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

September 2009 Clinical Trials Update

By Jim Hughes
LRG Clinical Trials Coordinator

USA and International:

1. **Phase 3 Nilotinib Versus Imatinib (NCT00785785):** This trial has 43 sites now recruiting. These include 15 sites in eight states in the US and 28 international sites in Austria, Canada, France, Japan, The Netherlands, Spain and Thailand.
2. **Phase 3 Nilotinib plus Imatinib (NCT00751036):** This trial is now re-

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Clinical Trial update for advanced resistant GIST

By Jim Hughes
LRG Clinical Trials Coordinator

There are several types of trials available for GIST patients including: treatment, adjuvant, observational, registry, continuation and post-marketing. This issue, we focus on the options for therapeutic treatment trials that are specifically for advanced resistant GIST.

Historically there has been one phase 3 or registration trial for advanced and resistant GIST every three years since Gleevec (imatinib) in 2001:

- **2000-2001/Gleevec**- Approved for GIST on February 1, 2002. Registration trial was phase 2
- **2004/Sutent**- Approved for GIST on January 26, 2006
- **2007/Tasigna**- Phase 3 trial has stopped recruiting but is still collecting data. Tasigna is still not approved for GIST

In April 2009, a phase 3 registration trial of IPI-504 for resistant GIST was terminated following a higher than anticipated mortality rate among patients enrolled in the treatment arm.

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It's time to consider mutational status for resistant GIST patients

By Jerry Call
LRG Science Coordinator

This is the first article in a series discussing mutational status Aand resistant GIST. In this issue, we will begin with a brief overview and wild-type GIST.

In the not too distant future, we may have newer KIT inhibitors that overcome most types of GIST resistance. But for the present, it is becoming increasingly clear that GIST can be divided into four main types based on mutational status; KIT exon 11, KIT exon 9, PDGFRA D842V and wild-type GIST. In addition, there is another group comprising the "rare" mutations (KIT exons 13 & 17, etc). The different types have different initial responses to Gleevec and resistance occurs via somewhat different mechanisms. GIST patients and doctors can use this knowledge to their advantage in choosing a clinical trial or, in some cases, to consider off-label treatment options.

Clinical Trials

The GIST clinical trial era began in earnest in 2000 with the first Gleevec trials. For almost ten years now, almost all GIST trials have been inclusive trials allowing most or all of the various sub-types of GIST. Today, some clinical trials have broad inclusion criteria designed to "cast a wide patient net". The intention has been if a diverse population of patients is exposed to a drug, that in addition to a group that is expected to respond, unexpected benefit might be seen in a population that was not predicted. While this approach has the potential to find unexpected benefit, it also has a downside, especially in registration trials. The downside is that the trial may not show enough overall benefit to be considered successful.

Conversely, a trial can be designed with more rigid criteria in an attempt to "enrich" the patient population. The goal would be to enroll only patients that are predicted to respond. An example of this is a new trial being planned by the National

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Save the Date! Life Fest 2010 will be held at the Hyatt Regency Jersey City on the Hudson June 25-27.

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Institutes of Health (NIH). This trial will test a new class of drug called an IGF-1R inhibitor. The trial will only be for wild-type GIST patients (patients whose tumors have no mutation in the KIT or PDGFRA genes). While details are lacking, we expect this trial to allow both pediatric (under 18) and adult patients who have wild-type GIST. Preliminary information leads us to believe this trial will be for R1507, an IGF -1R inhibitor made by Roche.

