May 2009 Clinical Trials Update

By Jim Hughes
LRG Clinical Trials Coordinator

Infinity IPI-504 Phase 3 RING trial in resistant GIST terminated:
Infinity Pharmaceuticals Inc. announced April 15 that it had elected to terminate the IPI-504 phase 3 RING trial in resistant GIST upon the recommendation of its independent data monitoring committee (IDMC). The IDMC’s recommendation to halt the trial was based on an early review of safety data from the first 46 patients enrolled in the study, which showed a higher than anticipated mortality rate among patients enrolled in the treatment arm. Infinity also announced that patients participating in the trial would no longer receive IPI-504. The Life Raft Group continues to explore the options available for RING trial participants and will report additional details as they are available and can be verified. Patients who participated in (or were planning on entering) the RING trial and are now seeking options can call the LRG office at 973-837-9092 or email us at liferaft@liferaftgroup.org

Novartis Imatinib or Nilotinib Phase 3 first line advanced GIST now recruiting in US:
This is a large international trial designed to ascertain if nilotinib is a better therapy for newly diagnosed advanced GIST patients. GIST patients who have not received prior TKI (tyrosine kinase inhibitor) therapy will be randomly assigned to receive either imatinib or nilotinib. The primary goal is to determine progression-free survival in both groups. Sites are now open in Southern California (City of Hope), Austria, Canada, Spain and Thailand. This trial plans to accrue over 700 participants in North and South America, Europe, Africa and South-East Asia. And will be collecting data for over ten years.

Astex Therapeutics AT13387 Phase 1 HSP-90 inhibitor added for resistant solid tumors:
This phase 1 trial is designed to determine the maximum tolerable dose and the safety of AT13387. AT13387 is a small molecule HSP-90 inhibitor. It differs from IPI-504 in that it was designed specifically for HSP-90 inhibition. IPI-504 is a soluble refinement of the drug 17-AAG which in turn is a synthetic form of the antibiotic Geldanamycin. Geldanamycin has HSP-90 inhibition properties but also exhibits hepatotoxicity. Astex describes their fragmented drug design platform which they claim uses as starting points very small, low molecular weight, drug fragments. Astex asserts that these fragments have the potential to keep the overall complexity and molecular weight of each drug candidate low. Astex also claims that this results in “high ligand efficiency” and “results in drug candidates having lower molecular weight, reduced metabolic liability, improved target selectivity and ease of chemical synthesis.” This trial is running at three closely related centers in the Longwood medical area of Boston. The Principal Investigator is Geoffrey Shapiro, MD, PhD and Director of the Early Drug Development Center at Dana-Farber Cancer Institute (DFCI) a position similar to George Demetri’s at the Sarcoma Center. We are publishing all contact information but would suggest contacting Dana-Farber first and coordinating participation with the Sarcoma Center.

“Preoperative and Postoperative Imatinib Mesylate Study in Patients With c-Kit Positive GIST” at MD Anderson:
This Phase 2 trial has stopped recruiting new patients and is now ongoing.

Mt Sinai School of Medicine Added Sunitinib & Stereotatic Radiation Phase 2:
This trial will accept GIST patients. It is similar to a trial now running in Helsinki, Finland and another in Australia. Historically, GIST tumors have not responded to radiotherapy. Concurrent TKI therapy and the advent of newer radiation technologies may open the pos-
From Page 1

sibility of effectively treating selected tumors with radiation. This trial targets “oligometastatic disease”. “Oligo” is a prefix meaning roughly “a few”. A recent retrospective of 12 GIST patients treated with radiation therapy at the Royal Marsden in London was presented at the 2008 Connective Tissue Oncology Society (CTOS) conference. The poster concluded that “A dose of 30 Gy in 10# given over 2 weeks appears to give effective, durable symptom control with minimal toxicity and should be considered for selected patients with this diagnosis (GIST).”

**Novartis Nilotinib Phase 2 Japan for resistant GIST:**
This trial is ongoing and no longer recruiting participants.

**Southwest Oncology Group (SWOG)**

First Line Options for Advanced GIST

### Figure 1: United States

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<tr>
<th>Drugs</th>
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### Figure 2: International

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

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**

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**Figure 4: International**

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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/PDGFRα inhibitor
- **Strategy:** Block KIT
- **NCT #:** NCT00764595
- **Contact:** Tatsuo Kanda, MD
  - Niigata University Medical and Dental Hospital
  - Niigata, Japan
  - 81-25-227-2228

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

#### 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

- **Lombardi CCC at Georgetown University**
  - Washington, DC USA
  - Clinical Trials Office
  - 202-444-0381

- **Iowa Oncology Research Association - CCOP**
  - Des Moines, IA USA
  - Clinical Trials Office
  - 515-244-7586
  - Roscoe F. Morton, MD

- **Carle Cancer Center - CCOP**
  - Urbana, IL USA
  - Clinical Trials Office
  - 217-383-3394
  - Kendrith Rowland, MD

- **University of Chicago**
  - Chicago, IL USA
  - Clinical Trials Office
  - 773-702-4324
  - Hedy Kindler, MD

### Treatment Stage: First-line

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

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

### Additional Trial Sites

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

- **Kalamazoo - CCOP**
  - Kalamazoo, MI USA
  - 269-373-7458
  - Raymond S. Lord, MD

- **Metro Minnesota - CCOP**
  - St. Louis ParK, MN USA
  - 592-993-1517
  - Patrick J. Flynn, MD

- **Ozarks Regional - CCOP**
  - Springfield, MO USA
  - 417-269-4520
  - John W. Goodwin, MD

