THE LIFE RAFT GROUP
CLINICAL TRIALS BULLETIN
Our navigation for the trials you seek

August 2009 Clinical Trials Update

By Jim Hughes
LRG Clinical Trials Coordinator

This month we have added a Phase I trial of Vorinostat and Bortezomib at the Carbone Cancer Center, at the University of Wisconsin, Madison. This trial was reported at ASCO in June. Bortezomib is a proteasome inhibitor. This class of drugs has been identified as having potential therapeutic application in GIST. Three GIST patients have entered this trial. So far, researchers report that the best response has been a short term stable. We will be watching this trial for additional reports.

Additional sites have been added to the Nilotinib versus Imatinib Phase III first-line trial ongoing worldwide. There are 75 sites listed, of which 30 are recruiting. Two of these are in City of Hope Hospital in California and MD Anderson in Texas. This trial is for newly diagnosed and recurrent patients who have not had prior Sutent or Gleevec therapy except with Gleevec for adjuvant use.

The sites for the SF1126 Phase I trial have been updated to include Emory University in Atlanta, Georgia as well as Scottsdale and Tucson, Arizona and Indianapolis, Indiana.

Don't forget to check out the LRG Newsletter at www.gistnews.org!

GIST management requires an understanding of mutation status

By Jim Hughes
LRG Clinical Trials Coordinator

Mutation status is a predictor of response to standard imatinib and sunitinib therapy. Mutation status may also have prognostic value regarding the potential aggressive behavior of certain mutations. For high risk or advanced GIST patients, whether newly diagnosed or longer term survivors, understanding genetic mutation is a necessary component of GIST management strategy. Mutation testing is recommended for all GIST patients.

At the recent 2009 American Society of Clinical Oncologists conference, Dr. Chris Corless gave an oral presentation on the role of tumor genotyping in optimizing the treatment of GIST. Dr. Corless' presentation emphasized the integral role of genotyping in GIST treatment.

One slide showed the results of an informal survey he conducted among colleagues in the United States and Europe concerning the percentage of newly diagnosed GIST patients who have mutation testing:

- Germany- 40% to 50%
- France- 60%
- United States- 2% - 20% (estimated)

In Dr Corless' words, "...in the US we are lagging far behind…We are not doing all that good a job of genotyping…"

Dr. Corless noted possible barriers to testing. First among them was the perception (among clinicians) that testing "is not critical to treatment…so we don't necessarily need to bother". Then he noted "there is the hassle factor, because not all labs offer the testing and you (oncologists) have to reach out and find a lab to do it…And there is the concern over costs."

The availability, hassle, and cost issues have been solved with the advent of the GIST Collaborative Tissue Bank. Patients can now get GIST mutation testing for free. The test is done by Dr. Corless' team at Oregon Health & Science University (OHSU), arguably one of the best in the United States for GIST.

The perception issue may be more persistent. This was evident at the meeting during the question and answer period when Corless was asked about the potential utility of mutation testing in gastric GIST "which is probably overwhelmingly exon 11". Citing the risk of a potential PDGFRA mutation, Dr. Corless responded that, "If I was diagnosed with a gastric GIST and it had any mitotic activity, I would definitely get genotyping done."

Assuming the perception issue remains, patients who understand the need for mutation testing will be better equipped to address this issue with their medical team.

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for GIST recommends mutation testing for all GISTs as part of the diagnostic process. The NCCN authors include several recognized GIST specialists who both treat and study GIST. These are the consensus guidelines for managing GIST in the US.

Primary mutation refers to the mutation status of the primary tumor or the tumor

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tissue from the first surgery or biopsy before imatinib therapy. The tissue is usually collected as part of the GIST diagnostic process. The test is most often performed immediately after the first surgery or biopsy. But it can be performed anytime, even years later, using the paraffin tissue blocks stored by the hospital where the first surgery or biopsy took place.