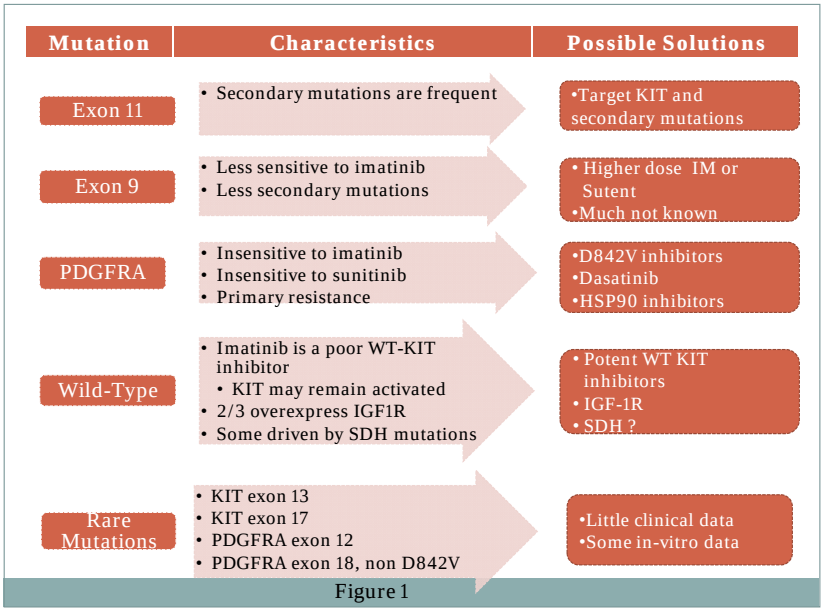
The reason that the NIH is planning to limit the R1507 trial to patients with wild-type GIST is that the biology of wild-type is distinct from other types of GIST, and R1507 targets one of the differences. Several different research groups (Dr. Antonescu's lab at Memorial Sloan-Kettering Institute, Dr. Godwin's lab at Fox Chase Cancer Center, Dr. Corless' lab at Oregon Health & Science University (OHSU)) have shown that IGF-1R is over-expressed in wild-type GIST. Most recently, Dr. Christopher Corless and colleagues at OHSU have shown that IGF-1R is over-expressed in two-thirds of patients with wild-type GIST. While IGR1R may be less important for other types of GIST, this is still under investigation.

The new IGF-1R inhibitor trial by the NIH is the most obvious example of a GIST trial where mutational status would be used to decide which patient might benefit the most from the trial. In fact, checking mutational status will be mandatory to ensure that the patients enrolled have wild-type GIST. Specifically targeted trials have a better chance of both answering the scientific question and benefiting the targeted patient population.

The time has also come when patients with other mutational types might also have more potential to benefit from one type of trial compared to another type. Certain trials/sponsors might also stand to benefit from more selective trials.

GIST can be broken down in many ways including by primary mutational status. When considering primary mutational status, GIST can be divided into four main types:

- KIT exon 11 mutations
- KIT exon 9 mutations



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cruiting. One site is now open in Colombia, South America.

3. **Phase 3 Adjuvant Gleevec (NCT00867113):** This trial is now recruiting and is open at seven sites.

4. **Phase 3 Sunitinib or imatinib (NCT00372567):** This trial changed status from 'Open' to 'Terminated'. According to a Pfizer contact, the decision to terminate was due to the low rate of enrollment particularly in the US. Clinicians have apparently preferred to increase imatinib dosage rather than enroll patients in this randomized open-label study of 800 mg imatinib versus daily 37.5 mg sunitinib.

Pfizer assured us that patients who received sunitinib and benefitted will continue to have access to the drug. Plans for publishing results are up in the air until the trial data is collected and reviewed by trial investigators.

An independent investigation of genotype coupled with this trial had received no tumor samples to analyze.

5. **Phase 1 BIIB028 (NCT 00725933):** Dr. Jonathan Trent at MD Anderson (MDA) sent out a notice regarding a phase 1 trial in advanced solid tumors of HSP90 inhibitor BIIB028 that will accept GIST patients. The Principal Investigator at MDA is Dr. David Hong, 713-563-5844, dshong@mdanderson.org. Prior treatment with HSP90 inhibitors is excluded. BIIB028 is administered by IV twice weekly. Trial sites are open at MDA in Houston and at Los Angeles and Encinitas CA. The overall trial contact is via the Manufacturer, Biogen Idec at: oncologyclinicaltrials@biogenidec.com

You can find the details on all these trials and others in the LRG GIST Clinical Trial Database at: http://www.liferaftgroup.org/treat_trials.html. Use the pre-defined search links or click the "Search Trials" button at the top of the Clinical Trials frame.