- **University of Mississippi Cancer Clinic**
  - Jackson, MS USA
  - Robert D. Hamilton
  - 601-984-5590

- **Montana Cancer Consortium - CCOP**
  - Billings, MT USA
  - 406-238-6290
  - Benjamin Marchello, MD

- **Southeast Cancer Control Consortium - CCOP**
  - Winston-Salem, NC USA
  - 910-777-3036
  - James M. Atkins, MD

- **University of New Mexico Cancer Clinic**
  - Albuquerque, NM USA
  - 505-272-6972

- **Syracuse Hematology-Oncology Associate of Central New York - CCOP**
  - East Syracuse, NY USA
  - 315-472-7504
  - Jeffrey J. Kirshner, MD

- **Roswell Park Cancer Institute**
  - Buffalo, NY USA
  - 877-275-7724

- **Dayton Clinical Oncology Program - CCOP**
  - Kettering, OH USA
  - 937-395-8678
  - Howard M Gross, MD
**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/PDGFRα inhibitor
- **Strategy:** Block KIT
- **NCT #:** NCT00812240
- **Contact:** Antoine Adenis, M.D. +33 (0)3 20 29 59 59 a-adenis@o-lambret.fr

**Centre Oscar Lambret - Lille**
Lille, France
Antoine Adenis, MD

**Centre Leon Berard**
Lyon, France
+33607507064
blay@lyon.fnclcc.fr
Jean Yves-Blay, MD, PhD

**Centre Georges Francois Leclerc**
Dijon, France

**Hopital Charles Nicolle**
Rouen, France

**Centre Hospitalier Victor Joussetin**
Dreux, France

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

**Centre Rene Gauducheur**
Nantes, France

**Hopital Jean Minjorg**
Besancon, France

**Institut Paoli Calmette**
Marseilles, France
Patrice Viens, MD, PhD

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

**Hopital de la Source**
Orleans, France

**Hopital Europeen Georges Pompidou**
Paris, France

**Institut Bergonie**
Bordeaux, France
Binh Bui Nguyen, MD

**Hopital Robert Debre**
Reims, France

**Hopital Saint-Georges**
Beirut, Lebanon

**Hopital Saint-Joseph**
Dora, Lebanon

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

**Hamoud Hospital**
Saida, Lebanon

**American University Hospital**
Beirut, Lebanon

**MD Anderson - Orlando**
Orlando, FL USA
Clinical Trials Office - M.D. Anderson Cancer Center,
713-792-3245
Jon Trent, MD, PhD

**Henry Ford Health System**
Detroit, MI USA

**Beth Israel Medical Center**
New York, NY USA
**Nilotinib or Imatinib**

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

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<td>Contact:</td>
<td>Novartis Pharmaceuticals +1-800-340-6843</td>
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</table>

**National Cancer center Hospital East**
Chiba, Japan
Toshihiko Doi, MD +81-4-7133-1111
tdoi@east.ncc.go.jp
Toshihiko Doi, MD

**Shizuoka Cancer Center**
Shizuoka, Japan
Yusuke Onozawa +81-55-989-5222
y.onozawa@scchr.jp
Yusuke Onozawa, MD

**Aichi Cancer center Hospital**
Aichi, Japan
Ando Rie +81-52-762-6111
jutaku_a@aiuchi.cc.jp
Akira Sawaki, MD

**Hokkaido University Hospital**
Hokkaido, Japan
Yoshito Komatsu +81-11-706-5657
Yoshito Komatsu, MD

**National Cancer Center Hospital Singapore**
Singapore, Singapore
Simon Ong, MD +65 6436 8000
Simon Ong, MD

**The Cancer Institute/National University Hospital**
Singapore, Singapore
Yong W. Peng, MD +65 6772 4670
wei_peng_yong@nuh.com.sg
Yong W. Peng, MD

**Chulalongkorn University**
Bangkok, Thailand
Virote Sriumpong, MD +66-2-256-4533
vsrmtcu40@gmail.com
Virote Sriumpong, MD

**Prince of Songkla University**
Songkla, Thailand
Patrapim Sunpaweravong, MD +66-74-451-469
patrapim@medicine.psu.ac.th
Patrapim Sunpaweravong, MD

**Khon Kaen University**
Khon Kaen, Thailand
O-Tur Saeseow, MD +66-43-366-569
otur2000@yahoo.com
O-Tur Saeseow, MD

**Sriraj Hospital**
Bangkok, Thailand
Vichien Srimuninnimit, MD +66-2-419-4488
vsrimuninnimit@gmail.com
Vichien Srimuninnimit, MD

**Universitätsklinik f. Innere Medizin**
Vienna, Austria
Thomas Brodowicz, MD +43-40400-4466
Thomas Brodowicz, MD

**GVI Oncology**
Panorama, South Africa
J. C. Hanekom +27-21-930-7602
je.hanekom@cancercare.co.za
J. I. Raats, MD

**National Cancer Center Hospital East**
Chiba, Japan
Toshihiko Doi, MD +81-4-7133-1111
tdoi@east.ncc.go.jp
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**Shizuoka Cancer Center**
Shizuoka, Japan
Yusuke Onozawa +81-55-989-5222
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jutaku_a@aiuchi.cc.jp
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Yong W. Peng, MD

**University Hospital La Paz**
Madrid, Spain
Cristobal Belda-Iniesta, MD 34-1-2071138
cbelda.hulp@salud.madrid.org
Cristobal Belda-Iniesta, MD

