

# THE LIFE RAFT GROUP

## CLINICAL TRIALS BULLETIN

*Our navigation for the trials you seek*

# July 2009 Clinical Trials Update

By Jim Hughes

LRG Clinical Trials Coordinator

In this month's Clinical Trials Bulletin we highlight a new class of drugs that target Insulin-like Growth Factor 1 Receptor (IGF-1R). IGF-1R is a tyrosine kinase that, much like KIT, protrudes through the cell surface and begins to signal when an extracellular Insulin Growth Factor (IGF1) attaches to the outside portion of the receptor. Unlike KIT, IGF-1R has not been found to be mutated in GIST. However, IGF-1R has been found to be over-expressed in wild-type GIST tumor tissue. Up to now, KIT inhibitors have had limited impact in wild type GIST. IGF-1R is now viewed as a component of a potential "side channel" providing an alternative signaling path to KIT and potentially a target in GIST.

In experiments with wildtype GIST cells, researchers at Fox Chase Cancer

Center have demonstrated the ability to slow cell growth with both IGF-1R inhibitors and combinations of IGF-1R and KIT inhibitors. These promising results are leading to new trial designs specifically for GIST patients.

IGF-1R inhibitors are a very active area of drug development. We have identified over a dozen compounds both in the lab and in early clinical trials. Many are in trials that are open to solid tumors or advanced malignancies and should accept GIST patients.

As with all Phase I trials, the trial objective is to determine a safe dosage and to document safety issues. Efficacy is not determined until phase II or III. Patients entering phase I are not guaranteed a therapeutic dosage nor is there an easy way of measuring all the risks. However, for those experiencing resistance or uncontrollable growth, Phase I trials provide an option until the new GIST-specific trials, such as the planned NIH

trial, are on-line.

IGF-1R inhibitors are of two types: small molecule and monoclonal-antibodies.

Small molecule inhibitors work in much the same way as Imatinib or Sunitinib work against KIT. They block the IGF-1R molecule usually at a signaling point inside the cell.

Monoclonal antibodies work by binding to the IGF-1R protein portion outside the cell and thereby prevent the IGF1 ligand from binding to the receptor and initiating the tyrosine kinase signaling process.

Both methods can effectively stop IGF-1R signaling. Monoclonal antibodies tend to be more specific to their targets.

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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](http://liferaftgroup.org/treat_trials.html).

## Insulin-like Growth Factor Receptor signaling

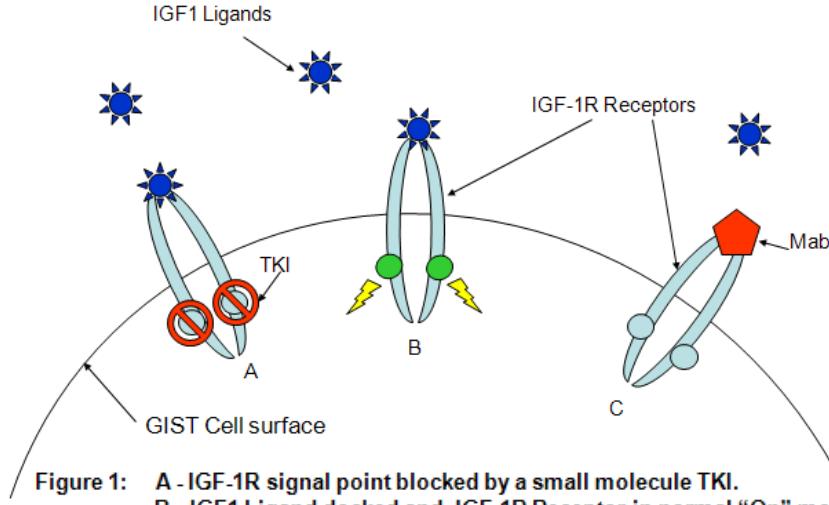


Figure 1: A - IGF-1R signal point blocked by a small molecule TKI.  
B - IGF1 Ligand docked and IGF-1R Receptor in normal "On" mode.  
C - IGF1 Ligand docking site blocked by a Monoclonal Antibody

## FROM PAGE 1

Small molecules can have collateral targets that can either enhance tumor inhibition and/or cause unwanted side-effects. Most IGF-1R inhibitors in trials today are monoclonal antibodies. The exceptions are OSI-906 and XL228.