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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•Wild-type GIST
•PDGFRA D842V mutations

In addition to the four main types, there are a number of rare mutations (less than 1% each) that can be lumped into another group for which there is little clinical data. In this group, in-vitro data can give some guidance. This group includes KIT exon 13, KIT exon 17, PDGFRA exons 12 and 13 and PDGFRA exon 18 mutations other than the D842V mutation.

At its most basic, matching a mutation type to a clinical trial requires knowing both the primary mutation status and potential effectiveness of the trial drugs against that mutation. Evidence of effectiveness typically comes from lab experiments although in some cases it can come from earlier clinical trials. Although lab evidence can suggest that one strategy might be more appropriate than another strategy, ultimately effectiveness must be proven in a clinical trial. There are many examples of drugs that appeared to work in the lab and failed in clinical trials (including examples in trials with GIST patients).

See Figure 1 for an overview of mutational types and possible strategies.

Table 1: Wild-type GIST

Without SDH mutations Two treatment options		WITH SDH mutations Could pursue a SDH directed path OR A WT-GIST path
Potent wild-type KIT inhibitors	**IGF-1R inhibitors**	**SDH directed therapies**
•Sutent[1] •Tasigna[2] •No secondary mutations •Little need for a "wide spectrum" KIT inhibitor	•Many drugs in trials •Affects 2/3 of WT-GIST •No GIST specific trials •Planned NIH trial •Phase I trials for solid tumors	•HIF1α inhibitors[3] •Derivatives of a ketoglutarate •Dichloroacetate (DCA)
One phase I trial combines both: potent WT-KIT inhibitor (Sutent) + IGF-1R inhibitor (CP-751,871)		

1.Approved for GIST,
2.Approved for CML, in trials for GIST
3.HIF1α inhibitors may be a more advanced concept than the other two SDH directed strategies. All of the SDH directed therapies probably have less evidentiary support than the therapies for wild-type GIST without SDH mutations.

Wild-type GIST

The case that mutational testing can be useful for clinical trial decision-making is most apparent when looking at PDGFRA D842V mutations and wild-type GIST. These two groups are quite different from the KIT exon 11 and exon 9 groups, both in their initial response to drugs and in resistance. In this month's issue of the LRG Clinical Trials Bulletin, we will discuss a rationale for decision-making for wild-type GIST. In upcoming editions of the Bulletin, we will discuss other mutational types.

Even though the KIT gene is not mutated in wild-type GIST, Dr. Katherine Janeway of Dana-Farber has shown that the KIT protein is still activated in wild-type, specifically in patients with the pediatric form of wild-type. In support of the importance of KIT signaling, we also know that some patients with wild-type have responded to

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The options available today do not include any phase 3 or registration trials in GIST. As in much of the past, there is presently a mix of phase 1 and 2 trials of potential therapies and varying strategies.

United States

Sorafenib Phase 2: This trial, sponsored by the University of Chicago under Dr. Hedy Kindler, has been running for four years and is very near the accrual goal. Currently this trial is open in Chicago. However, several sites outside Chicago have recruited patients in the past. Interim results were reported at the 2008 American Society of Clinical Oncologists conference (ASCO). Out of 24 patients, three had partial response and 14 had stable disease as best response for a total 71 percent benefit rate. Because sorafenib controls a broad range of resistant GIST mutations there have been recent calls to evaluate sorafenib as second-line therapy in place of sunitinib. This phase 2 trial would be a good option for exon 11 patients failing both imatinib and sunitinib, but it will close shortly.

Nilotinib Phase 2: This trial is only at Fox Chase Cancer Center. It was initiated to provide an option to access Nilotinib after closure of the phase 3 registration trial. It requires a weekly visit for the first month then every four weeks afterwards.

Results from this trial and the phase 3 trial have yet to be reported. However, at ASCO 2008 there was a report on the patients in the nilotinib compassionate access program. These patients could not participate in the phase 3 trial and were resistant to both imatinib and sunitinib. Of the 42 patients evaluable, four achieved partial response and 15 had stable disease for a total 45 percent benefit rate.

Nilotinib probably has a lower level of side-effects compared to imatinib, sunitinib and sorafenib. For patients intolerant of standard therapies, nilotinib may be an alternative to moving directly to sorafenib. Nilotinib is also reported to have excellent activity against wild-type KIT. This trial would provide access for those unable to obtain nilotinib off-label. However, it re-

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quires frequent visits to the trial site.