**Consorci Hospitalal Parc Tauli**
Barcelona, Spain
Jose G. Ruiz +34-93-242-579
jgarciar@tauli.cat
Charles Pericay, MD

**Chulalongkorn University**
Bangkok, Thailand
Virote Sriumpong, MD +66-2-256-4533
vsrmtcu40@gmail.com
Virote Sriumpong, MD

** prince of Songkla University**
Songkla, Thailand
Patrapim Sunpaweravong, MD +66-74-451-469
patrapim@medicine.psu.ac.th
Patrapim Sunpaweravong, MD

**Khon Kaen University**
Khon Kaen, Thailand
O-Tur Saeseow, MD +66-43-366-569
otur2000@yahoo.com
O-Tur Saeseow, MD

**Sriraj Hospital**
Bangkok, Thailand
Vichien Srimuninnimit, MD +66-2-419-4488
vsrimuninnimit@gmail.com
Vichien Srimuninnimit, MD

**Universitätsklinik f. Innere Medizin**
Vienna, Austria
Thomas Brodowicz, MD +43-40400-4466
Thomas Brodowicz, MD

**Site name unknown, Sao Paulo**
Sao Paulo/SP, Brazil

**Site name unknown, Uberlandia**
Uberlandia/MG, Brazil

**Oncologos del Occidente S.A.**
Pareira, Colombia
Paula Londono, MD +57-6-3310712
palodelosrios@gmail.com
Gustavo Rojas, MD

**Fundacion Santa Fe Bogota**
Bogota, Colombia
Natalia Arango, MD +57-1-5207787
natiarang@hotmail.com
Carlos Vargas, MD

**Oncomedica S.A./Instituto Medico de Alta Tecnologia**
Monteria, Colombia
Sandra Aruachan, MD +57-4-7854344
sandra.aruachan@gmail.com
Manuel Gonzalez, MD

**Birmingham Heartlands Hospital**
Birmingham, UK
James Whitehouse +44-0121-424-2187
james.whitehouse@heartofengland.nhs.uk
Ian Geh, MD

**Royal Marsden Hospital**
London, UK
Ian Judson +44-207-808-2200
Ian Judson, MD

**Beatson West of Scotland Cancer Centre**
Glasgow, UK
Jeff White, MD 011-0141-3017060
jeff.white@ggc.scot.nhs.uk
Jeff White, MD

