



June 2009 Clinical Trials Update

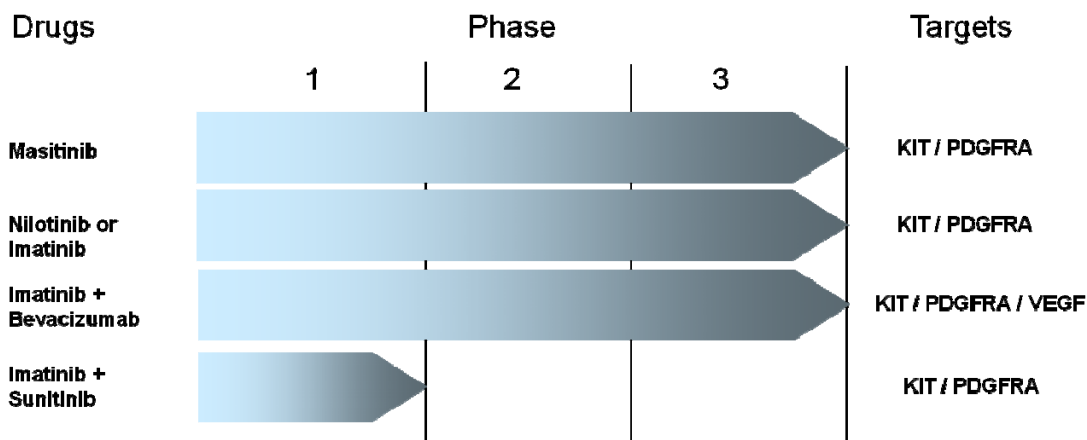
By Jim Hughes
LRG Clinical Trials Coordinator

BKM120 Phase 1: A new Novartis PI3K inhibitor, BMK120, is now recruiting at Sarah Cannon in Nashville, Tenn. As with most Phase 1 trials, this trial is for “Solid Tumors” which should include GIST. BMK120 inhibits PI3K but unlike the other Novartis PI3K inhibitors, BEZ235 and BGT226, it does not also inhibit mTOR.

Nilotinib Versus Imatinib: 15 new sites are listed as recruiting in Austria, Brazil, Canada and Japan

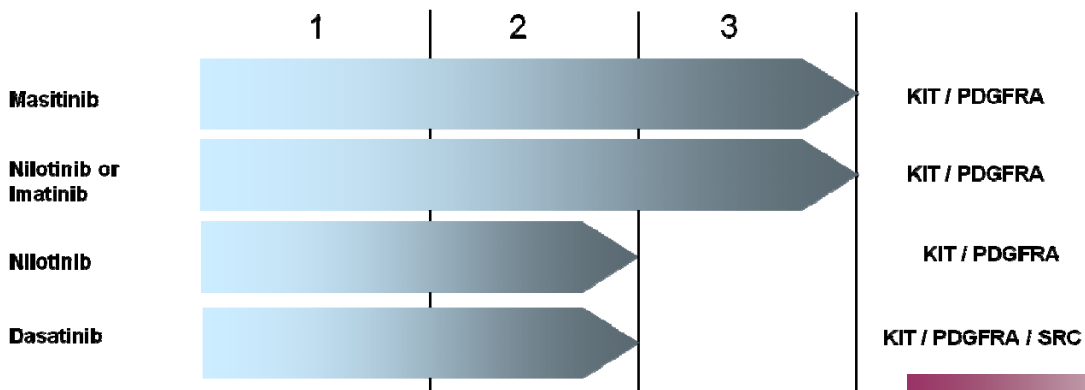
First Line Options for Advanced GIST

Figure 1: United States



Figures 1 and 2 represent an overview of first-line options for advanced GIST in the United States and internationally.

Figure 2: International



First line trials represent a new opportunity for GIST patients to try to improve on their initial treatment.