BIIB021 Phase 2: This drug is also called CNF-2024. The phase 2 trial for GIST is currently at Memorial Sloan-Kettering Cancer Center and in Rochester, Minnesota. CNF2024 is also in phase 1 for solid tumors in Arizona and California. BIIB021 is a third generation oral HSP90 inhibitor. Data from phase 1 trials indicates some short term efficacy in solid tumors. The tolerability of oral HSP90 inhibitors may be a concern; we also have anecdotal reports of moderate to severe intestinal distress in a GIST patient on BIIB021. This trial would be appropriate for patients failing standard treatment and also sorafenib. A detailed discussion concerning side-effects would be advised.

Imatinib + Sunitinib Phase 1: This trial is ongoing at Vanderbilt Ingram Cancer Center in Nashville and Franklin, Tennessee. The trial objective is to determine the maximum tolerated dose (MTD) of both drugs in combination. "If the combination of full doses of both drugs is well tolerated, no further dose escalation will be performed. The MTD of the combination can then be used in a phase II study to explore its efficacy in patients with imatinib-refractory GIST." Although both drugs are FDA approved for GIST the combination of the two is considered investigational. The combined toxicity profile is unknown.

There have been no clinical reports on this trial or on the combined use of imatinib and sunitinib in the lab. There have been anecdotal reports of a patient who has benefited at less than the full dose of each drug. While combination trials are scarce and their need is clear this trial is not an obvious fit for any one patient category. Imatinib and sunitinib together cover a broad range of mutations, and there is also the theory that even during progression imatinib is still controlling some tumor growth. Therefore, adding rather than replacing inhibitors makes some sense. However, there are still some holes particularly in the frequent and problematic exon 17 area. Neither of these drugs blocks exon 17 mutations well in the lab. This trial also requires frequent site visits in the early stages.

Note: There are three trials that target a range of cancers and also specify GIST. These are not as focused on GIST; however, they do tend to be at cancer centers and under investigators with experience in GIST. Two of these are notable.

Dasatinib Phase 2: This trial has been ongoing for sarcoma and was opened up last year for GIST patients. Lab tests have shown Dasatinib effectively inhibits the PDGFRA D842V mutation. The D842V mutation is resistant to both imatinib and sunitinib in the lab. Nilotinib and sorafenib are also not as effective as dasatinib

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KIT inhibitors such as Gleevec and Sutent.

As noted previously, IGF-1R signaling may be important in wild-type and pediatric GIST. In addition, Dr. P. Aidan Carney (retired) of the Mayo Clinic and Dr. Constantine Stratakis, Dr. Su Young Kim and Dr. Lee Helman from the NIH, have shown that a subset of wild-type GISTs have mutations in one of four genes that form the SDH complex.

So the first step for wild-type patients might be to do additional testing for mutations in the SDH genes. This testing can be done by the NIH (contact Dr. Su Young Kim for details).

With complete mutational testing that includes testing for SDH mutations, wild-type GIST can be sub-divided into two main mutation types and three main treatment categories as shown in Table 1.

Off-label treatment

In addition to clinical trials, some GIST patients may have the opportunity for off-label treatment. Table 2 shows the potency of KIT inhibitors against wild-type KIT. While these drugs are all approved, only Sutent and Gleevec are currently approved for GIST. The other drugs listed are all in clinical trials for GIST.

As can be seen from Table 2, Gleevec is not a very good inhibitor of wild-type GIST. In fact, Gleevec is about 10 times more potent at inhibiting KIT exon 11 mutations compared to wild-type KIT (data not shown here). For patients with wild-type GIST, Gleevec may not inhibit wild-type KIT strongly enough. This opens the possibility that these patients might respond better to a more potent wild-type KIT inhibitor.