When drugs are assigned a generic

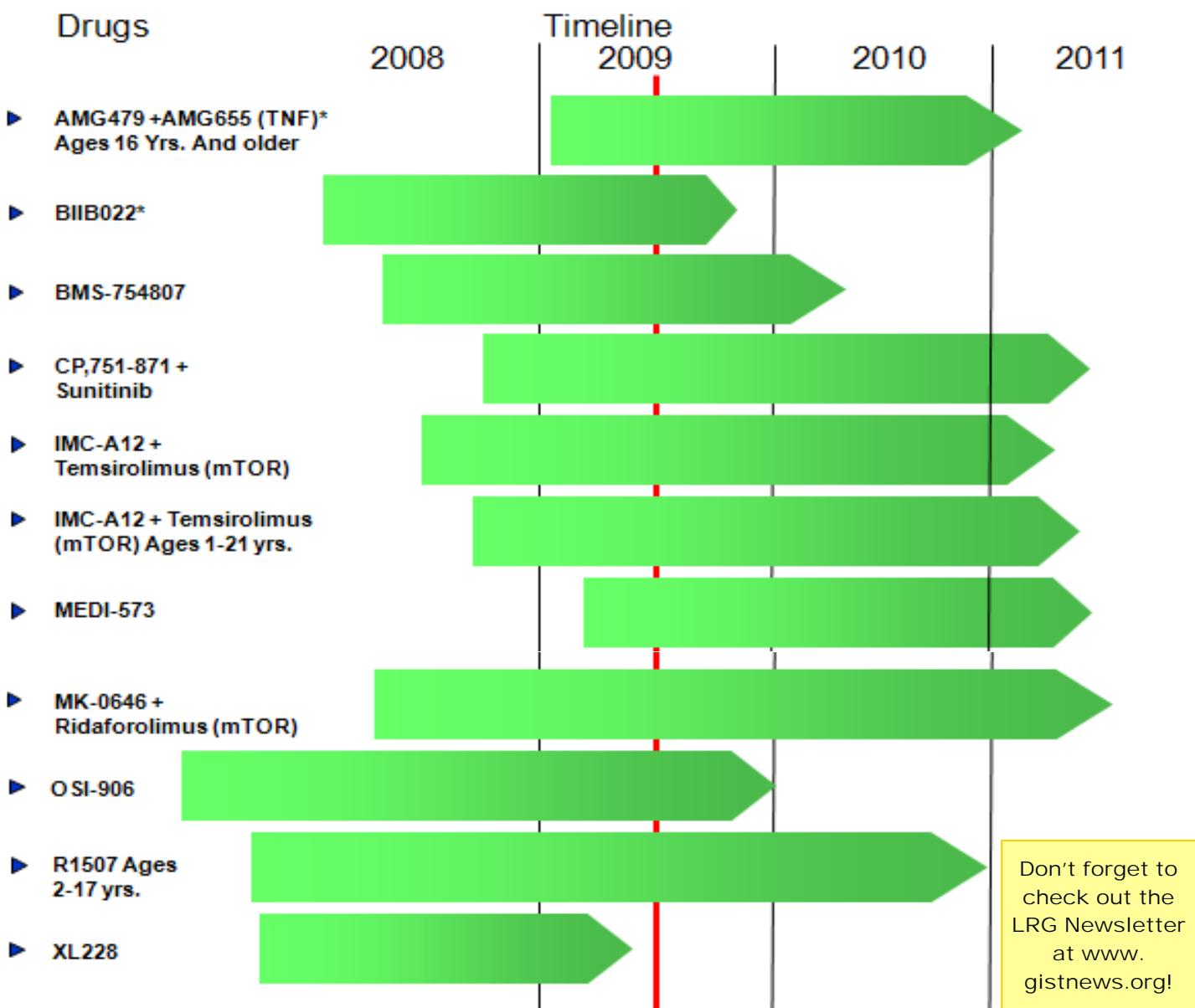
name you can usually tell which are monoclonal antibodies because they all have the suffix 'mab'. Figitumumab (CP-751,871) and Cixutumumab (IMC-A12) are two examples.

