

# THE LIFE RAFT GROUP CLINICAL TRIALS BULLETIN

*Our navigation for the trials you seek*

## How it all Began April 2009 Clinical Trial Update

**By Jerry Call**  
LRG Science Coordinator

Unlike many types of cancer, clinical trials have been an important part of the lives of many GIST patients. This close association began in the summer of 2000. At that time most GIST patients did not even know they had GIST. GIST was considered a subtype of leiomyosarcoma (LMS). At that time leiomyosarcoma (and GIST) was treated with a toxic mix of chemotherapy called MAID. Unfortunately MAID and other types of chemotherapy had little or no effect on GIST.

Word began to arrive in what was at that time the leiomyosarcoma listserv ran by ACOR that a new oral drug was working in a phase II trial for GIST. Life Raft Group Executive Director Norman Scherzer was the first to report dramatic results for his wife, Anita. This was quickly fol-

**See GIST History on page 2**

**By Jim Hughes**  
LRG Clinical Trials Coordinator

### United States

#### *Bevacizumab plus Imatinib Phase 3:*

This trial continues at over 200 regional cancer centers across the United States. Recently added were major GIST trial sites including Fox Chase Cancer Center, Oregon Health & Science University and the University of Chicago. This first line trial is for patients recently diagnosed with unresectable GIST. The trial exclusion criteria include "No prior imatinib mesylate, Bevacizumab, or other agents targeting KIT, vascular endothelial growth factor (VEGF), VEGF receptor, or platelet-derived growth factor receptor (PDGFR) for advanced disease. These agents may have been used in the adjuvant setting provided no recurrence for  $\geq 12$  months after completion of therapy." Bevacizumab is an anti-VEGF agent intended to reduce the ability of the

tumor to grow new blood vessels. The trial is intended to answer the question of whether the addition of Bevacizumab to Imatinib will lead to longer progression-free survival. Half the patients will receive Bevacizumab, which is administered intravenously once every three weeks. All patients will receive Imatinib.



### US and International

#### *Sunitinib or Imatinib Phase 3:*

New sites have opened in Michigan, Nevada, Ohio, Wisconsin, Germany, the United Kingdom and the Republic of Korea. This trial is for patients having progression while on Imatinib at 400 mg. Patients are randomly assigned to receive either 800 mg Imatinib or 37.5 mg Sunitinib daily.

### International

**IPI-504 Phase 3:** This trial is for patients failing both Imatinib and Sunitinib. It now has multiple new sites in Australia, Belgium, France, Germany, Sweden and the Republic of Korea. IPI-504 is a HSP-90 inhibitor administered intravenously. Patients are randomized to receive either IPI-504 or a placebo.

#### *Nilotinib Versus Imatinib Phase*



Dr. George Demetri of Dana-Farber Cancer Institute has been one of the leaders in clinical trials for GIST

**See Trials Update on page 2**

## Trials Update from page 1

**3:** This trial for first line patients is now recruiting at two sites in Canada, and one each in Austria and Spain. In the US 19 sites, 11 states are listed in clinicaltrials.gov along with detailed contact information. All are listed as 'Not yet recruiting'. That could change quickly.

This phase 3 trial will test whether nilotinib (also known as AMN107 and Tasigna) given as initial treatment for metastatic GIST is better than the current initial therapy, imatinib (Gleevec). Nilotinib is a more powerful inhibitor of KIT and PDGFRA than Gleevec. Lab tests also show it is more effective than imatinib against both wild-type GIST and the exon 13 mutant GIST. Nilotinib also showed higher concentrations levels inside GIST tumor cells in the lab.

Patients entering the trial will be randomized to receive either imatinib or nilotinib. Estimated enrollment for the trial will be 736 patients.

## GIST History from page 1

Followed by similar reports from Gary Golnik. Gary's wife, Mary, was being treated at Dana-Farber Cancer Institute and Gary and Mary met a few other GIST patients in the trial and arranged to keep in touch about side effects and the trial. This group of patients was the very beginning of what we now know as the Life Raft Group.

Word quickly spread on the LMS list that patients with abdominal LMS might instead have GIST and they needed to have their tumors tested for a protein called c-Kit (now usually just called KIT). With no other effective options for GIST, the phase II trial quickly enrolled its allotted number of patients. Interest in the trial was so high that the trial quickly expanded to allow 147 patients and it filled within a few months even though it was only recruiting in 4 sites.