**Arhus University Hospital**
Arhus, Denmark
Malene Bendix +45-8949-2683
malebend@rm.dk
Akmal Safwat, MD
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<td>Weiijing Sun, MD</td>
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<tr>
<td>Brad Baltz, MD</td>
<td>City of Hope - Pasadena</td>
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<tr>
<td><a href="mailto:narora@coh.org">narora@coh.org</a></td>
<td>412-647-6468</td>
</tr>
<tr>
<td>Warren Chow, MD</td>
<td><a href="mailto:schmotzerar@upmc.edu">schmotzerar@upmc.edu</a></td>
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<tr>
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<tr>
<td>J. Randolph Hecht</td>
<td>412-647-6468</td>
</tr>
<tr>
<td>Moores Cancer Center/UCSD Medical center</td>
<td><a href="mailto:schmotzerar@upmc.edu">schmotzerar@upmc.edu</a></td>
</tr>
<tr>
<td>La Jolla, CA USA</td>
<td>Nathan Bahary, MD</td>
</tr>
<tr>
<td>Sue A Castro</td>
<td>Mazdaonueve-Rosemont Hospital</td>
</tr>
<tr>
<td>858-822-5353</td>
<td>Montreal, QC Canada</td>
</tr>
<tr>
<td><a href="mailto:scastro@ucsd.edu">scastro@ucsd.edu</a></td>
<td>Lucas Sideris, MD</td>
</tr>
<tr>
<td>Tony Reid, MD</td>
<td>514-252-3489</td>
</tr>
<tr>
<td>Stanford Cancer Center</td>
<td>Lucas Sideris, MD</td>
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<tr>
<td>Palo Alto, CA USA</td>
<td>MD Anderson Cancer Center</td>
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<tr>
<td>Diane Ayala</td>
<td>Houston, TX USA</td>
</tr>
<tr>
<td>650-725-9057</td>
<td>Diane Gravel</td>
</tr>
<tr>
<td><a href="mailto:dayala1@stanford.edu">dayala1@stanford.edu</a></td>
<td>713-563-6702</td>
</tr>
<tr>
<td>George A. Fisher, MD</td>
<td><a href="mailto:dgravel@mdanderson.org">dgravel@mdanderson.org</a></td>
</tr>
<tr>
<td>Samuel Oschin Comprehensive Cancer Center</td>
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<tr>
<th><strong>University of Colorado</strong></th>
<th><strong>Simmons Cancer Center</strong></th>
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<tr>
<td>Aurora, CO USA</td>
<td>Univ. of Texas SW Medical Center</td>
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<tr>
<td>Heather Hallman</td>
<td>Dallas, TX USA</td>
</tr>
<tr>
<td>720-848-0678</td>
<td>Shelly Shereda</td>
</tr>
<tr>
<td><a href="mailto:Heather.hallman@ucdenver.edu">Heather.hallman@ucdenver.edu</a></td>
<td>214-648-7094</td>
</tr>
<tr>
<td>Anthony D. Elias, MD</td>
<td><a href="mailto:Shelly.sheridan@utsouthwestern.edu">Shelly.sheridan@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>Mary Potter Oncology Center</td>
<td>Deni von Merveldt</td>
</tr>
<tr>
<td>Pretoria, Gauteng South Africa</td>
<td>214 648 5107</td>
</tr>
<tr>
<td>Erika Bosch</td>
<td><a href="mailto:Dendra.vonmerveldt@utsouthwestern.edu">Dendra.vonmerveldt@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>+27-12-346-6701</td>
<td>Parkland Health &amp; Hospital System</td>
</tr>
<tr>
<td><a href="mailto:ericka.bosch@mpoc.co.za">ericka.bosch@mpoc.co.za</a></td>
<td>Dallas, TX USA</td>
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<tr>
<td>G. L. Cohen, MD</td>
<td>Yull Arriaga, MD</td>
</tr>
<tr>
<td>Sandton Oncology Centre</td>
<td>214-648-4180</td>
</tr>
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<td>Johannesburg, Gauteng</td>
<td>Yull Arriaga, MD</td>
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<td>South Africa</td>
<td>University of Pittsburgh Cancer Center</td>
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<tr>
<td>Robert Lurie Comp.</td>
<td>Pittsburgh, PA USA</td>
</tr>
<tr>
<td>Cancer Center</td>
<td>Amy Schmotzer</td>
</tr>
<tr>
<td>Northwestern University</td>
<td>412-647-6468</td>
</tr>
<tr>
<td>Hospital</td>
<td><a href="mailto:schmotzerar@upmc.edu">schmotzerar@upmc.edu</a></td>
</tr>
<tr>
<td>Chicago, IL USA</td>
<td>Nathan Bahary, MD</td>
</tr>
<tr>
<td>Christopher Curtin</td>
<td>Mazdaonueve-Rosemont Hospital</td>
</tr>
<tr>
<td>312-695-1331</td>
<td>Montreal, QC Canada</td>
</tr>
<tr>
<td><a href="mailto:c-curtin@northwestern.edu">c-curtin@northwestern.edu</a></td>
<td>Lucas Sideris, MD</td>
</tr>
<tr>
<td>Drashi Desai</td>
<td>MD Anderson Cancer Center</td>
</tr>
<tr>
<td>312-695-1378</td>
<td>Houston, TX USA</td>
</tr>
<tr>
<td>Mark Agulnik, MD</td>
<td>Diane Gravel</td>
</tr>
<tr>
<td>University of Kansas</td>
<td>713-563-6702</td>
</tr>
<tr>
<td>Cancer Center</td>
<td><a href="mailto:dgravel@mdanderson.org">dgravel@mdanderson.org</a></td>
</tr>
<tr>
<td>Westwood, KS USA</td>
<td>Vu Ta</td>
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<tr>
<td>Christopher Baierl</td>
<td>713-792-2848</td>
</tr>
<tr>
<td>913-588-4721</td>
<td>Jon Trent, MD, PhD</td>
</tr>
<tr>
<td>Margaret Hapgood</td>
<td>Simmons Cancer Center</td>
</tr>
<tr>
<td>913-588-2566</td>
<td>Univ. of Texas SW Medical Center</td>
</tr>
<tr>
<td><a href="mailto:mhapgood@kumc.edu">mhapgood@kumc.edu</a></td>
<td>Dallas, TX USA</td>
</tr>
<tr>
<td>Stephen Williamson, MD</td>
<td>Shelly Shereda</td>
</tr>
<tr>
<td>Dana Farber Cancer Institute</td>
<td>214-648-7094</td>
</tr>
<tr>
<td>Boston, MA USA</td>
<td><a href="mailto:Shelly.sheridan@utsouthwestern.edu">Shelly.sheridan@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>George Demetri, MD</td>
<td>Deni von Merveldt</td>
</tr>
<tr>
<td>617-632-3985</td>
<td>214 648 5107</td>
</tr>
<tr>
<td><a href="mailto:gdemetri@partners.org">gdemetri@partners.org</a></td>
<td><a href="mailto:Dendra.vonmerveldt@utsouthwestern.edu">Dendra.vonmerveldt@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>George Demetri, MD, PhD</td>
<td>Parkland Health &amp; Hospital System</td>
</tr>
<tr>
<td>Johns Hopkins Sidney</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Baltimore, MD USA</td>
<td>214-648-4180</td>
</tr>
<tr>
<td>Margaret Fogle</td>
<td>Yull Arriaga, MD</td>
</tr>
<tr>
<td>410-955-7349</td>
<td>University of Pittsburgh Cancer Center</td>
</tr>
<tr>
<td><a href="mailto:mfogel@jhmi.edu">mfogel@jhmi.edu</a></td>
<td>University of Pennsylvania</td>
</tr>
<tr>
<td>Susan Huddock</td>
<td>Philadelphia, PA USA</td>
</tr>
<tr>
<td>410-502-1036</td>
<td>Robin Holmes</td>
</tr>
<tr>
<td><a href="mailto:shudock@jhmi.edu">shudock@jhmi.edu</a></td>
<td>215-615-0360</td>
</tr>
<tr>
<td>Katherine Thornton, MD</td>
<td><a href="mailto:robin.holmes@uphs.upenn.edu">robin.holmes@uphs.upenn.edu</a></td>
</tr>
<tr>
<td>University of Michigan</td>
<td>Lauren Mennine</td>
</tr>
<tr>
<td>Ann Arbor, MI USA</td>
<td>215-349-8913</td>
</tr>
<tr>
<td>Gino Metko</td>
<td><a href="mailto:lauren.mennine@uphs.upenn.edu">lauren.mennine@uphs.upenn.edu</a></td>
</tr>
<tr>
<td>734-647-2095</td>
<td>Weiijing Sun, MD</td>
</tr>
<tr>
<td><a href="mailto:minomi@umich.edu">minomi@umich.edu</a></td>
<td>City of Hope - Pasadena</td>
</tr>
<tr>
<td>Rivka Siden</td>
<td>Doni Macnamara, MD</td>
</tr>
<tr>
<td>734-936-8210</td>
<td>Stanford Cancer Center</td>
</tr>
<tr>
<td><a href="mailto:sidenr@umich.edu">sidenr@umich.edu</a></td>
<td>Palo Alto, CA USA</td>
</tr>
<tr>
<td>Scott Schuetze, MD</td>
<td>Diane Ayala</td>
</tr>
<tr>
<td>Regional Cancer center</td>
<td>626-256-4673 xt 63019</td>
</tr>
<tr>
<td>University of Ottawa</td>
<td><a href="mailto:narora@coh.org">narora@coh.org</a></td>
</tr>
<tr>
<td>Ottawa, Ontario Canada</td>
<td>Warren Chow, MD</td>
</tr>
<tr>
<td>Tim Asmis, MD</td>
<td>Duke University Cancer Center</td>
</tr>
<tr>
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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/PDGFRα inhibitor + SRC inhibitor
Strategy: Block KIT + Block KIT Signal Path
NCT #: NCT00568750
Contact: Centre Hospitalier Universitaire Vaudois Lausanne, Switzerland, CH
41-21-314-0150
Centre Hospitaile Universaire 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: + 41 61 324 1111
Site name unknown, Bad Saarow
Bad Saarow, Germany