Table 2: Potency of approved KIT inhibitors against wild-type KIT*

Drug	Generic	IC50	
Tasigna	Nilotinib	35 nmol/L	Most potent
Sutent	Sunitinib	245 nmol/L	
Sprycel	Dasatinib	316 nmol/L	
Nexavar	Sorafenib	910 nmol/L	
Gleevec	Imatinib	3,132 nmol/L	Least potent

*Antonescu et. al, Clin Cancer Res 2008;14(10)May 15, 2008

NOTE: This table is based on in vitro data (lab experiments). This information should be considered to be preliminary. Response of patients to treatment may vary from this table. IC50 is the concentration of drug required to inhibit cell proliferation by 50%. A higher number indicates more drug was required to inhibit cell proliferation.

Important points to remember about wild-type GIST:

- Resistance is not driven by secondary mutations
- KIT signaling still appears to be important
- The relative potency of a drug against wild-type KIT appears to be more important than the drugs ability to inhibit many different secondary mutations
- IGF-1R signaling may be important. IGF-1R is over-expressed in 2/3 of wild-type GIST and represents a new therapeutic target.
- Little is known about the best way to treat GISTs in patients with SDH mutations. One possibility may be to target SDH mechanisms rather than KIT, however this remains speculative.

As demonstrated by wild-type GIST, knowing the GIST mutation type offers new opportunities for more tailored targeted therapies. Next issue we will discuss the importance of other mutation types in the selection of therapy options.

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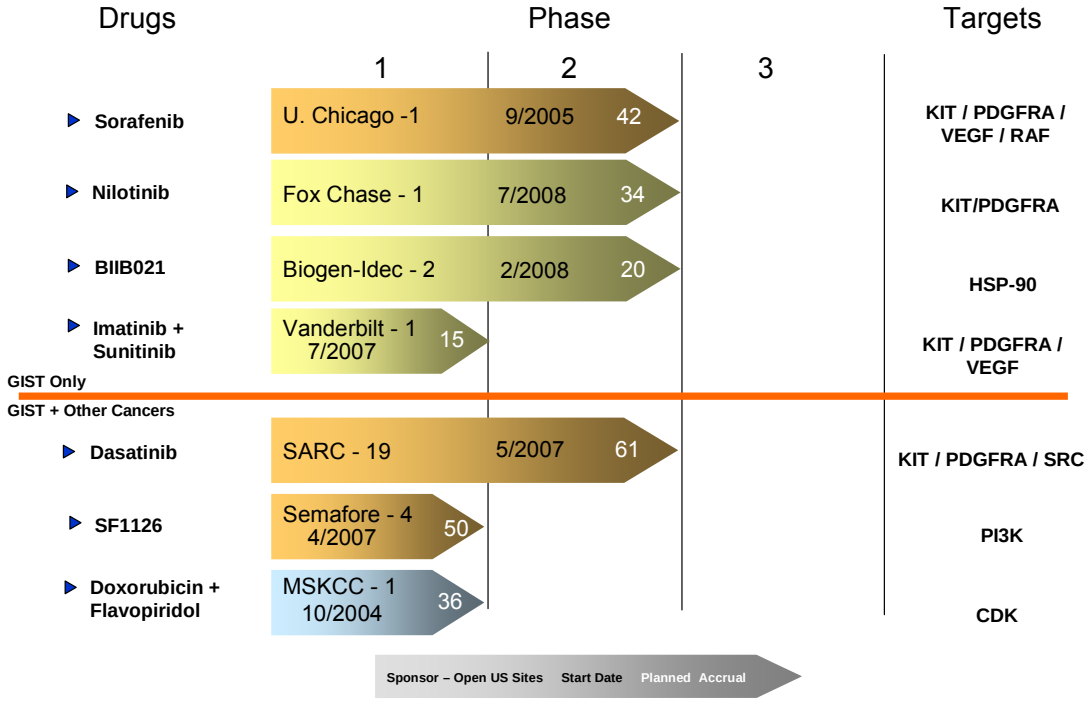
Figure 1: US Options for Resistant GIST



against D842V. Patients with this mutation may want to consider this trial and possibly an HSP90 trial. The benefit of dasatinib for other secondary mutation types is not as clear. Like sunitinib, dasatinib inhibits a subset of the most frequent secondary mutations.