Because of the demand from patients that were finding out about Gleevec thanks to ACOR and the early members of the Life Raft Group, and because of

### *Inclusion Criteria include:*

1. Histologically confirmed diagnosis of GIST which is unresectable and/or metastatic and either:
  - No prior therapy with imatinib or any investigational therapies (e.g. sunitinib). Note: newly diagnosed patients may have received up to 14 days imatinib treatment for disease management while awaiting study start.
  - Recurrent GIST after stopping adjuvant treatment with imatinib and no subsequent treatment with any other investigational therapies (for example sunitinib).
2. At least one measurable site of disease on CT/MRI scan
3. Performance status  $\leq 2$  (capable of self-care but unable to carry out any work)
4. Normal organ, electrolyte and marrow function

### *Exclusion Criteria include:*

1. Prior treatment with nilotinib or any other drug in this class or other targeted therapy agents with the exception of adjuvant imatinib.
  2. Disease progression during adjuvant therapy with imatinib
  3. Prior or concomitant malignancy that is currently clinically significant or currently requires active intervention.
  4. Impaired cardiac function
- Other protocol-defined inclusion/exclusion criteria may apply

## 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 a rare cancer called 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.

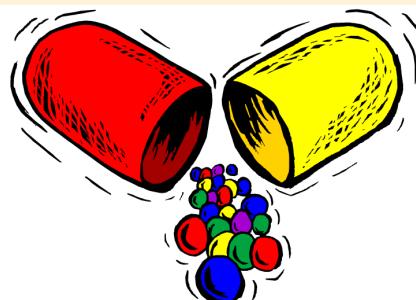
### How to help

Donations to The Life Raft Group, a 501(c)(3) nonprofit organization, are tax deductible in the United States. You can donate by credit card at [www.liferaftgroup.org/donate.htm](http://www.liferaftgroup.org/donate.htm) or by sending a check to:

The Life Raft Group  
40 Galesi Dr., Suite 19  
Wayne, NJ 07470

### Disclaimer

We are patients and caregivers, not doctors. Information shared is not a substitute for discussion with your doctor.



the hard work of the trial investigators in the US, Europe, Asia and Australia, phase III trials were quickly formed and up and running by late 2000/early 2001.

Phase III trial accrual was nearly as quick as the phase II accrual. Word was spreading quickly in the tight sarcoma community of doctors and in the online community of GIST patients. During those early years before Gleevec was approved, almost 2000 GIST patients entered clinical trials. This appreciation of trials and willingness to participate continues today as GIST patients continue to join trials in high numbers.

# US Clinical Trials Listing

## Imatinib + Bevacizumab

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

Phase: 3  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
     Block tumor blood vessel growth  
 NCT #: [NCT00324987](#)  
 Contact: See each trial site.  
**Geisinger Clinical & Medical Center - CCOP**  
 Danville, PA  
 570-271-6413  
 Albert M. Bernath, MD  
**Montana Cancer Consortium - CCOP**  
 Billings, MT  
 406-238-6290  
 Benjamin Marchello, MD  
**Dayton Clinical Oncology Program - CCOP**  
 Kettering, OH  
 937-395-8678  
 Howard M Gross, MD  
**Toledo Community Hospital Oncology - CCOP**  
 Toledo, OH  
 419-255-5433  
 Paul L. Schaefer, MD  
**Columbus - CCOP**  
 Columbus, OH  
 614-443-2267  
 Philip J. Kuebler, MD  
**Gibbs Regional Cancer Center - CCOP**  
 Spartanburg, SC  
 864-560-7050  
 James Bearden, III, MD  
**Southeast Cancer Control Consortium - CCOP**  
 Winston-Salem, NC  
 910-777-3036  
 James M. Atkins, MD

**Syracuse Hematology-Oncology Associate of Central New York - CCOP**  
 East Syracuse, NY  
 315-472-7504  
 Jeffrey J. Kirshner, MD  
**Ozarks Regional - CCOP**  
 Springfield, MO  
 417-269-4520  
 John W. Goodwin, MD  
**Columbia River Oncology Program - CCOP**  
 Portland, OR  
 503-216-6260  
 Keith Larimer, MD  
**Carle Cancer Center - CCOP**  
 Urbana, IL  
 217-383-3394  
 Kendrith Rowland, MD  
**Metro Minnesota - CCOP**  
 St. Louis Park, MN  
 592-993-1517  
 Patrick J. Flynn, MD  
**Kalamazoo - CCOP**  
 Kalamazoo, MI  
 269-373-7458  
 Raymond S. Lord, MD  
**Iowa Oncology Research Association - CCOP**  
 Des Moines, IA  
 515-244-7586  
 Roscoe F. Morton, MD  
**Wichita - CCOP**  
 Wichita, KS  
 316-262-4467  
 Shaker R. Dakhil, MD  
**Oregon Health Sciences University (OHSU)**  
 Portland, OR  
 503 494-6594  
 Michael Heinrich  
**University of Chicago**  
 Chicago, IL  
 Clinical Trials Office, 773-834-7424  
 Hedy Kindler, MD  
**Fox Chase Cancer Center**  
 Philadelphia, PA  
 1-888-FOX-CHASE  
 Margeret von Mehren, M.D.