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/PDGFRα inhibitor
Strategy: Block KIT
NCT #: NCT00372567
Contact: Pfizer Oncology Clinical Trial Information Service 1-877-369-9753
PfizerCancerTrials@emerginngmed.com
1-800-718-1021
1-877-369-9753
PfizerCancerTrials@emerginngmed.com
Site name unknown, Hamburg 22767
Hamburg, Germany

Istituto Nazionale Dei Tumori
Milan, Italy
Paolo Casali MD
Site name unknown, Bologna 40138
Bologna, Italy

Site name unknown, Seoul 135-710
Seoul, Republic of Korea

Site name unknown, Seoul 138-736
Seoul, Republic of Korea

Site name unknown, Barcelona 08036
Barcelona, Spain

Site name unknown, Valencia 46009
Valencia, Spain

Royal Marsden Hospital
London, UK
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: oncologyclinicaltrials@biogenidec.com

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/PDGFRA inhibitor mTOR inhibitor
Strategy: Block KIT
NCT #: NCT00510354
Contact: Novartis Basel 41 61 324 1111

Site name unknown, Bad Saarow
Bad Saarow, Germany

Site name unknown, Koln
Koln, Germany

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

Site name unknown, Mannheim
Mannheim, Germany

Site name unknown, Goettingen 37075
Goettingen, Germany

Site name unknown, Glasgow G12 0YH
Glasgow, UK

Site name unknown, London NW1 2PG
London, UK

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

Site name unknown, Henderson 89074
Henderson, NV USA

Site name unknown, Henderson 89074
Henderson, NV USA

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

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

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

New York Presbyterian Hospital - Columbia University Medical Center
New York, NY USA
Robert Taub, MD

Cleveland Clinic Taussig Cancer Center
Cleveland, OH USA

Fox Chase Cancer Center
Philadelphia, PA USA
1-888-FOX-CHASE
Margaret von Mehren, M.D.

Evanston Hospital
Evanston, IL USA
Bruce Brockstein, MD

Glenbrook Hospital
Glenside, IL USA
Bruce Brockstein, MD

Highland Park Hospital
Highland Park, IL USA
Bruce Brockstein, MD

Site name unknown, Lai Chi Kok 0
Lai Chi Kok, Kowloon Hong Kong SAR

Christie Hospital NHS Trust
Manchester, Lancashire UK

Karmanos Cancer Institute
Detroit, MI USA
all (800) KARMANOS (1-800-527-6266) or e-mail info@karmanos.org.
Anthony Sheilts, MD
Nilotinib in Advanced GIST

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor
Strategy: Block KIT

Sorafenib (Nexavar, BAY 43-9006)

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

Phase: 2
Stage: Gleevec-resistant
Conditions: Gastrointestinal Stromal Tumor
Drug Type: KIT/PDGFRA inhibitor + VEGF inhibitor (TKI) + RAF inhibitor
Strategy: Block KIT + Block KIT Signal Path
NCT #: NCT00265798
Contact: Clinical Trials Office - University of Chicago Cancer Research 773-834-7424
City of Hope Duarte, CA USA Warren A. Chow, MD, (866) 434-4673 xt 64215 Warren A. Chow, MD
USC-Norris Cancer Center Los Angeles, CA USA 323-865-3955 lenz@hsc.usc.edu Hein-Josef Lenz, M.D
UC-Davis Sacramento, CA USA 916-734-3771 David Gandara, MD
University of Chicago Chicago, IL USA Clinical Trials Office, 773-834-7424 Hedy Kindler, MD
Illinois CancerCare Peoria, IL USA John Kugler, MD, (309) 243-3605 John Kugler, MD
Cancer Care Specialists Decatur, IL USA James Wade III, MD, 217-876-6617, jlwade3@sbcglobal.net James Wade III, MD
**Imatinib + Sunitinib**

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

- **Phase:** 1
- **Stage:** Gleevec-resistant
- **Conditions:** Gastrointestinal Stromal Tumor
- **Drug Type:** KIT/PDGFRA inhibitor
- **Strategy:** Block KIT
- **NCT #:** NCT00573404
- **Contact:** Cancer Information Program 800-811-8480

