

September 2008 international clinical trial update

By **Jim Hughes**
Clinical Trials Coordinator

United States

IPI-504 Phase III: The first open site for the IPI-504 Phase III trial has been reported at Park Ridge, IL. Please contact the GIST Phase 3 Team at 877-504-INFI or IPI-504inGIST@infi.com.

IPI-493 Phase I: Infinity has announced the opening of a Phase I trial for IPI-493 an oral HSP-90 inhibitor. The goal of the trial is to determine the safety and maximum tolerable dose and to determine a dosing schedule for future trials. The trial is open to patients with advanced malignancies who are progressing. Patients who have had prior HSP-90 therapy appear to be excluded. Concurrent use of tyrosine kinase therapy (Gleevec,

Sutent, Tasigna) appears also to not be allowed. There is a long list of specific exclusions that can be reviewed at clinicaltrials.gov by searching for the NCT # 00724425 and/or by calling the site contacts. The trial is reportedly open at two locations in California: Premiere Oncology in Santa Monica, Calif. Contact Marilyn Mulay at 310-633-8400 or mmulay@premiereoncology.com.

The other site is San Diego Pacific Oncology and Hematology Associates in Encinitas, Calif. Contact Karen Brady at 760-752-3340 or kbrady@premiereoncology.com.

PX-866 Phase I: ProIX has initiated a phase I trial of an oral PI3K inhibitor PX-866 for advanced solid tumors. The trial is listed as currently recruiting at two sites: University of Colorado Health Sciences Center in Aurora, Colo. Con-

tact Sharon Hecker at 720-848-0667 or sharon.hecker@ucdenver.edu. Also MD Anderson Cancer Center in Houston, Texas. Contact Rhonda Clement at 713-563-3559 or rclement@mdanderson.org.

International

LBH589 Phase I & Dasatinib Phase I: These two trials, both only in Japan, are now listed as no longer recruiting and have been removed from the list.

Imatinib or Sunitinib Phase III: This trial has added new sites in Italy, Spain and the United Kingdom.

AUY922 Phase I & BGT226 Phase I: These two trials have been recruiting in the US and now have now added sites in Switzerland and Spain respectively.

OSI-930 Phase I: This trial is listed as no longer recruiting in the UK.

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
Contact: Pfizercancertrials@emergingmed.com
Sites: Milano, Italy, 20133
Bologna, Italy, 40138
San Giovanni Rotondo, Foggia, Italy, 71013
Barcelona, Spain, 08036
Valencia, Spain, 46009
London, United Kingdom, SW3 6JJ
Lai Chi Kok, Kowloon, Hong Kong
Tuen Mun, New Territories, Hong Kong
Seoul, Republic of Korea, 135-710
Seoul, Republic of Korea, 138-736

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: **Hospitalier Universitaire Vaudois**,
Lausanne, Switzerland CH-1011
Michael Montemurro, MD

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

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.

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
 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
 Sites: **Krankenhaus Nordwest**, Frankfurt, Germany

AUY922

Phase I-II study to determine the MTD of AUY922 in advanced solid malignancies and efficacy in HER2+ or ER+ locally advanced or metastatic breast cancer.

Phase: I
 Conditions: Breast Cancer/Solid Malignancies
 Strategy: Destroy KIT (HSP-90)
 NCT#: NCT00526045
 Contact: **Novartis**
 Telephone: 800-340-6843
 Sites: Bellinzona, Switzerland

BGT226

A phase I/II study of BGT226 in patients with advanced solid malignancies including those with advanced breast cancer.

Phase: I
 Conditions: Solid Tumors, Breast Cancer, Cowden Syndrome
 Strategy: Target KIT downstream signal (PI3K)
 NCT#: NCT00600275
 Contact: Novartis
 Telephone: 800-340-6843
 Sites: **Hospital Vall d'Hebron**, Barcelona, Spain

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: **This study is ongoing, but not recruiting participants**

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, gsala@vhebron.net
 Telephone: +34 93 489 4158
 Sites: **Hospital Universitario Vall d'Hebron**, Barcelona, Spain, 08035
 Jose Baselga, MD, PhD

XL765

Study of safety and pharmacokinetics of XL765 in adults with solid tumors

Phase: I
 Conditions: Cancer
 Strategy: Target KIT downstream signaling (PI3-K)
 NCT#: NCT00485719
 Contact: Gemma Sala, gsala@vhebron.net
 Telephone: +34 93 489 4158
 Sites: **Hospital Universitario Vall d'Hebron**, Barcelona, Spain, 08035
 Jose Baselga, MD, PhD