**Marshfield Medical Research & Education Foundation**  
 Marshfield, WI  
 715-387-5426  
 Mohammad Q. Khan, MD, FACP

## IPI-504

*Study of IPI-504 in GIST patients following failure of at least imatinib and sunitinib*

Phase: 3  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Destroy KIT  
 NCT #: [NCT00688766](#)  
 Contact: GIST Phase 3 Team  
<http://www.ringtrial.com/>  
 877-504-4634  
[RINGtrialinfo@infi.com](mailto:RINGtrialinfo@infi.com)  
**Dana Farber Cancer Institute**  
 Boston, MA  
 Tarsha Colon, RN  
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[tcolon@partners.org](mailto:tcolon@partners.org)  
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 Rick Gorman Jr.M.D.  
**Fox Chase Cancer Center**  
 Philadelphia, PA  
 New Patient Office  
 1-888-FOX-CHASE  
 Margeret von Mehren, M.D.  
**City of Hope**  
 Duarte, CA  
 1-866-434-4673  
 Warren Chow, MD

**Cedars-Sinai Outpatient Cancer Center**  
 Los Angeles, CA  
 Ginny Naessig  
 310-423-0721  
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 Charles Forscher

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 212-604-6020  
 Gerald Rosen, MD

**Oregon Health Sciences University (OHSU)**  
 Portland, OR  
 OHSU Knight Cancer Institute Clinical Trials Hotline  
 503-494-1080  
 Michael Heinrich, MD

## Masitinib, (AB1010)

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

Phase: 3  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
 NCT #: [NCT00812240](#)  
 Contact: Antoine Adenis, M.D.  
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[a-adenis@o-lambret.fr](mailto:a-adenis@o-lambret.fr)

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 Anderson Cancer Center,  
 713-792-3245  
 Jon Trent, MD, PhD

**Henry Ford Health System**  
 Detroit, MI

**Beth Israel Medical Center**  
 New York, NY

## 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  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
 NCT #: [NCT00372567](#)  
 Contact: Pfizer Oncology Clinical Trial Information Service  
 1-877-369-9753  
[PfizerCancerTrials@emergen-gmed.com](mailto:PfizerCancerTrials@emergen-gmed.com)  
 1-800-718-1021  
 1-877-369-9753  
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**Evanston Hospital**  
 Evanston, IL  
 Bruce Brockstein, MD

**Glenbrook Hospital**  
 Glenview, IL  
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**Highland Park Hospital**  
 Highland Park, IL  
 Bruce Brockstein, MD

**Karmanos Cancer Institute**  
 Detroit, MI  
 all (800) KARMANOS (1-800-527-6266) or e-mail [info@karmanos.org](mailto:info@karmanos.org).  
 Anthony Sheilds, MD

**Siteman Cancer Center, Creve Coeur**  
 Creve Coeur, MO

**Washington University**  
 St. Louis, MO

**Siteman Cancer Center, St. Peters**  
 St. Peters, MO

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Farmington Hills, MI

**Site name unknown,  
Henderson 89074**  
Henderson, NV

**Site name unknown, Las  
Vegas 89102**  
Las Vegas, NV

**Site name unknown, Las  
Vegas 89106**  
Las Vegas, NV

**Site name unknown, Las  
Vegas 89148**  
Las Vegas, NV

**Site name unknown,  
Cleveland 44195**  
Cleveland, OH

## BIIB021 (CNF2024)

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

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor  
Strategy: Destroy KIT  
NCT #: [NCT00618319](#)  
Contact: Biogen Idec

[oncologyclinicaltrials@biogenidec.com](mailto:oncologyclinicaltrials@biogenidec.com)

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

**Site name unknown,  
Rochester**  
Rochester, MN

## Nilotinib

### *Nilotinib in Advanced GIST*

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor  
Strategy: Block KIT  
NCT #: [NCT00782834](#)  
Contact: FOX CHASE  
1-888 FOX-CHASE (369)  
**Fox Chase Cancer Center**  
Philadelphia, PA  
1-888-FOX-CHASE  
Margeret von Mehren, M.D.

