

# July 2008 international clinical trials update

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## Internationally:

### **Dasatinib Phase I and LBH589 Phase I:**

These trials in Japan are no longer recruiting patients.

**Imatinib or Sutent Phase III:** This trial has expanded to new sites in Hong Kong, Italy, Korea and Spain

## In the US:

### **Imatinib + Bevacizumab Phase III:**

This is a large phase III trial accruing over 570 GIST patients who have not received any TKI therapy in the US and Canada. Patients are randomized to either daily imatinib alone or daily imatinib plus Bevacizumab administered by IV on day one of a 21 day cycle. Patients enrolled must have histologically confirmed GIST (must be c-KIT positive) and must be metastatic or unresectable. Biopsy is not required. Patients must not have taken imatinib or other agents targeting KIT, PDGFRA or VEGF. The only exception to this rule is prior adjuvant therapy longer than 12 months before trial entry.

Since April this trial has started recruiting at 24 sites in six states. Study chairs are listed as Charles Blanke (now at University of British Columbia in Vancouver), George Demetri at Dana-Farber and Vivien Bramwell at Tom Baker Cancer Center in Calgary, Alberta. Margaret von Mehren at Fox Chase is listed as an investigator. Sponsors include the NCI, The Canadian NCIC, the Southwest Oncology Group and the Cancel and Leukemia Group B.

## **Imatinib (Glivec) or Sunitinib (Sutent)**

*Safety and effectiveness of daily dosing with sunitinib or imatinib in patients with GIST*

Phase: III  
Conditions: GIST  
Strategy: Inhibit KIT and/or impede tumor vascularization  
NCT#: NCT00372567  
Telephone: 1-877-369-9753  
Sites: Milano, Italy, 20133  
Bologna, Italy  
Lai Chi Kok, Kowloon, Hong Kong  
Tuen Mun, New Territories, Hong Kong  
Seoul, Republic of Korea  
Barcelona, Spain

## **Dasatinib (BMS-354825)**

*Dasatinib as first-line therapy in treating GIST patients*

Phase: II  
Conditions: GIST  
Strategy: Inhibit KIT  
NCT#: NCT00568750  
Telephone: 41-21-314-0150  
Sites: **Hospitaller Universitaire Vaudois**, Lausanne, Switzerland CH-1011  
Michael Montemurro, MD

## **Imatinib + RAD001 (everolimus)**

*Treatment with everolimus + imatinib in progressive GIST and imatinib-resistance*

Phase: II  
Conditions: GIST  
Strategy: Inhibit target KIT downstream signaling (mToR)  
NCT#: NCT00510354  
Telephone: 41-6-1324-1111  
Sites: Clinicaltrials.gov lists 9 sites as open in Germany. Use the Novartis number above for specific site information or go to the German Novartis site at [www.novartis.de](http://www.novartis.de).

## **LBH589**

*LBH589 in patients with advanced solid tumors or cutaneous T-Cell lymphoma*

Phase: I  
Conditions: Tumors  
Strategy: Destroy KIT + Inhibit cell cycle + Induce apoptosis (HDAC)  
NCT#: NCT00412997  
Telephone: +81-3-3797-8748  
Sites: Tokyo, Japan

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

Phase: I/II  
Conditions: GIST  
Strategy: Kill GIST cells (Radiation)  
NCT#: NCT00515931  
Telephone: 947173208 Ext. 358  
Sites: **Helsinki University Central Hospital**, Helsinki, Finland  
[heikki.joensuu@hus.fi](mailto:heikki.joensuu@hus.fi)

## **Dasatinib (BMS-354825)**

*Study of dasatinib(BMS-354825) in patients with solid tumors*

Phase: I  
Conditions: Tumors  
Strategy: Inhibit KIT  
NCT#: NCT00339144  
Contact: **This site is no longer recruiting.**

## **Glivec + Interleukin 2 (IL2)**

*Phase I trial in solid tumor and GIST resistant to imatinib and/or sunitinib (IMAIL-2)*

Phase: I  
Conditions: Solid tumors and GIST  
Strategy: Kill GIST cells (Immunotherapy)  
Contact: Dr. Nathalie Chaput  
[nathalie.chaput@igr.fr](mailto:nathalie.chaput@igr.fr)  
Telephone: +33(0)1 42 11 50 05  
Sites: **Institute Gustave Roussy**, Villejuif, France

## **Multi-Bacteria Vaccine**

*A Phase I study of mixed bacteria vaccine in patients with tumors expressing NY-ESO-1 Antigen*

Phase: I  
Conditions: GIST  
Strategy: Immune response attacks tumor  
NCT#: NCT00623831  
Contact: Antje Neumann,  
069 7601 4161  
[neumann.antje@khnw.de](mailto:neumann.antje@khnw.de)  
Sites: **Krankenhaus Nordwest**, Frankfurt, Germany

## **OSI-930**

*Dose escalation study of daily oral OSI-930 in patients with advanced solid tumors*

Phase: I  
Conditions: Solid Tumors/Sarcoma  
Strategy: Multiple Targets  
NCT#: NCT00513851  
Contact: [ContactUs@emergingmed.com](mailto:ContactUs@emergingmed.com)  
Telephone: (877) 601-8601  
Sites: **Dept. of Cancer Therapeutics Institute of Cancer Research**, Sutton, Surrey, United Kingdom

## **XL147**

*Study of safety and pharmacokinetics of XL147 in adults with solid tumors*

Phase: I  
Conditions: Cancer  
Strategy: Target KIT downstream signaling (PI3-K)  
NCT#: NCT00486135  
Contact: Gemma Sala  
Telephone: +34 93 489 4158  
Sites: **Hospital Universitario Vall d'Hebron**, Barcelona, Spain, 08035  
Jose Baselga, MD, PhD

**Have a technical question about a drug or protocol? Email LRG Science Coordinator, Jerry Call at [jcall@liferaftgroup.org](mailto:jcall@liferaftgroup.org)**