Large series of primary GIST tumors have been analyzed and mutation frequency has been established over time. Looking at these mutation frequencies, the patterns of occurrence by organ and the patterns of imatinib response one can make some estimations of risk Table 1).

Table 1: Genotype & imatinib response

Mutation	Exon	Region	Location	Freq. %*	IM response~
KIT	11	Juxtamembrane	all sites	67%	Best response
Wild Type	n/a	N/A	all sites	13%	Less
KIT	9	Extracellular	small bowel, colon	10%	Less (dose dependent)
PDGFRA	18 D842	Activation Loop	stomach, mesentery, omentum	5%	Resistant
Rare #	Multiple	Multiple	all sites	4%	Good - Mixed - Unknown

These rare (1% or less each) primary mutations include KIT exons 13 & 17 PDGFRA exons 12 & 14 & 18 (not in D842) as well as the familial and syndromic GISTs. Data for most of these is sparse and not definitive.

All sites = all sites along the gastrointestinal tract (esophagus, stomach, small intestine, colon and rectum).

*Sources; *Corless, Heinrich Ann. Rev. of Pathology, 2007. ~Lasota, Miettinen Histopathology, 2008 & Van Glabbeke ASCO, 2007*

Genotyping for newly diagnosed GIST patients

Genotype can be prognostic.

There are many factors that drive malignancy in cancer. Although these are not all understood, primary GIST genotype has been noted many times in the research literature.

Growth and progression of Wildtype and PDGFRA mutant tumors appears to be slower than KIT-mutant

Tumors with KIT exon 9 mutation are more aggressive than other GISTs

Tumors with KIT exon 11 deletions (especially codons 557-558) appear more likely to progress than other types of GIST

Genotype can predict response to standard therapy.

In the best case, the odds are roughly one in four that the primary mutation is less responsive to imatinib therapy. If the primary tumor is in the lower GI tract or outside the GI tract, the odds increase that it will be less responsive. For newly diagnosed patients the substantial possibility of a non-responsive GIST is the main reason for mutation testing

Patients who are considering adjuvant therapy can also benefit from mutation testing. A genotype that is more aggressive could be a key factor in the decision to start adjuvant therapy. KIT exon 11 deletions of codons 557 and 558 are associated with a more malignant GIST. If a resected GIST tumor was in a borderline risk area based on size and mitotic rate, knowing if it was this mutation might help with decision making

Patients considering neoadjuvant imatinib therapy might also benefit. PDGFRA mutation D842V does not respond to imatinib. A genotype that does not respond to imatinib could be a key factor in the decision to not delay surgery while undergoing neoadjuvant treatment.

There is also a time value with mutation testing. Should resistance eventually occur, it will take some time to get results and select the best treatment plan. Having primary mutation status in hand can avoid lost time while managing progression. There is no downside and a significant benefit to mutational testing at the outset of treatment and before resistance occurs.

Genotyping for patients with early resistance

Patients lacking mutation status and experiencing early resistance are prime candidates for mutation testing.

Mutation situations that can lead to early resistance include:

KIT exon 9 mutant GIST has been shown to respond better to 800 mg of imatinib in the clinic. KIT exon 9 mutant GIST may also respond better to sunitinib therapy.

PDGFRA D842V mutant GIST is resistant to imatinib and sunitinib and has been shown to respond to both dasatinib and HSP90 inhibitors in the lab. For this mutation it may be prudent to go directly to dasatinib therapy or into an HSP90 trial.

Wildtype GIST has shown variable response to imatinib. Wildtype has been shown to respond better to sunitinib in the clinic and nilotinib in the lab. Wildtype GIST has also recently been shown to over-express IGF1R and to sometimes

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The Life Raft Group

Who are we, what do we do?