## Sorafenib (Nexavar, BAY 43-9006)

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

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor  
Strategy: Block KIT + Block KIT  
Signal Path  
NCT #: [NCT00265798](#)  
Contact: Clinical Trials Office -  
University of Chicago Cancer Research  
773-834-7424  
**University of Chicago**  
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Clinical Trials Office, 773-834-7424  
Hedy Kindler, MD

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Warren A. Chow, MD

**Illinois CancerCare**  
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**Cancer Care Specialists**  
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Scott Schuetze, MD

**Medical College of  
Wisconsin**  
Milwaukee, WI  
414 805-4603  
Stuart Wong, MD

## Imatinib + Sunitinib

*Imatinib Mesylate and Sunitinib in Treating Patients With Gastrointestinal Stromal Tumors*

Phase: 1  
Conditions: Gastrointestinal Stromal Tumor  
Strategy: Block KIT  
NCT #: [NCT00573404](#)  
Contact: Cancer Information Program  
800-811-8480

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

**Vanderbilt-Ingram Cancer Center at Franklin**  
Franklin, TN  
615 343-4128  
Jordan Berlin

**Vanderbilt-Ingram Cancer Center**  
Nashville, TN  
800 811-8480  
Clinical Trials Office

## Dasatinib (BMS-354825)

### *Trial of Dasatinib in Advanced Sarcomas*

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT + Block KIT Signal Path

NCT #: [NCT00464620](#)

Contact: Kathleen Granlund  
734-930-7607  
[kegranolund@sarctrials.org](mailto:kegranolund@sarctrials.org)  
734-930-7607  
[kegranolund@sarctrials.org](mailto:kegranolund@sarctrials.org)

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[melanie-frees@uiowa.edu](mailto:melanie-frees@uiowa.edu)  
Mohammed Milhem, MD

## Doxorubicin + Flavopiridol

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

Phase: 1  
 Conditions: Gastrointestinal Stromal Tumor  
 Sarcoma  
 Strategy: Freeze the cell division cycle  
 NCT #: [NCT00098579](#)  
 Contact: David R. D'Adamo, MD, PhD  
 212-639-7573  
[dadamod@mskcc.org](mailto:dadamod@mskcc.org)  
**Memorial Sloan-Kettering Cancer Center**  
 New York, NY  
 David D'Adamo, MD, PhD, 212-639-7573.  
 David D'Adamo, MD, PhD, 212-639-7573.

## SF1126

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path  
 NCT #: [NCT00098579](#)  
 Contact: Joyce Ingold RN MSN OCN  
 TGen Clinical Research Services @ SHC  
 Debi & Jerry Bisgrove Research Pavilion  
 10510 N. 92nd Street, 2nd Floor  
 480 323-1339  
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 Elena Chiorean  
**Arizona Cancer Center**  
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 (520) 694-CURE(2873)  
 Daruka Mahadevan, MD, PhD

## AUY922

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Destroy KIT  
 NCT #: [NCT00526045](#)  
 Contact: 1 800 340-6843  
**Dana Farber Cancer Institute**  
 Boston, MA  
 617 632-5053  
[stephen\\_hodi@dfci.harvard.edu](mailto:stephen_hodi@dfci.harvard.edu)  
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**Cancer Therapy and Research Center**  
 San Antonio, TX  
 210-562-1797  
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 Houston, TX  
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 703-792-6363  
[vpapadim@mdanderson.org](mailto:vpapadim@mdanderson.org)  
 Jon Trent, MD, PhD

## BGT226

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path

NCT #: [NCT00600275](#)

Contact: Novartis  
 800 340-6843

**Nevada Cancer Institute**  
 Las Vegas, NV  
 Dianna Tercan  
 (702) 822-5483  
 Lin-Chi Chen, M.D., Ph.D.

**Dana Farber Cancer Institute**  
 Boston, MA  
 Melissa Hohos  
 617 632-2201  
[mhohos@partners.org](mailto:mhohos@partners.org)  
 George Demetri, MD, PhD

**Massachusetts General Hospital**  
 Charlestown, MA  
 617-726-6225  
[nisaac1@partners.org](mailto:nisaac1@partners.org)  
 Stephen Isakoff, MD

**Cancer Therapy and Research Center**  
 San Antonio, TX  
 Clinical Studies Referral Office  
 Telephone: 210-450-5798  
 Fax: 210-616-5844  
 E-mail: [onctrial@idd.org](mailto:onctrial@idd.org)  
 Or contact Dr. Francis Giles directly at (210) 450-3838.