One caution when evaluating IGF-1R trials is to be aware that some trials preclude the use of any prior IGF-1R therapy (BII022 and AMG 479). You may

want to take this into account in optimizing your trial plan.

In this month's report we have included eleven new Phase 1 trials of IGF-1R inhibitors. Two of these will accept patients younger than eighteen. This month's report also reflects the termination of the imatinib plus RAD001 trial that was accruing at nine sites in Germany.

## Phase 1 Options for Advanced Wild Type GIST: IGF-1R Inhibitors



\*Exclude prior IGF-1R inhibitor therapy

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/PDGFRα 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**  
 Niigata, Japan  
 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/PDGFRα 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  
 Clinical Trials Office  
 323-865-0451

### Iowa Oncology Research Association - CCOP

Des Moines, IA USA  
 515-244-7586  
 Roscoe F. Morton, MD

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

### Wichita - CCOP

Wichita, KS USA  
 316-262-4467  
 Shaker R. Dakhil, MD

### Michigan Cancer Research Consortium - CCOP

Ann Arbor, MI USA  
 734-434-4930  
 Phillip J. Stella, MD

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 269-373-7458  
 Raymond S. Lord, MD

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 406-238-6290  
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Michael Heinrich, MD

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Margeret von Mehren, M.D.

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Clinical Trials Office  
210-616-5798

**University of Texas Health Science Center**  
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206-386-2441  
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FACP

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## Masitinib, (AB1010)

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

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Phase: 3

Stage: First-line

Conditions: Gastrointestinal Stromal Tumor

Drug Type: KIT/PDGFRα inhibitor

Strategy: Block KIT

NCT #: **NCT00812240**

Contact: Centre Oscar Lambret  
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**Henry Ford Health System**  
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**Beth Israel Medical Center**  
New York, NY USA

## **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/PDGFRα inhibitor

Strategy: Block KIT

NCT #: **NCT00785785**

Contact: Novartis Pharmaceuticals  
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dgravel@mdanderson.org  
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**Site name unknown, Milan**  
Milan, Italy

**Treatment Stage:**  
**Gleevec-resistant**

## **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/PDGFRα inhibitor + SRC inhibitor  
Strategy: Block KIT + Block KIT Signal Path  
NCT #: [NCT00568750](#)  
Contact: See site contact info below  
**Centre Hospitalier Universitaire Vaudois**  
Lausanne, Switzerland  
41-21-314-0150  
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/PDGFRα inhibitor  
Strategy: Block KIT  
NCT #: [NCT00756509](#)  
Contact: Novartis Basel  
+ 41 61 324 1111  
**Site name unknown, Bad Saarow**  
Bad Saarow, Germany

**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/PDGFRα inhibitor  
Strategy: Block KIT  
NCT #: [NCT00793871](#)  
Contact: Pfizer Oncology Clinical Trial Information Service  
1-877-369-9753  
PfizerCancerTrials@emergen 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**  
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**Site name unknown, Beijing 100021**  
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**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 $\alpha$  inhibitor

Strategy: Block KIT

NCT #: [NCT00372567](#)

Contact: Pfizer Oncology Clinical Trial Information Service  
1-877-369-9753

PfizerCancerTrials@emergen  
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1-800-718-1021

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Margaret von Mehren, M.D.