The Life Raft Group (LRG) directs research to find a cure for a rare cancer and help those affected through support and advocacy until we do.
The LRG provides support, information and assistance to patients and families with Gastrointestinal Stromal Tumor (GIST). The LRG achieves this by providing an online community for patients and caregivers, supporting local in-person meetings, patient education through monthly newsletters and webcasts, one-on-one patient consultations, and most importantly, managing a major research project to find the cure for GIST.

Disclaimer

We are patients and caregivers, not doctors. Information shared is not a substitute for discussion with your doctor. For the very latest information, see the LRG Clinical Trials database at: http://liferaftgroup.org/treat_trials.html.

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harbor SDH mutations. Both these new targets are being addressed in later phase clinical trials for IGF-1R inhibitors and drugs that augment the mitochondrial respiration function lost when SDH is mutated. These trials could be options if mutation status is known and these tests have been included.

Genotyping for patients on longer term imatinib therapy

Patients who are longer term responders to imatinib can also benefit from mutation testing. Researchers attribute 80 percent and more of the resistance in GIST to the emergence of resistant mutations. This is clearly the case in patients with KIT exon 11 primary mutations. The effect of imatinib is to suppress typically responsive exon 11 mutations. Researchers believe that resistant mutation cells are present from the beginning of GIST. As the dominant primary exon 11 mutants are suppressed these other mutations emerge and are now better able to compete for cell growth resources in the established or new tumor beds.

It has also been shown that GIST can develop more than one secondary mutation and that even a single tumor may have multiple mutations. Secondary mutations seem to be additive. The primary mutation is still there. The secondary mutations show up as a tumor within a tumor or as new growth or as a "rogue" tumor that grows when others are stable. Highly sensitive genetic analyses have shown the presence of multiple mutations in the typical imatinib/sunitinib resistant GIST. Knowing the primary mutation (exon 11) is helpful in anticipating the pattern of resistance. However, because of the likelihood of multiple secondary mutantions resistance genotype is of limited use in the clinic.

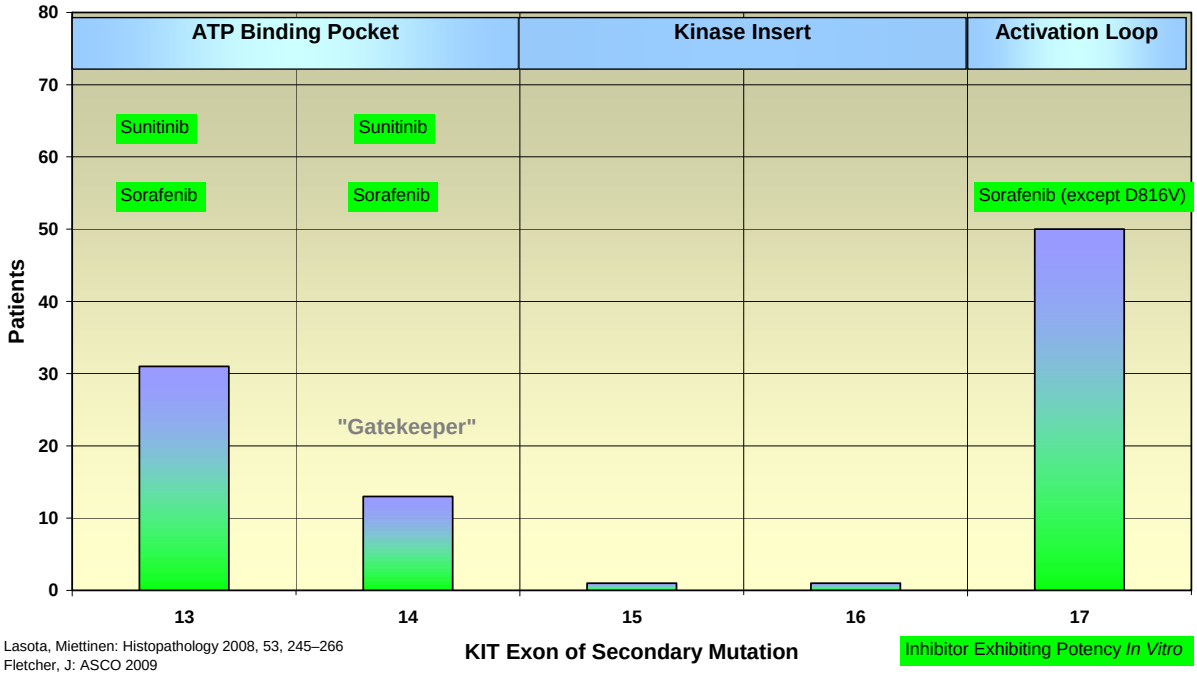
Broad spectrum drugs like sunitinib, sorafenib and dasatinib have been shown to be effective against different sets of secondary mutations. No one drug covers them all, and each drug has its own set of side effects. Currently sorafenib appears to have the broadest spectrum of potency across a wide range of secondary mutations. Secondary resistance may also be managed in clinical trials of drugs that target downstream signal points or that target irrespective of mutation status (HSP90 and HDAC inhibitors) (See figure below).