## MP470

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

Phase: 1  
 Conditions: Advanced Stage Solid Tumors

Strategy: Block KIT  
 NCT #: [NCT00504205](#)

Contact: TGen Clinical Research Services Cancer Care Coordinator  
 480-323-1255

**South Texas Accelerated Research Therapeutics (START)**  
 San Antonio, TX  
 Anthony Tolcher, MD, (210) 593-5255  
 Note: Contact number is not verified.  
 Anthony Tolcher, MD

**Virginia Piper Cancer Center**  
 Scottsdale, AZ  
 Raoul Tibes, MD, 480-323-1350  
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**TGen Clinical Research Services**  
 Scottsdale, AZ  
 TGen Clinical Research Services  
 Patient Care Coordinator  
 10460 N. 92nd Street, Suite 206  
 Scottsdale, AZ 85258  
 Office 480-323-1339  
 Fax 480-323-1259

## SNX-5422

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

Phase: 1  
 Conditions: Solid Tumors

Strategy: Destroy KIT  
 NCT #: [NCT00644072](#)

Contact: Clinical Trials Office - Warren Grant Magnusen Clinical Center  
 888-NCI-1937

**Warren Grant Magnuson Clinical Center**  
 Bethesda, MD  
 Clinical Trials Office - Warren Grant Magnusen Clinical Center 888-NCI-1937  
 Giuseppe Giaccone, MD, PhD

## BAY 73-4506

*Phase I study of BAY 73-4506*

Phase: 1  
 Conditions: Solid Tumors

Strategy: Block KIT

NCT #:  
 Contact: Tracy Dufresne, RN, BSN, OCN, CCRP  
 Physician Referral Coordinator  
 210 593-5265  
[tracy.dufresne@start.stoh.com](mailto:tracy.dufresne@start.stoh.com)

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**MD Anderson Cancer Center**  
 Houston, TX  
 Clinical Trials Office - M.D. Anderson Cancer Center, 713-792-3245  
 Jon Trent, MD, PhD

## BEZ235

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path

NCT #: [NCT00620594](#)

Contact: Novartis  
 862-778-8300

### Nevada Cancer Institute

Las Vegas, NV

Dianna Tercan  
 (702) 822-5483

Wolfram Samlowski, M.D.

### Sarah Cannon Research Institute

Nashville, TN  
 615-329-7224

615-986-4347

[hburris@tnonc.com](mailto: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  
 Conditions: Solid Tumors  
 Strategy: Destroy KIT

NCT #: [NCT00618735](#)

Contact: Biogen Idec

[oncologyclinicaltrials@biogenidec.com](mailto:oncologyclinicaltrials@biogenidec.com)

### South Texas Accelerated Research Therapeutics (START)

San Antonio, TX

## 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  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path

NCT #:

Contact:

### Dana Farber Cancer Institute

Boston, MA

Melissa Hohos

617 632-2201

[mhohos@partners.org](mailto:mhohos@partners.org)

George Demetri, MD, PhD

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206

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Office 480-323-1339

Fax 480-323-1250

## IPI-493

*A Phase I Dose Escalation Study of IPI-493*

Phase: 1  
 Conditions: Solid Tumors

Strategy: Destroy KIT

NCT #: [NCT00724425](#)

Contact:

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Scottsdale, AZ

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480 860-5000

[pshannon@premiereoncology.com](mailto:pshannon@premiereoncology.com)

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Lee Rosen M.D.

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[stacy.grolnic@uchsc.edu](mailto:stacy.grolnic@uchsc.edu)

Colin Weeks, MD, PhD

## PX-478

*Phase I Trial of PX-478*

Phase: 1

Conditions: Solid Tumors

Strategy: Block related tumor signal paths

Block tumor blood vessel

NCT #: [NCT00522652](#)

Contact:

### TGen Clinical Research Services

Scottsdale, AZ

Lynne Hull

480-323-1071

[lhull@shc.org](mailto:lhull@shc.org)

Daniel D. Hoff, MD

### MD Anderson Cancer Center

Houston, TX

Hala Abdulkadir

713-792-9944

[habdulka@mdanderson.org](mailto:habdulka@mdanderson.org)

Roy S. Herbst, PhD

## PX-866

*Phase I Trial of Oral PX-866*

Phase: 1

Conditions: Solid Tumors

Strategy: Block KIT Signal Path

NCT #: [NCT00726583](#)

Contact:

### University of Colorado

Aurora, CO

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720-848-0667

[sharon.hecker@ucdenver.edu](mailto:sharon.hecker@ucdenver.edu)

Antonio Jimeno, MD

**MD Anderson Cancer Center**  
 Houston, TX  
 Rhonda Clement  
 713-563-3559  
 rclement@mdanderson.org  
 Roy Herbst, MD

## R1507

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block related tumor signal paths  
 NCT #: [NCT00560144](#)  
 Contact: Please reference Study ID Number: PDO\_NO21200  
                   973-235-5000 or 800-526-6367 (FOR US ONLY)  
                   973 235-5000