## **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

**Memorial Sloan-Kettering Cancer Center**  
New York, NY USA  
Robert Maki, MD

## **Nilotinib**

### *Nilotinib in Advanced GIST*

Phase: 2  
 Stage: Gleevec-resistant  
 Conditions: Gastrointestinal Stromal Tumor  
 Drug Type: KIT/PDGFR $\alpha$  inhibitor  
 Strategy: Block KIT  
 NCT #: [NCT00782834](#)  
 Contact: See site contact info below  
**Fox Chase Cancer Center**  
 Philadelphia, PA USA  
 1-888-FOX-CHASE (369-2427)  
 Margaret 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/PDGFR $\alpha$  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/PDGFR $\alpha$  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/PDGFR $\alpha$  inhibitor  
 Strategy: Block KIT  
 NCT #: [NCT00573404](#)  
 Contact:

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

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 Nashville, TN USA  
 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  
**University Medical Center Nijmegen st Raboud**  
 Nijmegen, Gelderland Netherlands  
 31 24 3610353  
 c.vanherpen@onco.umcn.nl

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/PDGFR $\alpha$  inhibitor + SRC inhibitor  
 Strategy: Block KIT + Block KIT Signal Path  
 NCT #: [NCT00464620](#)  
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Shreyas Patel, MD

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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

**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  
**Memorial Sloan-Kettering Cancer Center**  
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 #: [NCT00907205](#)  
Contact: See site contact info below  
**Institut Gustave-Roussy**  
Villejuif Cedex, France  
Patricia Pautier, MD  
33 (0) 1 42 11 42 11  
pautier@igr.fr  
Laurence Zitvogel, MD

## 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  
**Krankenhaus Nordwest**  
Frankfurt, Germany  
Antje Neumann  
neumann.antje@khnw.de  
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  
**Site Name unknown, Bellinzona**  
Bellinzona, Switzerland

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713-792-6161 (outside U.S.A.)  
Jon Trent, MD, PhD

**Cancer Therapy and Research Center**  
San Antonio, TX USA  
210-562-1797  
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/PDGFRα 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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**South Texas Accelerated Research Therapeutics (START)**  
San Antonio, TX USA  
Jim Agnew, RN  
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:

**Warren Grant Magnuson Clinical Center**  
Bethesda, MD USA  
Clinical Trials Office  
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**  
Madison, WI USA  
Clinical Trials Office  
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 + TNF Inhibitor
Strategy:	Block related tumor signal paths
NCT #:	<a href="#">NCT00819169</a>
Contact:	Amgen Call Center 866-572-6436
<b>Site name unknown, Barcelona 08036</b>	Barcelona, Spain
<b>Site name unknown, Santa Monica 90403</b>	Santa Monica, CA USA
<b>University of Chicago</b>	Chicago, IL USA
Clinical Trials Office, 773 -834-7424	Hedy Kindler, MD
<b>Site name unknown, Indianapolis</b>	Indianapolis, IN USA
<b>Site name unknown, Detroit</b>	Detroit, MI USA

## **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 #:	<a href="#">NCT00878423</a>
Contact:	Andrew Wolanski 617-632-6623 Andrew_Wolanski@dfci.harvard.edu

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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/PDGFRα inhibitor VEGFR inhibitor (TKI)
Strategy:	Block KIT
NCT #:	
Contact:	See site contact info below
<b>MD Anderson Cancer Center</b>	Houston, TX USA
Clinical Trials Office	713-792-3245
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<b>South Texas Accelerated Research Therapeutics (START)</b>	San Antonio, TX USA
Tracy Dufresne, RN	210-593-5265
tracy.dufresne@start.stoh.com	

## **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 #:	<a href="#">NCT00620594</a>
Contact:	Novartis 862-778-8300
<b>Nevada Cancer Institute</b>	Las Vegas, NV USA
Dianna Tercan	(702) 822-5483
Wolfram Samlowski, M.D.	
<b>Sarah Cannon Research Institute</b>	Nashville, TN USA
615-329-7274	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 #:	<a href="#">NCT00618735</a>
Contact:	Biogen Idec oncologyclinicaltrials@biogenidec.com
<b>Premier Oncology, Santa Monica</b>	Santa Monica, CA USA
<b>South Texas Accelerated Research Therapeutics (START)</b>	San Antonio, TX USA