This topic will be addressed more fully in a series of Clinical Trial Bulletin articles starting this month with an overview of mutation status and clinical trial options.

Free mutational testing is available via the GIST Collaborative Tissue Bank. The donation process is detailed on the LRG website at www.liferaftgroup.org/TissueBank.html. Patients can also contact the LRG at 973-837-9092 or liferaft@liferaftgroup.org to inquire about donating tissue for research and as part of the process obtaining a free GIST mutation analysis.

For patients seeking new options or just reassurance, mutation analysis via the GIST Collaborative Tissue Bank can serve another vital purpose. Tissue donations will be a contribution to the largest organized research effort to find a cure for GIST. In addition to obtaining mutation status, patients will be giving key GIST researchers access to data about the nature and progress of GIST before, during and after standard therapy. Patients and their medical teams can gain valuable information for managing GIST and also make a lasting contribution by donating to the GIST Collaborative Tissue Bank.

Frequency of GIST Secondary KIT Mutations by Exon and Protein Region - with Inhibitor Potency



Lasota, Miettinen: Histopathology 2008, 53, 245–266
Fletcher, J: ASCO 2009

Note: Trials are first grouped together by treatment phase. For example, the first grouping lists 2 trials that are open to patients in all treatment stages. Each trial description also lists the treatment stage under the "Stage" heading. Trials that are specifically for GIST are listed first. Trials are then sorted by phase in descending order) and then by drug name. Trial sites are sorted by country, state and then city.

Treatment Stage: All

Imatinib

Imatinib Mesylate in Treating Patients With Liver Metastasis From a Gastrointestinal Stromal Tumor

Phase: 2
Stage: All
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: **NCT00764595**
Contact: See site contact info below

Niigata University Medical and Dental School
Niigata, Japan
81-25-227-2228
Tatsuo Kanda, MD

Surgery

Surgery in Treating Patients With Liver Metastasis From a Gastrointestinal Stromal Tumor

Phase: 2
Stage: All
Conditions: Gastrointestinal Stromal Tumor
Drug Type: Surgery
Strategy: Surgery
NCT #: **NCT00769782**
Contact: See site contact info below

Niigata University Medical and Dental School
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Treatment Stage: First-line

Imatinib + Bevacizumab

Imatinib Mesylate With or Without Bevacizumab in Treating Patients With Metastatic or Unresectable Gastrointestinal Stromal Tumor

Phase: 3
Stage: First-line
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor+ VEGF inhibitor (antibody)
Strategy: Block KIT
Block tumor blood vessel growth
NCT #: **NCT00324987**
Contact: See each trial site.