**Memorial Sloan-Kettering Cancer Center**  
 New York, NY  
 212-639-8267  
 Dr. Tanya Trippett

**MD Anderson Cancer Center**  
 Houston, TX  
 800-392-1611 Patients  
 800-392-1611 Referring MD  
 Cynthia E. Herzog

**Site name unknown, Denver 80218**  
 Denver, CO

**Site name unknown, Bethesda 20982**  
 Bethesda, MD

## SNX-5422

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

Phase: 1  
 Conditions: Solid Tumors  
 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  
                   877-369-9753  
[PfizerCancerTrials@emergen  
gmed.com](mailto:PfizerCancerTrials@emergen<br/>gmed.com)

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 Office 480-323-1339  
**Sarah Cannon Research Institute**  
 Nashville, TN  
 Jessica Gilbert  
 615 329-7238  
 Howard A. Burris, III MD

## SNX-5422

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

Phase: 1  
 Conditions: Solid Tumors  
 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  
                   1-877-369-9753  
[PfizerCancerTrials@emergen  
gmed.com](mailto:PfizerCancerTrials@emergen<br/>gmed.com)  
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 Bethesda, MD  
 Contact: Pfizer Oncology Clinical Trial Information Service 1-877-369-9753  
                   PfizerCancerTrials@emergen  
                   gmed.com

## Sorafenib + Vorinostat

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT + Unblock cell death genes + Destroy KIT  
 NCT #: [NCT00635791](#)  
 Contact:  
**University of Colorado**  
 Aurora, CO  
 Stacy Grolnic  
 720-848-0655  
 stacy.grolnic@uchsc.edu  
 David Ross Camidge MD

## STA-9090

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Destroy KIT  
 NCT #: [NCT00687934](#)

Contact:  
**Premier Oncology, Santa Monica**  
 Santa Monica, CA  
 310-633-8400  
 Lee Rosen  
**US Oncology - Dayton Oncology & Hematology**  
 Kettering, OH  
 robert.raju@usoncology.com  
 (937)293-1622  
 Robert Raju

## STA-9090

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Destroy KIT  
 NCT #: [NCT00688116](#)

Contact:  
**Dana Farber Cancer Institute**  
 Boston, MA  
 Melissa Hohos, RN,  
 617-632-2201  
 Geoffrey Shapiro, MD, PhD  
**Karmanos Cancer Institute**  
 Detroit, MI  
 Dr. Patricia LoRusso  
 313-576-8716  
  
**Massachusetts General Hospital**  
 Charlestown, MA  
 Pilar De La Roche Mur  
 617-632-5841  
  
**Beth Israel Deaconess Medical Center**  
 Boston, MA  
 Pilar De La Roche Mur  
 617-632-5841

## Sunitinib + CP-751

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT + Block related tumor signal paths  
 NCT #: [NCT00729833](#)  
 Contact: Pfizer CT.gov Call Center  
 EmergingMed  
 800 718-1021  
[PfizerCancerTrials@emergin\\_gmed.com](mailto:PfizerCancerTrials@emergin_gmed.com)  
**Premier Oncology, Santa Monica**  
 Santa Monica, CA  
 310 633-8400  
 Lee Rosen  
**South Texas Accelerated Research Therapeutics (START)**  
 San Antonio, TX

## XL765

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block related tumor signal paths  
 NCT #: [NCT00485719](#)  
 Contact: Exelixis Contact Line  
 866-939-4041  
**Karmanos Cancer Institute**  
 Detroit, MI  
 Theresa Laeder 313-576-9386  
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**South Texas Accelerated Research Therapeutics (START)**  
 San Antonio, TX  
 Gina Mangold, MBA 210-413-3594  
[gmangold@start.stoh.com](mailto:gmangold@start.stoh.com)  
 Kyriakos Papadopoulos, MD

## XL147

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path  
 NCT #: [NCT00486135](#)  
 Contact: Exelixis Contact Line  
 866-939-4041  
**Dana Farber Cancer Institute**  
 Boston, MA  
 Pilar de la Rocha Mur  
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[pilar\\_DeLaRochaMur@dfci.harvard.edu](mailto:pilar_DeLaRochaMur@dfci.harvard.edu)  
 Geoffrey Shapiro, MD  
**Mary Crowley Medical Research Center**  
 Dallas, TX  
 J.R. Dolan  
 214-658-1943  
 Gerald Edelman MD, PhD

# International Clinical Trial Update

## Sunitinib

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

Phase: 4

Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT

NCT #: [NCT00793871](#)

Contact: Pfizer Oncology Clinical Trial Information Service 1 -877-369-9753  
[PfizerCancerTrials@emergen gmed.com](mailto:PfizerCancerTrials@emergen gmed.com)  
 Pfizer CT.gov Call Center 1 -800-718-1021  
 1-877-369-9753

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 Beijing, China

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

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

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

## IPI-504

*Study of IPI-504 in GIST patients following failure of at least imatinib and sunitinib*

