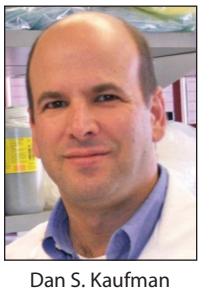
Disclosure: Kumar reports no relevant financial disclosures.

PERSPECTIVE: BLINATUMOMAB


Dan S. Kaufman

Blinatumomab (AMG 103, Amgen) is the first of a new class of agents called bi-specific T-cell engagers (BiTEs) that provide a novel strategy to direct cytotoxic lymphocytes to engage and kill tumor cells. Monoclonal antibodies (mabs) such as rituximab (Rituxan; Genentech, Biogen Idec) and trastuzumab (Herceptin, Genentech) that mediate antitumor activity have been a tremendous advance in cancer therapeutics.

Although bispecific antibodies that chemically link two distinct monoclonal antibodies were first developed in the 1980s, clinical trials with these agents typically demonstrated relatively little benefit. Also, large-scale production was apparently difficult. Although this approach never led to a routine clinical product, the strategy remained of interest. By the 1990s, a new technology to genetically link two or more single-chain variable regions (scFv) was developed to provide a more efficient means to produce bispecific agents.

Blinatumomab consists of an anti-CD3 and an anti-CD19 scFv linked together to direct T cells to B-cell leukemias and lymphomas. The most interesting and promising studies demonstrate significant activity against B-cell acute lymphoblastic leukemia that is refractory to standard chemotherapy. In a phase 2 study, minimal residual disease was obtained in 16 of 20 evaluable patients after one cycle of treatment (Topp MS. *J Clin Oncol*. 2011;29:2493-2498). After more than a year post-treatment, 78% of patients who received blinatumomab remained in remission. Some underwent allogeneic hematopoietic cell transplant while in remission, but many had not received additional therapy. Longer-term follow-up of this initial cohort remains promising (Topp MS. *Blood*. 2012;120:5185-5187). Similar promising results have been seen in pediatric patients with ALL, as well as adults with non-Hodgkin's lymphoma and chronic lymphocytic leukemia. Administration of blinatumomab does have toxicities, notably lymphopenia and flu-like symptoms. Tremors and/or other neurologic effects also can occur. Serum immunoglobulins transiently decrease during treatment. Notably, blinatumomab does have a short half-life (1 to 2 hours), requiring administration by pump for several weeks. However, these limitations seem relatively modest compared with the clinical efficacy of blinatumomab. Although not yet FDA approved, blinatumomab is likely the first of many BiTEs and similar agents to join the cancer immunotherapy repertoire in the near future.

— Dan S. Kaufman, MD, PhD

HEMONC TODAY Editorial Board member

Disclosure: Kaufman reports no relevant financial disclosures.

PERSPECTIVE: MOMELOTINIB, PACRITINIB


Ruben A. Mesa

Momelotinib (CYT-387, Gilead Sciences) is selective JAK1/JAK2 inhibitor in development for myelofibrosis (MF).

Ruxolitinib (Jakafi, Incyte) is approved for intermediate- and high-risk MF based on randomized studies that demonstrated improvements in splenomegaly, symptomatic burden and survival (Verstovsek S. *N Engl J Med*. 2012;366:799-807. Harrison C. *N Engl J Med*. 2012;366:787-798). However, ruxolitinib has limited efficacy for MF-associated anemia.

The phase 1/phase 2 clinical trial of momelotinib (Pardanani A. *Leukemia*. 2013;27:1322-1327) demonstrated this JAK1/JAK2 improves splenomegaly, symptoms and anemia (either improvement from baseline or less drug-associated anemia, with an overall response rate of 59%). Grade 3 and grade 4 toxicities included thrombocytopenia (32%) and amylasemia (5%). Grade 1 peripheral neuropathy was prevalent at 22% new onset but did not seem to worsen. There is no FDA-approved therapy for anemia in MF, but immunomodulatory drugs sometimes can help. A successful phase 3 clinical trial demonstrating superior activity of momelotinib compared with ruxolitinib in the area of anemia would be viewed as an important therapeutic advance and likely lead to approval.