SF1126 Phase 1: SF1126 is a novel drug in GIST. It targets the PI3K protein which is in the downstream signal path of the KIT and PDGFRA oncoproteins. Therefore, primary and secondary KIT/PDGFRA mutation status may be less important. Early results reported at ASCO 2009 indicated stability in three GIST patients. SF1126 inhibits a broad range of PI3K/P110 isoforms, but it does not inhibit KIT or PDGFRA, although future trials may include combinations with KIT/PDGFRA inhibitors. This will be an interesting strategy to watch develop. This trial would be suitable for patients who have failed both imatinib and sunitinib and requires twice weekly site visits for intravenous (IV) infusions. Sites are open in Indianapolis, Atlanta, Scottsdale and Tucson.

Doxorubicin + Flavopiridol Phase 1: This trial has been ongoing since 2004. As of late last year, it had not accrued any GIST patients. Flavopridol inhibits Cyclin-dependent kinase (CDK) which regulates the cell cycle. It also inhibits transcription of KIT. In the lab, Flavopridol has been shown to cause GIST cell death. However, this trial also includes a chemotherapy agent (Doxorubicin) which has not been shown to be effective in GIST as a single agent. Both drugs are administered by IV and the trial requires site visits every three weeks.

International

The options for advanced GIST patients experiencing resistance are even more limited on an international basis. GIST specific trials are few and sites are widespread.

Imatinib versus Nilotinib Phase 3: This trial is just getting underway in Latin America with the first site opening in Colombia, but additional sites are planned in Southeast Asia and Russia. Patients who are failing 400 mg imatinib are eligible. Patients who have used more than 400 mg of imatinib or other tyrosine kinase inhibitors are excluded. This trial is suitable for most patients who experience resistance at 400 mg of imatinib.

Sunitinib Phase 4: This trial in China is testing safety and efficacy in imatinib resistant patients. Patients who may be unable to access nilotinib under the current health authority may do so in this trial at three locations in Beijing and one in Nanjing.

Nilotinib Phase 2: This trial in Israel is testing the safety and efficacy of nilotinib in imatinib and sunitinib resistant patients. Patients who may be unable to access nilotinib under the current health authority may do so in this trial at sites in Tel Aviv and Tel Hashomer.

Oral Angiogenesis Inhibitor Phase 4: This trial is looking at the effect of antiangiogenesis therapy on tumor size and or growth. It has sometimes been observed that tumors appear to grow on antiangiogenic drugs as a result of necrosis and edema caused by the positive effects of therapy. The inherent risk is that patients are being removed from treatment because of growth that is really an artifact. This trial looks at tumor growth patterns over a period of four weeks both during and after stopping anti-angiogenic therapy. Sunitinib is antiangiogenic through inhibition of VEGF. Both GIST and Renal Cell Cancer patients are eligible. This trial might be appropriate for patients who are on sunitinib and who would benefit from the additional monitoring (MRI and PET scans) that are part of the protocol. This trial is only open in Nijmegen, Netherlands

Everolimus Phase 2: This trial at five sites in Germany is for patients failing both imatinib and sunitinib. Everolimus targets mTOR, a protein in the signal path downstream from KIT/PDGFRA. In theory, this drug is appropriate for any GIST mutation type. An Italian poster at ASCO 2009 indicated everolimus combined with imatinib or PKC412 produced response in patients with PDGFRA mutation D842V. It is not

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clear from the protocol of this trial if concurrent imatinib or sunitinib therapy is allowed with everolimus.

Imatinib + IL-2 Phase 1: This trial has been running since 2006. The goal at the outset was to enroll five GIST patients. The research behind this trial indicates that imatinib has an alternative mode of attacking GIST via the immune system. IL-2 is normally produced in the body during an immune response. Adding IL-2 to imatinib could enhance the immune response. This trial is appropriate for patients failing standard treatments. IL-2 is administered by IV during the second week of a three week cycle. This trial is currently open at Institute Gustave Roussy in Villejuif, France.