Options for Resistant GIST

Figure 3: United States

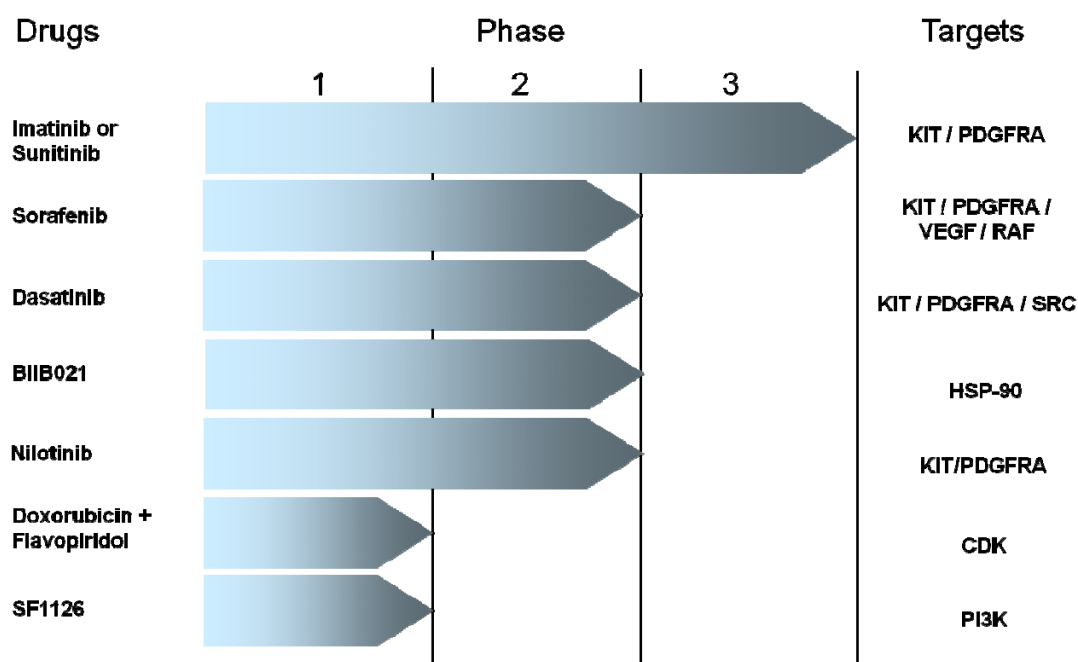
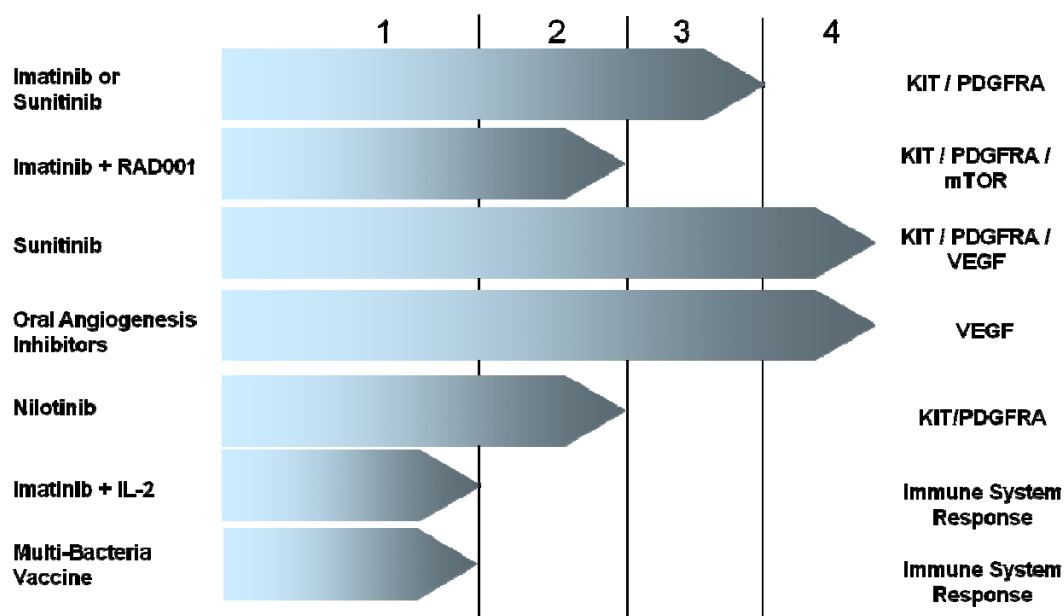


Figure 4: International



Figures 3 and 4 provide an overview of the available clinical trial options for Gleevec resistant GIST. Some trials require resistance to Sutent as well.