## **BIIB022**

### *Phase I 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 #:	<a href="#">NCT00555724</a>
Contact:	Biogen Idec oncologyclinicaltrials@biogenidec.com
	<b>Site name unknown, Los Angeles, CA</b> Los Angeles, CA USA
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	<b>Fox Chase Cancer Center</b> Philadelphia, PA USA Kathleen Lear, RN, OCN, CCRP Phone: 215-214-1511 Email: kathleen.lear@fccc.edu Roger Cohen, MD

## **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 <b>Sarah Cannon Research Institute</b> 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 #:	<a href="#">NCT00569036</a>
Contact:	For site information outside the USA please email: Clinical.Trials@bms.com First line of email MUST contain NCT# & Site#.
	<b>Site name unknown, East Melbourne</b> East Melbourne, Australia Site # 003
	<b>Site name unknown, Footscray, Australia</b> Footscray, Victoria Australia Site # 004
	<b>Site name unknown, Heidelberg Australia</b> Heidelberg, Victoria Australia Site # 002
	<b>Site name unknown, Parkville, Australia</b> Parkville, Victoria Australia Site #001

## **Cixutumumab + Temsirolimus**

### *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 #:	<a href="#">NCT00880282</a>
Contact:	

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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**  
Minneapolis, MN USA  
Clinical Trials Office  
612-624-2620

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

## 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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George Demetri, MD, PhD

### Karmanos Cancer Institute

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zhangj@karmanos.org

## 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

*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  
713-563-0181  
**Karmanos Cancer Institute**  
Detroit, MI USA  
all (800) KARMANOS (1-800-527-6266) or e-mail info@karmanos.org.  
**MD Anderson Cancer Center**  
Houston, TX USA  
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:  
**MD Anderson Cancer Center**  
Houston, TX USA  
Clinical Trials Office - M.D. Anderson Cancer Center,  
713-792-3245  
Aung Naing, MD

## IPI-493

*A Phase I Dose Escalation 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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**Mary Crowley Medical Research Center (Central Office)**  
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Kay Easterwood-Sanchez  
214-658-1943  
Neil Senzer, MD

## 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  
(609) 919-1100  
ddavis@kyowa-kirin-pharma.com  
Niranjan Rao  
(609) 919-1100  
nrao@kyowa-kirin-pharma.  
**Memorial Sloan-Kettering Cancer Center**  
New York, NY USA

## 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  
301-398-0000  
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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 ext 7821  
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  
medical-information@osip.com

**Department of Cancer Therapeutics, Institute of Cancer Research**  
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**MD Anderson Cancer Center**  
Houston, TX USA  
Edward Kim, MD

## PX-478

### Phase I Trial of PX-478

Phase: 1  
Stage: Gleevec-resistant  
Conditions: Solid Tumors  
Drug Type: HIF-1 $\alpha$  inhibitor  
Strategy: Block related tumor signal paths  
Block tumor blood vessel  
NCT #: [NCT00522652](#)  
Contact: See site contact info below

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Hala Abdulkadir  
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habdulka@mdanderson.org  
Roy S. Herbst, PhD

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## PX-866

### *Phase I Trial of Oral PX-866*

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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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Roy Herbst, MD

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## R1507

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

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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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**Site name unknown,  
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**MD Anderson Cancer Center**  
Houston, TX USA  
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800-392-1611 Referring MD  
Cynthia E. Herzog

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## SNX-5422

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

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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@emergen gmed.com  
Pfizer CT.gov Call Center  
1-800-718-1021

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Howard A. Burris, III MD

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## SNX-5422

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

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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@emergen gmed.com  
Pfizer CT.gov Call Center  
1-800-718-1021  
**Site name unknown,  
Bethesda 20982**  
Bethesda, MD USA