Phase: 3

Conditions: Gastrointestinal Stromal Tumor

Strategy: Destroy KIT

NCT #: [NCT00688766](#)

Contact: GIST Phase 3 Team  
<http://www.ringtrial.com/>  
 877-504-4634  
[RINGtrialinfo@infi.com](mailto:RINGtrialinfo@infi.com)

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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  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
 NCT #: [NCT00812240](#)  
 Contact: Antoine Adenis, M.D.  
 +33 (0)3 20 29 59 59  
[a-adenis@o-lambret.fr](mailto:a-adenis@o-lambret.fr)

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**Hopital Charles Nicolle**  
 Rouen, France

**Centre Hospitalier Victor Jousselain**  
 Dreux, France

**Centre Rene Huguenin**  
 Saint-Cloud, France

**Centre Rene Gauducheau**  
 Nantes, France

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 Besancon, France

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 Patrice Viens, MD, PhD

**Centre Val d'Aurele**  
 Montpellier, France

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 Orleans, France

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 Dora, Lebanon

**Middle East Institute of Health**  
 Bsalmi, Lebanon

**Hamoud Hospital**  
 Saida, Lebanon

**American University Hospital**  
 Beirut, Lebanon

## Nilotinib or Imatinib

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

Phase: 3  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
 NCT #: [NCT00785785](#)  
 Contact: Novartis Pharmaceuticals  
 +1-800-340-6843  
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**Regional Cancer center**  
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 Cristobal Belda-Iniesta, MD

## 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  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT  
 NCT #: [NCT00372567](#)  
 Contact: Pfizer Oncology Clinical Trial Information Service  
 1-877-369-9753  
[PfizerCancerTrials@emergen\\_gmed.com](mailto:PfizerCancerTrials@emergen_gmed.com)  
 1-800-718-1021  
 1-877-369-9753  
[PfizerCancerTrials@emergen\\_gmed.com](mailto:PfizerCancerTrials@emergen_gmed.com)

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**Royal Marsden Hospital**  
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**Southwest German Cancer Center at Eberhard-Karls University**  
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 49-707-1298-2127  
 joerg.hartmann@med.uni-tuebingen.de  
 Joerg T. Hartmann, MD

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 Mannheim, Germany

**Site name unknown, Goettingen 37075**  
 Goettingen, Germany

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 Glasgow, UK

**Site name unknown, London NW1 2PG**  
 London, UK

**Site name unknown, Seoul 110-744**  
 Seoul, Republic of Korea

**Site name unknown, London W1**  
 London, UK

## Dasatinib (BMS-354825)

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

Phase: 2

Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT + Block KIT Signal Path

NCT #: [NCT00568750](#)

Contact: Centre Hospitalier Universitaire Vaudois  
 Lausanne, Switzerland, CH-1011  
 41-21-314-0150

**Centre Hospitaleir Universitaire Vaudois**  
 Lausanne, Switzerland  
 41-21-314-0150

Michael Montemurro, MD

## Imatinib

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

Phase: 2

Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT

NCT #: [NCT00764595](#)

Contact: Tatsuo Kanda, MD  
 Niigata University Medical and Dental Hospital  
 81-25-227-2228

**Niigata University Medical and Dental School**  
 Niigata, Japan

81-25-227-2228  
 Tatsuo Kanda, MD

## Imatinib + RAD001

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

Phase: 2

Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT

Block KIT Signal Path

NCT #: [NCT00510354](#)

Contact: Novartis Basel  
 41 61 324 1111

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 Bad Saarow, Germany

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**Site name unknown, Mannheim**  
 Mannheim, Germany

**Site name unknown, Munchen**  
 Munchen, Germany

**Site name unknown, Tubingen**  
 Tubingen, Germany

**Site name unknown, Essen**  
 Essen, Germany

**Site name unknown, Hannover**  
 Hannover, Germany

## Nilotinib

*Efficacy and Safety of AMN107 in Patients With GastroIntestinal Stromal Tumors (GIST) Who Have Failed Both Imatinib and Sunitinib*

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT

NCT #: [NCT00718562](#)

Contact: Novartis Japan 81 3 3797 8748 Novartis US 862 -778-8330

**Site name unknown,**  
**Hokkaido**  
Hokkaido, Japan

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Niigata, Japan

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Chiba, Japan

**Site name unknown, Tokyo**  
Tokyo, Japan

**Site name unknown, Kyushu**  
Kyushu, Japan

**Site name unknown, Aichi**  
Aichi, Japan

**Site name unknown, Osaka**  
Osaka, Japan

**Site name unknown,**  
**Shizuoka**  
Shizuoka, Japan

## Nilotinib

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

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor

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

## Surgery

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

Phase: 2

Conditions: Gastrointestinal Stromal Tumor

Strategy: Surgery

NCT #: [NCT00769782](#)