Multi-Bacteria Vaccine (MBV) Phase 1: In a 2008 paper in the International Journal of Cancer, researchers in Germany and Switzerland showed the association of high levels of NY-ESO-1 type antigens in GIST tumors with aggressive tumor behavior. NY-ESO-1 was expressed in 20 percent of the GISTs tested. MBV can take advantage of this marker and theoretically direct the body's immune system to attack tumor cells expressing NY-ESO-1. Patients who either progress or are intolerant on imatinib and sunitinib are eligible. Patient tumor samples must also test positive for NY-ESO-1. This trial would be suitable for all mutation types as long as tumors express NY-ESO-1. Patients receive MBV injections twice weekly as the dose is increased. When the trial vaccine dose level induces a fever of 39.5 degrees centigrade, patients receive a four week course at that dose level.

Future trial directions for Advanced GIST

We occasionally hear about clinical trial plans from well-placed sources who communicate unofficially. Here is the latest:

LBH589 Phase 1 & 2 for GIST: This trial is in the later planning stages in Europe. LBH589 is an HDAC inhibitor that can affect the transcription of the KIT gene. It can also act to inhibit HSP90. Trial plans include a phase 1 & 2 study combining imatinib and LBH589 for patients who have failed standard treatment. The trial is expected to come on-line by the end of this year.

AUY922 for GIST: Planning has started in the United States for a trial of AUY922. AUY922 is a very potent HSP90 inhibitor. A combination trial with imatinib is being considered; if a combination, this trial will probably start as a phase 1 in order to address dosage and safety issues.

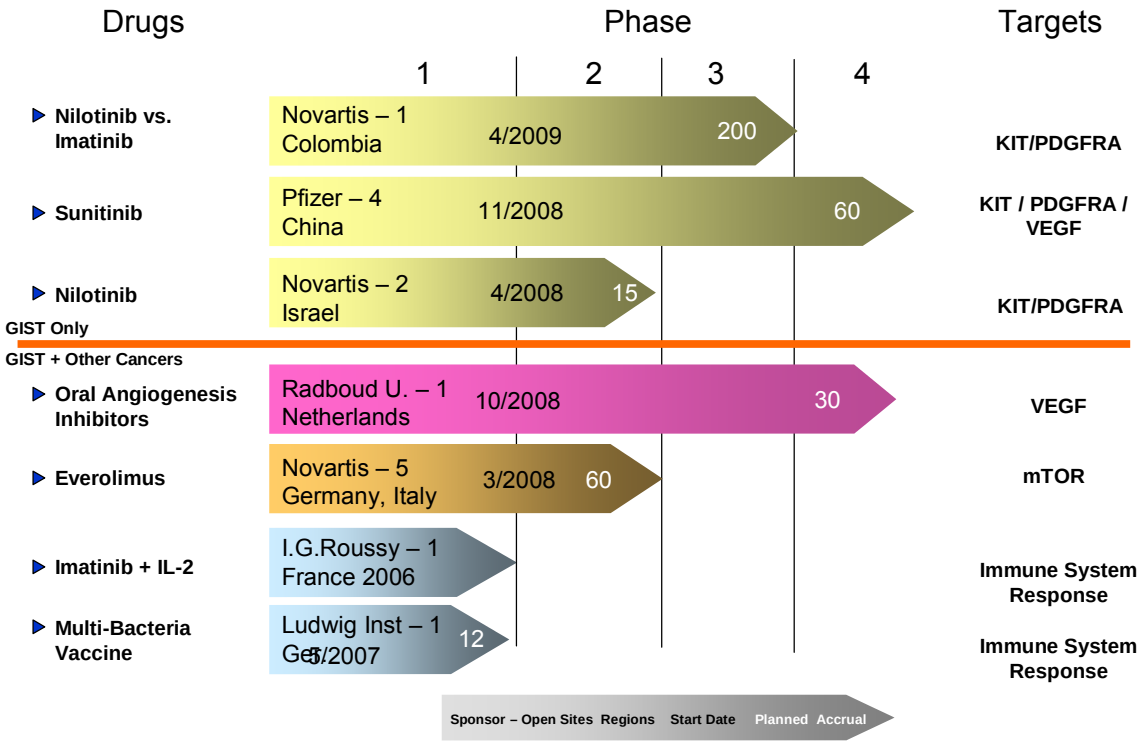
STA-9090 in GIST: This drug has been in phase 1 trials for solid tumors since late 2007. It has been reported to be one of the most effective HSP90 inhibitors in the lab. One of the first trial sites was Dana Farber Cancer Institute which continues to be the focus of plans for a follow-up trial in GIST.