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Masitinib, (AB1010)

Efficacy and Safety of Masitinib (AB1010) in Comparison to Imatinib in Patients With Gastro-Intestinal Stromal Tumour

Phase: 3
Stage: First-line
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: **NCT00812240**
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Nilotinib or Imatinib

Phase III, Open-Label Study of Nilotinib Versus Imatinib in GIST Patients

Phase: 3
Stage: First-line
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00785785
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Dasatinib (BMS-354825)

Dasatinib as First-Line Therapy in Treating Patients With Gastrointestinal Stromal Tumors

Phase: 2
Stage: First-line
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor + SRC inhibitor
Strategy: Block KIT + Block KIT Signal Path
NCT #: **NCT00568750**
Contact: See site contact info below

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Nilotinib

Treatment of Patients With Metastatic or Unresectable Gastrointestinal Stromal Tumors in First Line With Nilotinib. (OPEN)

Phase: 2
Stage: First-line
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: **NCT00756509**
Contact: Novartis Basel
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Treatment Stage: Gleevec-resistant

Sunitinib

Safety And Efficacy Study Of Sunitinib Malate In Chinese Patients With Imatinib Resistant Or Intolerant Malignant

Phase: 4
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: **NCT00793871**
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Sunitinib or Imatinib

Safety And Effectiveness Of Daily Dosing With Sunitinib Or Imatinib In Patients With Gastrointestinal Stromal Tumors (Resistant at 400 mg

Phase: 3
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00372567
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BIIB021 (CNF2024)

An Open-Label, 18FDG-PET Pharmacodynamic Assessment of the Effect of BIIB021 in Subjects With Gastrointestinal Stromal Tumors

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00618319
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Nilotinib

Nilotinib in Advanced GIST

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00782834
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Margeret von Mehren, M.D.

Nilotinib

Phase II Study Aiming to Evaluate the Efficacy and Safety of Nilotinib Patients With Gastrointestinal Stromal Tumors (GIST) Resistant or

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00633295
Contact: Novartis Basel
41 61 324 1111

Site name unknown, Tel Aviv
Tel Aviv, Israel

Site name unknown, Tel Hashomer
Tel Hashomer, Israel

Sorafenib (Nexavar, BAY 43-9006)

Sorafenib in Treating Patients With Malignant Gastrointestinal Stromal Tumor That Progressed During or After Previous Treatment With

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor+ VEGF inhibitor (TKI) + RAF inhibitor
Strategy: Block KIT + Block KIT Signal Path
NCT #: NCT00265798
Contact: Clinical Trials Office - University of Chicago Cancer Research
773-834-7424

University of Chicago
Chicago, IL USA
Clinical Trials Office, 773 -834-7424
Hedy Kindler, MD

Imatinib + Sunitinib

Imatinib Mesylate and Sunitinib in Treating Patients With Gastrointestinal Stromal Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00573404
Contact:

Vanderbilt-Ingram Cancer Center-Cool Springs
Franklin, TN USA
615 343-4128
Jordan Berlin

Vanderbilt-Ingram Cancer Center at Franklin
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800 811-8480
Clinical Trials Office

Study to the Optimal Duration of Therapy With Oral Angiogenesis Inhibitors

Phase: 4
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: VEGFR inhibitor (TKI)
Strategy: Block tumor blood vessel growth
NCT #: NCT00777504
Contact: See site contact info below

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C.M.L van Herpen, Md, Phd

Dasatinib (BMS-354825)

Trial of Dasatinib in Advanced Sarcomas

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor + SRC inhibitor
Strategy: Block KIT + Block KIT Signal Path
NCT #: NCT00464620
Contact: Kathleen Granlund
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Everolimus

Treatment of Patients With RAD001 Who Have Progressive Sarcoma

Phase:	2
Stage:	Gleevec-resistant
Conditions:	Sarcoma
Drug Type:	mTOR inhibitor
Strategy:	Block KIT Signal Path
NCT #:	**NCT00767819**
Contact:	Novartis Pharmaceuticals +1 800-340-6843

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Berlin, Germany

Site name unknown, Dusseldorf
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Site name unknown, Munchen
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Site name unknown, Milan
Milan, Italy