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## Sorafenib + Vorinostat

### *Phase I Vorinostat + Sorafenib in Patients With Advanced Solid Tumors*

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Phase: 1  
Stage: Gleevec-resistant  
Conditions: Solid Tumors  
Drug Type: HDAC inhibitor + KIT/PDGFR $\alpha$  inhibitor  
Strategy: Block KIT + Unblock cell death genes + Destroy KIT  
NCT #: [NCT00635791](#)  
Contact: See site contact info below

**University of Colorado**  
Aurora, CO USA  
Stacy Grolnic  
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stacy.grolnic@uchsc.edu  
David Ross Camidge MD

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## **STA-9090**

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

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Phase: 1  
Stage: Gleevec-resistant

Conditions: Solid Tumors

Drug Type: HSP90 inhibitor

Strategy: Destroy KIT

NCT #: [NCT00687934](#)

Contact: See site contact info below

**Premier Oncology, Santa Monica**

Santa Monica, CA USA  
310-633-8400  
Lee Rosen, MD

**US Oncology - Dayton Oncology & Hematology**  
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[robert.raju@usoncology.com](mailto:robert.raju@usoncology.com)  
(937)293-1622  
Robert Raju, MD

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## **STA-9090**

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

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Phase: 1  
Stage: Gleevec-resistant

Conditions: Solid Tumors

Drug Type: HSP90 inhibitor

Strategy: Destroy KIT

NCT #: [NCT00688116](#)

Contact: See site contact info below

**Dana Farber Cancer Institute**

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617-632-2201  
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**Massachusetts General Hospital**  
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**Beth Israel Deaconess Medical Center**  
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## **Karmanos Cancer Institute**

Detroit, MI USA  
Dr. Patricia LoRusso  
313-576-8716

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## **Sunitinib + CP-751,871**

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

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Phase: 1  
Stage: Gleevec-resistant

Conditions: Solid Tumors

Drug Type: KIT/PDGFRα inhibitor + IGF1R inhibitor

Strategy: Block KIT + Block related tumor signal paths

NCT #: [NCT00729833](#)

Contact: EmergingMed  
(877) 369-9753  
[PfizerCancerTrials@emergin gmed.com](mailto:PfizerCancerTrials@emergin gmed.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

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## **XL147**

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

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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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Geoffrey Shapiro, MD

**Mary Crowley Medical Research Center (Baylor)**  
Dallas, TX USA  
J.R. Dolan  
214-658-1943  
Gerald Edelman MD, PhD

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## **XL228**

*Study of XL228 Administered Intravenously to Subjects With Advanced Malignancies*

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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

**UCLA's Jonsson Comprehensive Cancer Center**  
Los Angeles, CA USA  
Lisa Yonemoto  
310-825-4477  
Carolyn Britten, MD

**University of Michigan**  
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Nabeela Iqbal  
734-232-0759  
David Smith, MD

**Duke University**  
Durham, NC USA  
Sharon Norman  
919-681-5257  
Herb Horowitz, 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  
866-939-4041

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gmangold@start.stoh.com  
Kyriakos Papadopoulos, MD

## 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  
**Helsinki University Central Hospital**  
Helsinki, Finland  
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heikki.joensuu@hus.fi  
Heikki Joensuu, 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/PDGFRα inhibitor  
Strategy: Block KIT  
NCT #:  
Contact: Anne Kirkpatrick  
Project Manager - EORTC,  
Brussels, Belgium  
anne.kirkpatrick@eortc.be  
+32 2 7741691

**Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital**  
Amsterdam, Netherlands

### Sunitinib + Radiation

#### *Sutent and Radiation as Treatment for Limited Extent Metastatic Cancer*

Phase: 2  
Stage: Palliative  
Conditions: Any type of Cancer  
Drug Type: KIT/PDGFRα inhibitor  
Strategy: Block KIT  
NCT #: [NCT00463060](#)  
Contact: See site contact info below  
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