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

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

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

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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:** C.M.L. van Herpen, Md, PhD 31 24 3610353
  vanherpen@onco.umcn.nl

**University Medical Center Nijmegen st Raboud**
- Nijmegen, Gelderland, Netherlands
- Contact: C.M.L. van Herpen, Md, Phd 31 24 3610353
  c.vanherpen@onco.umcn.nl

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**Dasatinib (BMS-354825)**

*Trial of Dasatinib in Advanced Sarcomas*

- **Phase:** 2
- **Stage:** Gleevec-resistant
- **Conditions:** Gastrointestinal Stromal Tumor
- **Drug Type:** KIT/PDGFRA inhibitor + SRC inhibitor
- **Strategy:** Block KIT + Block KIT Signal Path
- **NCT #:** NCT00464620
- **Contact:** Kathleen Granlund 734-930-7607
  kegranlund@sarctrials.org
  734-930-7607
  kegranlund@sarctrials.org

**Arkansas Children's Hospital**
- Little Rock, AR USA
- Bryce Warren
  WarrenBryceA@uams.edu
  Kimo Stine

---

**Stanford Cancer Center**
- Palo Alto, CA USA
- Marti Lohman 650-725-6413
  mlohan@stanford.edu

**City of Hope**
- Duarte, CA USA
- Neeti Arora 626-256-4673 ext. 63019
  NArora@coh.org
  Warren Chow, MD

**Cedars-Sinai Outpatient Cancer Center**
- Los Angeles, CA USA
- Chi Vu 310-423-2133
  CVu@csoce.com
  Charles Forsher, MD

**University Medical Center Nijmegen st Raboud**
- Nijmegen, Gelderland, Netherlands
- Contact: C.M.L. van Herpen, Md, Phd 31 24 3610353
  c.vanherpen@onco.umcn.nl

---

**Washington Cancer Institute**
- Washington, DC USA
- Christina Sheeran, 202 877-5371
  christina.m.
  sheeran@medstar.net
  Dennis A. Pribat, MD

**University of Iowa Hospitals and Clinics**
- Iowa City, IA USA
- Melanie Frees, RN 319-356-1228
  melanie-frees@uiowa.edu
  Mohammed Milhem, MD

**Kootenai Cancer Center**
- Coeur d'Alene, ID USA
- Sheryl Gordon 208-666-2093
  sgolden@kmc.org
  Brian Samuels, MD

**Oncology Specialists, Park Ridge**
- Park Ridge, IL USA
- Kathy Tölzien 847-268-8569
  ktolzien@oncmed.net
  Pamela Kaiser

**Indiana University Simon Cancer Center**
- Indianapolis, IN USA
- Kristen Potter, MS 317-278-6616
  krpotter@iupui.edu
  Daniel Rushing, MD
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 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

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: David R. D'Adamo, MD, PhD
  212-639-7573
dadamod@mskcc.org
- Memorial Sloan-Kettering Cancer Center
  New York, NY USA
  David D'Adamo, MD, PhD, 212-639-7573.
  David D'Adamo, MD, PhD, 212-639-7573.
**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:** Dr Patricia Pautier
téléphone direct/standard : - / 01 42 11 42 11
courriel : -

Institut Gustave Roussy (IGR)
+33 (0) 42 11 42 10
lannes@igr.fr

Institut Gustave-Roussy
Villejuif Cedex, France
Dr Patricia Pautier
téléphone direct/standard : - / 01 42 11 42 11
courriel : pautier@igr.fr
Laurence Zitvogel
Dr P. Pautier is listed as PI

**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:** Krankenhaus Nordwest
Frankfurt, Germany
Antje Neumann
069 7601 4161
neumann.antje@khnw.de

Krankenhaus Nordwest
Frankfurt, Germany
Elke Jaeger, MD

**SF1126**

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

- **Phase:** 1
- **Stage:** Gleevec-resistant
- **Conditions:** Solid Tumors
- **Drug Type:** PI3K inhibitor
- **Strategy:** Block KIT Signal Path
- **NCT #:**
- **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
jingold@shc.org

TGen Clinical Research Services
Scottsdale, AZ USA
TGen Clinical Research Services
Patient Care Coordinator
10460 N. 92nd Street, Suite 206
Scottsdale, AZ 85258
Office 480-323-1339
Fax 480-323-1259
jingold@shc.org

**Arizona Cancer Center**
Tucson, AZ USA
(520) 694-CURE(2873)
Daruka Mahadevan, MD, PhD

**Indiana University Simon Cancer Center**
Indianapolis, IN USA
(317) 278-6942
gchiorea@iupui.edu
Elena Chiorean

**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:** 1 800 340-6843

Site Name unknown, Bellinzona
Bellinzona, Switzerland

David Geffen School of Medicine at UCLA
Los Angeles, CA USA
CBbritten@mednet.ucla.edu
310-825-5268
Carolyn Britten, M.D.

Medical College of Georgia
Augusta, GA USA
706-721-2505
tsamuel@mcg.edu
Thomas Samuel, M.D.