Doxorubicin + Flavopiridol

Doxorubicin and Flavopiridol in Treating Patients With Metastatic or Recurrent Sarcoma That Cannot Be Removed By Surgery

Phase: 1
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Sarcoma
Drug Type: Transcription inhibitor + Chemotherapy
Strategy: Freeze the cell division cycle
NCT #: NCT00098579
Contact: See site contact info below

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David D'Adamo, MD, PhD,

Imatinib + IL-2

Imatinib + IL-2

Phase: 1
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT inhibitor + Immune stimulate
Strategy: Block KIT + Stimulate the immune system
NCT #:
Contact: See site contact info below

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Multi-bacteria vaccine (MBV)

A Phase 1 Study of Mixed Bacteria Vaccine (MBV) in Patients With Tumors Expressing NY-ESO-1 Antigen.

Phase: 1
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: Immune stimulate
Strategy: Stimulate the immune system
NCT #: NCT00623831
Contact: See site contact info below

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069 7601 4161
Elke Jaeger, MD

SF1126

A Phase I Open Label, Safety, Pharmacokinetic and Pharmacodynamic Dose Escalation Study in SF1126, a PI Kinase (PI3K)

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00907205
Contact: See site contact info below

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AUY922

Phase I-II Study to Determine the Maximum Tolerated Dose (MTD) of AUY922 in Advanced Solid Malignancies, and Efficacy in HER2

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00526045
Contact: Novartis Pharmaceuticals
1 800 340-6843

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mmita@idd.org
Monica Mita, M.D.

BGT226

A Phase I/II Study of BGT226 in Adult Patients With Advanced Solid Malignancies Including Patients With Advanced Breast Cancer

Phase:	1
Stage:	Gleevec-resistant
Conditions:	Solid Tumors
Drug Type:	mTOR inhibitor PI3K inhibitor
Strategy:	Block KIT Signal Path
NCT #:	**NCT00600275**
Contact:	Novartis 800 340-6843

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MP470

Safety Study to Determine the Maximum Tolerated Dose, Pharmacokinetics and Pharmacodynamics of Oral MP470,

Phase:	1
Stage:	Gleevec-resistant
Conditions:	Solid Tumors
Drug Type:	KIT/PDGFRA inhibitor
Strategy:	Block KIT
NCT #:	**NCT00894894**
Contact:	SuperGen Gil Fine, PhD 925-560-0100 gfine@supergen.com Angelique Mittan, CLS 925-560-0100

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Anthony Tolcher, MD

SNX-5422

SNX-5422 in Treating Patients With Solid Tumor or Lymphoma That Has Not Responded to Treatment

Phase:	1
Stage:	Gleevec-resistant
Conditions:	Solid Tumors
Drug Type:	HSP90 inhibitor
Strategy:	Destroy KIT
NCT #:	**NCT00644072**
Contact:	

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888-NCI-1937
Giuseppe Giaccone, MD, PhD

Vorinostat + Bortezomib

Vorinostat and Bortezomib in Treating Patients With Metastatic or Unresectable Solid Tumors

Phase:	1
Stage:	Gleevec-resistant
Conditions:	Solid Tumors
Drug Type:	HDAC inhibitor + Proteasome inhibitor
Strategy:	Inhibit protein translation + Unblock cell death genes
NCT #:	**NCT00227513**
Contact:	

Carbone Cancer Center, University of Wisconsin
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George Wilding, MD

AMG 479 + AMG 655

AMG 655 in Combination With AMG 479 in Advanced, Refractory Solid Tumors

Phase: 2
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor + DR5 Inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00819169
Contact: Amgen Call Center
866-572-6436

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Hedy Kindler, MD

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Site name unknown, Detroit
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AT13387

Phase 1 Study of HSP90 inhibitor AT13387 in solid tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00878423
Contact: Andrew Wolanski
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Geoffrey Shapiro, MD, PhD