SF1126 in GIST: At ASCO 2009, Dr. Gabriela Chiorean at the University of Indiana in Indianapolis presented encouraging results of a phase 1 trial in solid tumors that included GIST patients. SF1126 is a PI3K inhibitor that can work against a variety of GIST mutations. Dr. Chiorean expressed interest in a follow-up phase 2 trial in GIST.

Deciphera: This start-up has a new approach to inhibiting KIT that does not depend on blocking the ATP binding pocket, as do the current generation drugs imatinib and sunitinib. The new design may block KIT irrespective of mutation type. We are looking for phase 1 trials to start in 2010 in GIST.

R1507 for Wild Type GIST: Plans seem to be underway at the National Institutes of Health for a phase 2 trial in wild type GIST. We have been hearing for some time that a trial is months away.

Figure 2: International Options for Resistant GIST



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

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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
Niigata, Japan
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Tatsuo Kanda, MD

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
Contact: Novartis Pharmaceuticals
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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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Michael Montemurro, MD

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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Site name unknown, Milan
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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
Contact: Pfizer Oncology Clinical Trial Information Service
1-877-369-9753
PfizerCancerTrials@emergingmed.com
Pfizer CT.gov Call Center
1-800-718-1021

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Site name unknown Beijing 100071
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Site name unknown, Beijing 100021
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Site name unknown, Nanjing 210002
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Nilotinib or Imatinib

Nilotinib 800 Mg And Imatinib 800 Mg For The Treatment Of Patients With Gastrointestinal Stromal Tumors (Gist) Refractory To

Phase: 3
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00751036
Contact: Novartis US: 1-800-340-6843

Site name unknown Monteria
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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
Contact: Biogen Idec
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Robert Maki, MD

Nilotinib

Nilotinib in Advanced GIST

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT
NCT #: NCT00782834
Contact: See site contact info below

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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

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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:

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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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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
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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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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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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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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**
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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**
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MP470

MP470 in Treating Patients With Unresectable or Metastatic Solid Tumor or Lymphoma

Phase:	1
Stage:	Gleevec-resistant
Conditions:	Advanced Stage Solid Tumors
Drug Type:	KIT/PDGFRA inhibitor
Strategy:	Block KIT
NCT #:	**NCT00504205**
Contact:	TGen Clinical Research Services Cancer Care Coordinator 480-323-1255

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Anthony Tolcher, MD, (210) 593-5255
Note: Contact number is not verified.
Anthony Tolcher, MD

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**
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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:

Warren Grant Magnuson Clinical Center
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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:

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608-262-5223
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

Site name unknown, Barcelona 08036
Barcelona, Spain

Site name unknown, Santa Monica 90403
Santa Monica, CA USA

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

Site name unknown, Indianapolis
Indianapolis, IN USA

Site name unknown, Detroit
Detroit, MI USA

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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Eunice Kwak, MD

Dana Farber Cancer Institute
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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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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

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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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BIIB028

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HSP90 inhibitor
Strategy: Destroy KIT
NCT #: NCT00725933
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

Sarah Cannon Research Institute
Nashville, TN USA
615-329-SCRI (7274)

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#.

Site name unknown, East Melbourne
East Melbourne, Australia
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:

Children's Hospital of Orange County
Orange, CA USA
Violet Shen
714-532-8636

Children's National Medical Center
Washington, DC USA
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202-884-2549

Masonic Cancer Center at University of Minnesota
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Clinical Trials Office
612-624-2620

Cincinnati Children's Hospital Medical Center
Cincinnati, OH USA
Clinical Trials Office
513-636-2799

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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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
Contact: Jill Schmidt
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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

Beatson West of Scotland Cancer Centre
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
Contact: OSIP Medical Information
800.572.1932 ext 7821
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Edward Kim, MD

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
973-235-5000
800-526-6367 (US only)

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MD Anderson Cancer Center
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800-392-1611 Referring MD
Cynthia E. Herzog

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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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
PfizerCancerTrials@emergingmed.com
Pfizer CT.gov Call Center
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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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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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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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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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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