Dana Farber Cancer Institute
Boston, MA USA
617 632-5053
stephen_hodi@dfci.harvard.edu
Stephen Hodi, MD, PhD

Washington University
St. Louis, MO USA
800-600-3606 or info@ccadmin.wustl.edu
Timothy Pluard, MD

Nevada Cancer Institute
Las Vegas, NV USA
702 822-5433
nvogelzang@nv cancer.org
Nicholas Vogelzang, MD

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
- **Strategy:** Block KIT Signal Path
- **NCT #:** NCT00600275
- **Contact:** Novartis
  800 340-6843

**Hospital Vall d’Hebron**
Barcelona, Spain

**Dana Farber Cancer Institute**
Boston, MA USA
Melissa Hohos
617 632-2201
mhohos@partners.org
George Demetri, MD, PhD

**Massachusetts General Hospital**
Charlestown, MA USA
617-726-6225
nisac1@partners.org
Stephen Isakoff, MD

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

**Princess Margaret Hospital**
Toronto, ON Canada
Lillian Siu, M.D.

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

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**MP470**

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

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

**Virginia Piper Cancer Center**
Scottsdale, AZ USA
Raoul Tiber, MD, 480-323-1350
Raoul Tiber, MD, 480-323-1350

**TGen Clinical Research Services**
Scottsdale, AZ USA
TGen Clinical Research Services
Patient Care Coordinator
10460 N. 92nd Street, Suite 206
Scottsdale, AZ 85258
Office 480-323-1339
Fax 480-323-1259
ijnold@ascc.org

**South Texas Accelerated Research Therapeutics (START)**
San Antonio, TX USA
Anthony Tolcher, MD, (210) 593-5255
Note: Contact number is not verified.
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:** Clinical Trials Office - Warren Grant Magnuson Clinical Center
  888-NCI-1937

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

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**AT13387**

*Phase 1 Study of HSP90 inhibitor AT13387 in solid tumors*

- **Phase:** 1
- **Stage:** Gleevec-resistant
- **Conditions:** Solid Tumors
- **Drug Type:** HSP90 inhibitor
- **Strategy:** Destroy KIT
- **NCT #:** NCT00878423
- **Contact:** Andrew Wolanski
  6176326623
Andrew_Wolanski@dfci.harvard.edu

**Beth Israel Deaconess Medical Center**
Boston, MA USA
Sue Gotthardt RN, OCN
(617) 632-9272
Bruce Dezube M.D.

**Massachusetts General Hospital**
Charlestown, MA USA
Eunice Kwak, MD

**Dana Farber Cancer Institute**
Boston, MA USA
Geoffrey Shapiro, MD
**BAY 73-4506**

*Phase I study of BAY 73-4506*

**Phase:** 1  
**Stage:** Gleevec-resistant  
**Conditions:** Solid Tumors  
**Drug Type:** KIT/PDGFR inhibitor  
**Strategy:** Block KIT  
**NCT #:**  
**Contact:** Tracy Dufresne, RN, BSN, OCN, CCRP  
Physician Referral Coordinator  
210 593-5265  
tracy.dufresne@start.stoh.com

South Texas Accelerated Research Therapeutics (START)  
San Antonio, TX USA  
Tracy Dufresne, RN, BSN, OCN, CCRP  
Physician Referral Coordinator  
Phone: 210-593-5265  
Fax: 210-615-1075  
E-mail: tracy.dufresne@start.stoh.com

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

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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  
**Strategy:** Block KIT Signal Path  
**NCT #:** NCT00620594  
**Contact:** Novartis  
862-778-8300  
Nevada Cancer Institute  
Las Vegas, NV USA  
Dianna Tercan  
(702) 822-5483  
Wolfram Samiowski, M.D.  
Sarah Cannon Research Institute  
Nashville, TN USA  
615-329-7224  
615-986-4347  
hburris@tnonc.com  
Howard A. Burris, III MD

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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

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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:** Block KIT inhibitor  
**Strategy:** Block KIT Signal Path  
**NCT #:** NCT00876109  
**Contact:** Royal Marsden Hospital  
London, UK

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**TGen Clinical Research Services**  
Scottsdale, AZ USA  
Lynne Hull  
480-323-1071  
LHull@SHC.org  
Daniel D. Hoff, MD

**Dana Farber Cancer Institute**  
Boston, MA USA  
Melissa Hohos  
617 632-2201  
mhohos@partners.org  
George Demetri, MD, PhD

**Karmanos Cancer Institute**  
Detroit, MI USA  
Jie Zhang  
313-576-9365  
zhangj@karmanos.org

---

**Royal Marsden Hospital**  
London, UK

---

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

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**South Texas Accelerated Research Therapeutics (START)**  
San Antonio, TX USA
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:
  - Premier Oncology, Scottsdale
    Scottsdale, AZ USA
    Patricia Shannon, RN
    480-860-5000
    pshannon@premiereoncology.com
    David Mendelson, M.D.
  - Premier Oncology, Santa Monica
    Santa Monica, CA USA
    Marilyn Mulay, NP
    310-633-8400
    mmulay@premiereoncology.com
    Lee Rosen M.D.
  - San Diego Pacific Oncology and Hematology Associates
    Encinitas, CA USA
    Karen Brady, RN MSN
    760-752-3340
    kbrady@premiereoncology.com
    Richard Just, M.D.
  - University of Colorado
    Aurora, CO USA
    Stacy Grolnic, RN
    720-848-0655
    stacy.grolnic@uchsc.edu
    Colin Weeks, MD, PhD

PX-478
Phase I Trial of PX-478

- Phase: 1
- Stage: Gleevec-resistant
- Conditions: Solid Tumors
- Drug Type: HIF-1α inhibitor
- Strategy: Block related tumor signal paths
  - Block tumor blood vessel
- NCT #: NCT00522652
- Contact:
  - TGGen Clinical Research Services
    Scottsdale, AZ USA
    Lynne Hull
    480-323-1071
    lhull@shc.org
    Daniel D. Hoff, MD
    MD Anderson Cancer Center
    Houston, TX USA
    Hala Abdulkadir
    713-792-9944
    habdulk@mdanderson.org
    Roy S. Herbst, PhD