BAY 73-4506

Phase I study of BAY 73-4506

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: KIT/PDGFRA inhibitor
VEGFR inhibitor (TKI)
Strategy: Block KIT
NCT #:
Contact: See site contact info below

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BEZ235

A Phase I/II Study of BEZ235 in Patients With Advanced Solid Malignancies Enriched by Patients With Advanced Breast Cancer

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: mTOR inhibitor
PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00620594
Contact: Novartis
862-778-8300

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hburris@tnonc.com
Howard A. Burris, III MD

BIIB021 (CNF2024)

Once or Twice Daily Administration of BIIB021 to Subjects With Advanced Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00618735
Contact: Biogen Idec
oncologyclinicaltrials@biogenidec.com

Premier Oncology, Santa Monica
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South Texas Accelerated Research Therapeutics (START)
San Antonio, TX USA

BIIB022

Phase 1 Study of BIIB022 (Anti-IGF -1R Monoclonal Antibody) in Relapsed/Refractory Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00555724
Contact: Biogen Idec oncologyclinicaltrials@biogenidec.com

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BKM120

A Phase IA, Multi-Center, Open-Label, Dose- Escalation Study of BKM120, Administered Orally on a Continuous Daily Dosing Schedule

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #:
Contact: See site contact info below

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BMS-754807

Multiple Dose Study In Cancer Patients: Safety and Tolerability of BMS-754807 in Advanced or Metastatic Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00569036
Contact: For site information outside the USA please email: Clinical.Trials@bms.com
First line of email MUST contain NCT# & Site#.

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Site # 003

Site name unknown, Footscray, Australia
Footscray, Victoria Australia
Site # 004

Site name unknown, Heidelberg Australia
Heidelberg, Victoria Australia
Site # 002

Site name unknown, Parkville, Australia
Parkville, Victoria Australia
Site #001

GDC-0941

A Study of GDC-0941 in Patients With Locally Advanced or Metastatic Solid Tumors for Which Standard Therapy Either Does Not Exist or

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00876109
Contact: See site contact info below

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GDC-0941

A Study of GDC-0941 in Patients With Locally Advanced or Metastatic Solid Tumors or Non-Hodgkin's Lymphoma for Which Standard

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00876122
Contact: See site contact info below

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IMC-A12 + CCI-779

Cixutumumab and Temsirolimus in Treating Young Patients With Solid Tumors That Have Recurred or Not Responded to Treatment

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor + mTOR Inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00880282
Contact:

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IMC-A12 + CCI-779

IMC-A12 in Combination With Temsirolimus (CCI-779) in Patients With Advanced Cancers

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor + mTOR Inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00678769
Contact: Aung Naing, MD
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713-563-0181
Aung Naing, MD

IMC-A12 + CCI-779

Monoclonal Antibody IMC-A12 and Temsirolimus in Treating Patients With Locally Advanced or Metastatic Cancer

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor + mTOR Inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00678223
Contact:

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Aung Naing, MD

IPI-493

A Phase I Dose Escation Study of IPI -493

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00724425
Contact: See site contact info below

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KW2450

Safety Study to Evaluate KW-2450 in Subjects With Advanced Solid Tumor

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00921336
Contact: Danyel Davis
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MEDI-573

A Dose-Escalation Study to Evaluate the Safety, Tolerability, and Antitumor Activity of MEDI-573 in Subjects With Advanced Solid

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00816361
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OSI-906

Phase 1 Study of Continuous OSI -906 Dosing

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00514007
Contact: OSIP Medical Information
800.572.1932, x7821
medical-information@osip.com

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Glasgow, UK

Vanderbilt-Ingram Cancer Center
Nashville, TN USA

OSI-906

Phase 1 Study of Intermittent OSI -906 Dosing

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00514306
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PX-478