Contact: Tatsuo Kanda, MD  
Niigata University Medical and Dental Hospital  
81-25-227-2228

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

## Nilotinib

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

Phase: 2  
Conditions: Gastrointestinal Stromal Tumor

Strategy: Block KIT

NCT #: [NCT00756509](#)

Contact: + 41 61 324 1111

**Site name unknown, Bad Saarow**  
Bad Saarow, Germany

## Radiation

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

Phase: 1

Conditions: Gastrointestinal Stromal Tumor

Strategy: Radiation

NCT #: [NCT00515931](#)

Contact: Heikki Joensuu, M.D., Ph.D.  
947173208 Ext. 358  
[heikki.joensuu@hus.fi](mailto:heikki.joensuu@hus.fi)

**Helsinki University Central Hospital**  
Helsinki, Finland  
Heikki Joensuu, M.D., Ph.D.  
947173208 Ext. 358 heikki.  
Heikki Joensuu, MD

## *Study to the Optimal Duration of Therapy With Oral Angiogenesis Inhibitors*

Phase: 4  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block tumor blood vessel growth  
 NCT #: [NCT00777504](#)  
 Contact: C.M.L. van Herpen, Md, PhD  
 31 24 3610353  
[vanherpen@onco.umcn.nl](mailto:vanherpen@onco.umcn.nl)  
**University Medical Center Nijmegen st Raboud**  
 Nijmegen, Gelderland, GelderlandNetherlands  
 Contact: C.M.L. van Herpen, Md, PhD 31 24 3610353  
 C.M.L van Herpen, Md, PhD

## **Everolimus**

### *Treatment of Patients With RAD001 Who Have Progressive Sarcoma*

Phase: 2  
 Conditions: Sarcoma  
 Strategy: Block KIT Signal Path  
 NCT #: [NCT00767819](#)  
 Contact: Novartis Basel +41 61 324 1111 Novartis US 862-778-8300  
**Site name unknown, Berlin**  
 Berlin, Germany  
**Site name unknown, Munchen**  
 Munchen, Germany  
**Site name unknown, Dusseldorf**  
 Dusseldorf, Germany  
**Site name unknown, Mannheim**  
 Mannheim, Germany

## **Imatinib + IL-2**

### *Imatinib + IL-2*

Phase: 1  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Block KIT + Stimulate the immune system  
 NCT #:  
 Contact: Dr Patricia Pautier  
 téléphone direct/standard : - / 01 42 11 42 11  
 courriel : -  
 Institut Gustave Roussy (IGR)  
 +33 (0)1 42 11 42 10  
[lannes@igr.fr](mailto:lannes@igr.fr)  
**Institut Gustave-Roussy**  
 Villejuif Cedex, France  
 Dr Patricia Pautier  
 téléphone direct/standard : - / 01  
 Laurence Zitvogel

## **Multi-bacteria vaccine (MBV)**

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

Phase: 1  
 Conditions: Gastrointestinal Stromal Tumor  
 Strategy: Stimulate the immune system  
 NCT #: [NCT00623831](#)  
 Contact: Krankenhaus Nordwest Frankfurt, Germany  
 Antje Neumann 069 7601 4161  
[neumann.antje@khnw.de](mailto:neumann.antje@khnw.de)  
**Krankenhaus Nordwest**  
 Frankfurt, Germany  
 Elke Jaeger, MD

## **AUY922**

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Destroy KIT  
 NCT #: [NCT00526045](#)  
 Contact: 1 800 340-6843  
**Site Name unknown, Bellinzona**  
 Bellinzona, Switzerland

## **BGT226**

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

Phase: 1  
 Conditions: Solid Tumors  
 Strategy: Block KIT Signal Path  
 NCT #: [NCT00600275](#)  
 Contact: Novartis 800 340-6843  
**Hospital Vall d'Hebron**  
 Barcelona, Spain  
**Princess Margaret Hospital**  
 Toronto, ON, ONCanada  
 Lillian Siu, M.D.

## XL147

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

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Phase: 1  
Conditions: Solid Tumors  
Strategy: Block KIT Signal Path  
NCT #: [NCT00486135](#)  
Contact: Exelixis Contact Line  
866-939-4041  
**Hospital Vall d'Hebron**  
Barcelona, Spain  
Gemma Sala  
+34 93 489 4158  
Jose Baselga, MD, PhD

## XL765

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

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Phase: 1  
Conditions: Solid Tumors  
Strategy: Block related tumor signal  
paths  
NCT #: [NCT00485719](#)  
Contact: Exelixis Contact Line  
866-939-4041  
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