Check the actual trial listing for details about eligibility. Several trials are for patients that are resistant to 400 mg of Gleevec but have not yet tried 800 mg.

Don't forget to check out the LRG Newsletter at www.gistnews.org for the most up-to-date information on GIST research, advocacy issues and the GIST community.

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/PDGFR 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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81-25-227-2228
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/PDGFR inhibitor+ VEGF inhibitor (antibody)
Strategy: Block KIT
Block tumor blood vessel growth
NCT #: [NCT00324987](#)
Contact: See each trial site.

USC/Norris Comprehensive Cancer Center
Los Angeles, CA USA
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323-865-0451

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Des Moines, IA USA
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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/PDGFR 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/PDGFR 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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00756509](#)
Contact: Novartis Basel
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**Site name unknown, Bad
Saarow**
Bad Saarow, Germany

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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00793871](#)
Contact: Pfizer Oncology Clinical
Trial Information Service
1-877-369-9753
PfizerCancerTrials@emergin
gmed.com
Pfizer CT.gov Call Center
1-800-718-1021

**Site name unknown Beijing
100035**
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**Site name unknown Beijing
100071**
Beijing, China

**Site name unknown,
Beijing 100021**
Beijing, China

**Site name unknown,
Nanjing 210002**
Nanjing, Jiangsu China

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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00372567](#)
Contact: Pfizer Oncology Clinical
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Tuen Mun, New Territories
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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
oncologyclinicaltrials@biogenidec.com

Site name unknown, Rochester
Rochester, MN USA

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New York, NY USA
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Imatinib + RAD001

Treatment of Patients With Everolimus and Imatinib Mesylate Who Have Progressive Gastrointestinal Stromal Tumors (GIST)

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFR inhibitor
mTOR inhibitor
Strategy: Block KIT
Block KIT Signal Path
NCT #: [NCT00510354](#)
Contact: Novartis Basel
41 61 324 1111

Site name unknown, Bad Saarow
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Site name unknown, Munchen
Munchen, Germany

Site name unknown, Tubingen
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Nilotinib

Nilotinib in Advanced GIST

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00782834](#)
Contact: See site contact info below
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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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00633295](#)
Contact: Novartis Basel
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Site name unknown, Tel Aviv
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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/PDGFR 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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00573404](#)
Contact:

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Franklin, TN USA
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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/PDGFR 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
Site name unknown, Berlin
Berlin, Germany

Site name unknown, Dusseldorf
Dusseldorf, Germany

Site name unknown, Mannheim 68135
Mannheim, Germany

Site name unknown, Munchen
Munchen, Germany

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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New York, NY USA
212-639-7573
dadamod@mskcc.org
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
Institut Gustave-Roussy
Villejuif Cedex, France
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Multi-bacteria vaccine (MBV)

*A Phase I 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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Frankfurt, Germany
Antje Neumann
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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 #:
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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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
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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/PDGFR inhibitor
Strategy: Block KIT
NCT #: [NCT00894894](#)
Contact: SuperGen

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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:

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888-NCI-1937
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AT13387

*Phase I 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](#)
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BAY 73-4506

Phase I study of BAY 73-4506

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: KIT/PDGFR 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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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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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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615-329-SCRI (7274)

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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GDC-0941

An Open-Label, Phase I, Dose-Escalation Study of PI3 Kinase Inhibitor (GDC-0941) in Patients with Locally Advanced or Metastatic

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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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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PX-478

Phase I Trial of PX-478

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HIF-1 α 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
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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@emergin
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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@emergin
gmed.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/PDGFR 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](#)
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XL147

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

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
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Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: [NCT00486135](#)
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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](#)
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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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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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