Phase I Trial of PX-478

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HIF-1α inhibitor
Strategy: Block related tumor signal paths
Block tumor blood vessel
NCT #: NCT00522652
Contact: See site contact info below

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PX-866

Phase I Trial of Oral PX-866

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00726583
Contact: See site contact info below

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R1507

A Multiple Ascending Dose Study of R1507 in Children and Adolescents With Advanced Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00560144
Contact: Hoffmann-La Roche
Please reference Study ID Number: NO21200
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800-526-6367 (US only)

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SNX-5422

Safety and Pharmacology of SNX -5422 Mesylate in Subjects With Refractory Solid Tumor Malignancies

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00506805
Contact: Pfizer Oncology Clinical Trial Information
1-877-369-9753
PfizerCancerTrials@emergingmed.com
Pfizer CT.gov Call Center
1-800-718-1021

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Daniel D. Von Hoff, MD

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Jessica Gilbert
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SNX-5422

Safety Study Of SNX-5422 To Treat Solid Tumor Cancers And Lymphomas

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00647764
Contact: Pfizer Oncology Clinical Trial Information Service
1-877-369-9753
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1-800-718-1021

Site name unknown, Bethesda 20982
Bethesda, MD USA

Sorafenib + Vorinostat

Phase I Vorinostat + Sorafenib in Patients With Advanced Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HDAC inhibitor + KIT/PDGFRA inhibitor
Strategy: Block KIT + Unblock cell death genes + Destroy KIT
NCT #: NCT00635791
Contact: See site contact info below

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David Ross Camidge MD

STA-9090

Study of STA-9090, Administered Once-Weekly in Patients With Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00687934
Contact: See site contact info below

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Robert Raju, MD

STA-9090

Study of STA-9090, Administered Twice-Weekly in Patients With Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00688116
Contact: See site contact info below

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Sunitinib + CP-751,871

Phase 1 Study of CP-751,871 in Combination With Sunitinib in Patients With Advanced Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: KIT/PDGFRA inhibitor + IGF1R inhibitor
Strategy: Block KIT + Block related tumor signal paths
NCT #: NCT00729833
Contact: EmergingMed
(877) 369-9753
PfizerCancerTrials@emergingmed.com
Pfizer CT.gov Call Center
1-800-718-1021

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310 633-8400
Lee Rosen

South Texas Accelerated Research Therapeutics (START)
San Antonio, TX USA

XL147

Study of the Safety and Pharmacokinetics of XL147 in Adults With Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00486135
Contact: Exelixis Contact Line
866-939-4041

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XL228

Study of XL228 Administered Intravenously to Subjects With Advanced Malignancies

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: IGF1R inhibitor
Strategy: Block related tumor signal paths
NCT #: NCT00526838
Contact: Exelixis Contact Line
1-866-939-4041

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David Smith, MD

Duke University
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Sharon Norman
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Herb Horowttz, MD

XL765

Study of the Safety and Pharmacokinetics of XL765 in Adults With Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: mTOR inhibitor
PI3K inhibitor
Strategy: Block related tumor signal paths
NCT #: **NCT00485719**
Contact: Exelixis Contact Line
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Treatment Stage: Palliative

Radiation

Radiation Therapy as Palliative Treatment of GIST (GIST-RT)

Phase: 1
Stage: Palliative
Conditions: Gastrointestinal Stromal Tumor
Drug Type: None
Strategy: Radiation
NCT #: **NCT00515931**
Contact: See site contact info below

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Heikki Joensuu, MD

Sunitinib + Radiation

Sutent and Radiation as Treatment for Limited Extent Metastatic Cancer

Phase: 2
Stage: Palliative
Conditions: Any type of Cancer
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: **NCT00463060**
Contact: See site contact info below

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Johnny Kao, MD

Treatment Stage: Stable Disease

Imatinib

A phase III randomized study evaluating surgery of residual disease in patients with metastatic gastro-intestinal stromal tumor

Phase: 3
Stage: Stable Disease
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #:
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