Pacritinib (SB1518, Cell Therapeutics) is a selective JAK2/FLT3 inhibitor in development for patients with myelofibrosis. The dose-limiting toxicity of ruxolitinib is thrombocytopenia. It was originally indicated only for those with platelets >100 x 10^9/L (now for those above 50 x 10^9/L). Phase 1 and 2 trials of pacritinib in the United States and Australia (Komrokji RS. Abstract #3838. Presented at: ASH Annual Meeting; Dec. 10-13, 2011; San Diego. Deeg HJ. Abstract #6515. Presented at: ASCO Annual Meeting; June 3-7, 2011; Chicago) demonstrated activity in MF-associated splenomegaly and symptom burden without significant drug-associated thrombocytopenia or anemia. Toxicities primarily consisted of grade 1 and grade 2 gastrointestinal issues (nausea or diarrhea), which were controlled with supportive medications.

PERSIST1 — a randomized, phase 3 clinical trial (NCT01773187, www.clinicaltrials.gov) — is currently enrolling with broad inclusion criteria, allowing patients independent of platelet count to enroll if otherwise eligible. If the trial is successful, pacritinib could be positioned well for MF patients with advanced thrombocytopenia, and combination trials with other active agents that can cause thrombocytopenia (ie, immunomodulatory or hypomethylating agents).

— Ruben A. Mesa, MD

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Disclosure: Mesa reports research funding from Cell Therapeutics and Gilead.

PERSPECTIVE: IBRUTINIB, IDELALISIB


Bruce D. Cheson

A series of new targeted agents are poised to radically change how we approach patients with B-cell malignancies. Several target pathways downstream from the B-cell receptor that are involved in the perpetuation of the malignant process and longevity of malignant lymphocytes.

Ibrutinib (PCI-32765; Janssen, Pharmacyclics) is a specific Bruton's tyrosine kinase inhibitor. When administered in a daily oral dose, ibrutinib achieves durable responses — mostly partial — in more than 70% of patients with relapsed or refractory chronic lymphocytic leukemia, including those with the deletion 17p, as well as untreated patients older than 65, who have a an estimated 96% PFS at about 2 years. Responses have been reported in nearly 60% of patients with relapsed and refractory follicular lymphoma, and 68% of patients with mantle cell lymphoma. Toxicity has been acceptable, consisting mostly of diarrhea, cough, rash and fatigue. Impressive activity has also been reported in Waldenstrom's macroglobulinemia, and the nongerminal center subset of diffuse large B-cell non-Hodgkin's lymphoma.

Idelalisib (GS-1101, Gilead), an inhibitor of the PI3K-delta isoform, is administered orally twice daily. Lymph node responses have been reported in more than 80% of patients with relapsed and refractory CLL. A phase 3 trial of rituximab (Rituxan; Genentech, Biogen Idec) plus placebo or idelalisib in CLL patients with comorbidities closed early because of a favorable outcome in the treatment group. When combined with rituximab in untreated CLL, the response rate was 97% and PFS at 24 months was 93%. Almost 60% of patients with follicular lymphoma or mantle cell lymphoma respond to the single agent, and that rate increases to 75% to 85% when the drug is combined with rituximab or bendamustine (Treanda, Cephalon), or a combination of the three. Toxicity has included diarrhea and a transient transaminitis.

A notable phenomenon with both ibrutinib and idelalisib, primarily in CLL, is a lymphocytosis that occurs early as a result of redistribution and subsides over time. This observation confounds interpretation of response, which had, to date, required a decrease in circulating lymphocytes. Response criteria are being modified to take this effect into account. The availability of these agents, and other new targeted drugs, raises the potential for a chemotherapy-free approach to many patients with B-cell malignancies.

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Disclosure: Cheson reports no relevant financial disclosures.