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:
  - University of Colorado
    Aurora, CO USA
    Sharon hecker
    720-848-0667
    sharon.hecker@ucdenver.edu
    Antonio Jimeno, MD
    MD Anderson Cancer Center
    Houston, TX USA
    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
- Stage: Gleevec-resistant
- Conditions: Solid Tumors
- Drug Type: IGF1R inhibitor
- 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
- Site name unknown, Denver 80218
  Denver, CO USA
- Site name unknown, Bethesda 20982
  Bethesda, MD USA
- Memorial Sloan-Kettering Cancer Center
  New York, NY USA
  212-639-8267
  Dr. Tanya Trippett
  MD Anderson Cancer Center
  Houston, TX USA
  800-392-1611 Patients
  800-392-1611 Referring MD
  Cynthia E. Herzog
SNX-5422

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

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

NCT #: NCT00506805
Contact: Pfizer Oncology Clinical Trial Information Service, 1-877-369-9753, PfizerCancerTrials@emergin gmed.com

TGen Clinical Research Services
Scottsdale, AZ USA
Joyce Ingold RN MSN OCN
TGen Clinical Research Services
Patient Care Coordinator
10460 N. 92nd Street, Suite 206
Scottsdale, AZ 85258
Office 480-323-1339
Fax 480-323-1759

Sarah Cannon Research Institute
Nashville, TN USA
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
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

Site name unknown, Bethesda 20892
Bethesda, MD USA
Contact: Pfizer Oncology Clinical Trial Information Service 1-877-369-9753
PfizerCancerTrials@emergin gmed.com

Sorafenib + Vorinostat

Phase I Vorinostat + Sorafenib in Patients With Advanced Solid Tumors

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: HDAC inhibitor + KIT/PDGFRa inhibitor
Strategy: Block KIT + Unblock cell death genes + Destroy KIT

NCT #: NCT00635791
Contact: Dana Farber Cancer Institute
Boston, MA USA
Melissa Hohos, RN
617-632-2201
Geoffrey Shapiro, MD, PhD

Massachusetts General Hospital
Charlestown, MA USA
Pilar De La Roche Mur
617-632-5841

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: Sarah Cannon Research Institute
Nashville, TN USA
Jessica Gilbert
615-329-7238
Howard A. Burris, III MD

STA-9090

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

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

NCT #: NCT00688116
Contact: Beth Israel Deaconess Medical Center
Boston, MA USA
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
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: Block KIT + Block related tumor signal paths
NCT #: NCT00729833
Contact: Pfizer CT.gov Call Center
EmergingMed
800 718-1021
PfizerCancerTrials@emergin gmed.com

Premier Oncology, Santa Monica
Santa Monica, CA USA
310 633-8400
Lee Rosen

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

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

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: PI3K inhibitor
Strategy: Block KIT Signal Path
NCT #: NCT00486135
Contact: Exelixis Contact Line
866-939-4041
Hospital Vall d’Hebron
Barcelona, Spain
Gemma Sala
+34 93 489 4158
gsala@vhebron.net
Jose Baselga, MD, PhD

Dana Farber Cancer Institute
Boston, MA USA
Pilar de la Rocha Mur
617-632-5841
pilar_DeLaRochaMur@dfci. harvard.edu
Geoffrey Shapiro, MD

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

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

Phase: 1
Stage: Gleevec-resistant
Conditions: Solid Tumors
Drug Type: Block related tumor signal paths
NCT #: NCT00485719
Contact: Exelixis Contact Line
866-939-4041
Hospital Vall d’Hebron
Barcelona, Spain
Gemma Sala  +34 93 489 4158
gsala@vhebron.net
Jose Baselga, MD, PhD

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

Theresa Laeder
313-576-9386
Patricia LoRusso, DO

South Texas Accelerated Research Therapeutics (START)
San Antonio, TX USA
Gina Mangold, MBA  210-413-3594
gmangold@start.stoh.com
Kyriakos Papadopoulos, MD
## Radiation

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

<table>
<thead>
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<tr>
<td>Stage</td>
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<td>Conditions</td>
<td>Gastrointestinal Stromal Tumor</td>
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<td>Drug Type</td>
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<td>Strategy</td>
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<td>NCT #</td>
<td>NCT00515931</td>
</tr>
<tr>
<td>Contact</td>
<td>Heikki Joensuu, M.D., Ph.D. 947173208 Ext. 358 <a href="mailto:heikki.joensuu@hus.fi">heikki.joensuu@hus.fi</a></td>
</tr>
</tbody>
</table>

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

## Sunitinib + Radiation

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

<table>
<thead>
<tr>
<th>Phase</th>
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<tbody>
<tr>
<td>Stage</td>
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<td>Drug Type</td>
<td>KIT/PDGFRA inhibitor</td>
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<td>Strategy</td>
<td>Block KIT</td>
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<tr>
<td>NCT #</td>
<td>NCT00463060</td>
</tr>
<tr>
<td>Contact</td>
<td>Johnny Kao, MD 212-241-7503 <a href="mailto:Johnny.kao@mountsinai.org">Johnny.kao@mountsinai.org</a></td>
</tr>
</tbody>
</table>

**Mount Sinai School of Medicine**
New York, NY USA
212-241-7503 johnny.kao@mountsinai.org
Johnny Kao, MD