

August 2008 US clinical trials update

By Jim Hughes

LRG Clinical Trials Coordinator

STA9090 Phase I: This trial is now listed in clinicaltrials.gov. It is actually two trials at the same sites. In one trial the drug is administered once weekly. In the other it is administered twice weekly.

Imatinib + Bevacizumab: This trial is now listed in the US report. It was first reported last month. There are over 100 locations listed as recruiting in the U.S. Look up a location near you using the NCT# in clinicaltrials.gov advanced search for contact information

XL820 Phase I: This trial is now listed as “ongoing but not recruiting participants”.

Site information has been updated in nine trials in the table below.

Nilotinib Phase III: Fox Chase Cancer Center (FCCC) just opened this trial for GIST patients. It is listed at: <http://tinyurl.com/585fbm>

Patients must have confirmed GIST and must have failed both imatinib and sunitinib. Patients must have a measurable tumor. Patients may also have had other TKI therapy besides imatinib and sunitinib. There is a two week washout for prior investigational drugs.

There is no control arm. All patients will receive nilotinib. Interested patients should call 1-888 “Fox Chase” (369-2427).

Infinity Pharmaceuticals announced July 30 that their oral HSP-90 inhibitor IPI-493 will enter Phase I at multiple sites. IPI-493 is an oral version of intravenous drug IPI-504 which is now in Phase III in the U.S. and internationally. Currently two sites in California are listed as open.

Imatinib or Sunitinib
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
Contact: Pfizer
pfizerclinicaltrials@emergingmed.com
Telephone: 1-877-369-9753
Sites: FCCC, Philadelphia, Penn.
Dana-Farber Cancer Institute (DFCI), Boston, Mass.
Melissa Hohos, RN
617-632-2201
Creve Coeur, Mo.
St. Louis, Mo.
St. Peters, Mo.

Imatinib + Bevacizumab
Imatinib with or without Bevacizumab in patients with metastatic/unresectable GIST

Phase: III
Conditions: GIST
Strategy: Inhibit KIT
NCT#: NCT00324987
Contact: Over 120 US contacts. Check clinicaltrials.gov or cancer.gov for this NCT#

BIIB021 (CNF2024)
Open-Label, 18FDG-PET pharmacodynamic assessment of effect of drug in GIST

Phase: II
Conditions: GIST
Strategy: Destroy KIT (HSP90)
NCT#: NCT00618319
Contact: **Biogen-Idec**
oncologyclinicaltrials@biogenidec.com
Sites: Contact Biogen-Idec
Memorial Sloan-Kettering Cancer Center (MSKCC), New York, NY

Nilotinib
Evaluation of Nilotinib in advanced GIST previously treated with imatinib & sunitinib

Phase: III
Conditions: GIST
Strategy: Inhibit KIT
NCT#: Not Yet Available
Contact: Fox Chase Cancer Center (FCCC)
Telephone: 1-800-FOX-CHASE
Sites: FCCC, Philadelphia, Penn.
Monica Davey
Margaret von Mehren

XL820
Phase 2 study of XL820 in advanced GIST resistant to imatinib and/or sunitinib

Phase: II
Conditions: GIST
Strategy: Multiple Targets
NCT#: NCT00570635
Contact: **Ongoing but not recruiting patients**

Imatinib + Pegylated Interferon-a 2B

Phase II study combines targeted therapy with immunotherapy, Imatinib + Pegylated Interferon-a 2B in imatinib-naïve GIST patients

Phase: II
Conditions: GIST
Strategy: Kill GIST cells
NCT#: NCT00585221
Contact: **Huntsman Cancer Institute**
University of Utah, Salt Lake City, Utah
Jessica Moehle
801-587-4438
Suzanne Dodd
801-587-9834
Lei Chen, MD

Perifosine + Imatinib

Phase II study of Perifosine + Gleevec in GIST patients

Phase: II
Conditions: GIST
Strategy: Multiple Targets
NCT#: NCT00455559
Contact: **Online Collaborative Onc. Group**
ocogtrials@ocog.net
Telephone: 415-946-2410
Sites: Los Angeles, Calif.
Sant Chawla, Md.
Coeur D'Alene, Idaho
Park Ridge, Ill.
Oncology Specialists
Kathy Tolzein, RN
847-268-8200
Grand Rapids, Mich.
Sayre, Penn.
Houston, Texas
MD Anderson Cancer Center
800-392-1611

Doxorubicin + Flavopiridol

Doxorubicin and Flavopiridol in treating patients with metastatic or recurrent unresectable sarcomas

Phase: I
Conditions: GIST/Sarcoma
Strategy: Inhibits production of KIT
NCT#: NCT 00098579
Contact: David D'Adamo, MD
Telephone: 212-639-7573
Sites: **MSKCC**, NY, N.Y.

TRIALS

From Page 3

Imatinib + Sunitinib

Imatinib & sunitinib in treating GIST patients

Phase: I
Conditions: GIST
Strategy: Multiple targets
NCT#: NCT00573404
Contact: Clinical Trials Office
Telephone: 800-811-8480
Sites: **Vanderbilt-Ingram CC**,
Nashville, TN
Jordan Berlin, MD
615-343-4128

Sorafenib (Nexavar)

Sorafenib in treating patients with malignant GIST that progressed during or after previous treatment with imatinib and sunitinib.

Phase: II
Conditions: GIST
Strategy: Multiple Targets
NCT#: NCT00265798
Contact: **Univ. Of Chicago Cancer Res. Center**,
Chicago, Ill.
Ravi Salgia, MD
rsalgia@medicine.bsd.uchicago.edu
Blase Polite, MD
bpolite@medicine.bsd.uchicago.edu
Telephone: 773-834-7424
Sites: **City of Hope**, Duarte, Calif.
Warren Chow, MD, 626-256-4673
USC-Norris Cancer Center,
Los Angeles, Calif.
Hein-Josef Lenz, MD,
323-865-3955
UC-Davis, Sacramento, Calif.
David Gandara, MD,
916-734-3771
Decatur Memorial Hospital,
Decatur, Ill.
James Wade, MD, 217-876-6617
Oncology/Hematology Assoc.,
Peoria, Ill.
John Kugler, MD, 309-671-5180
James Knost, MD,
jknost@ohaci.com
Central Illinois Hem/Onc,
Springfield, Ill.
Edem Agamah, MD, 217-525-2500
Univ. of Michigan, Ann Arbor, Mich.
Scott Schuetz, MD, 734-647-8925
Memorial Sloan-Kettering CC (MSKCC), New York, N.Y.
David D'Adamo, MD, 212-639-5720
Medical College of Wisconsin
Milwaukee, Wis.
Stuart Wong, MD, 414-805-4603

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: **Nevada Cancer Institute**
Las Vegas, Nev.
Sunil Sharma, MD

BEZ235

A Phase I/II multi-center, open-label study, administered orally on a continuous daily schedule in adult patients with advanced solid malignancies.

Phase: I/II
Conditions: Adv. Solid Malignancies/ Adv.
Breast Cancer
Strategy: Target KIT downstream signal
(PI3K)
NCT#: NCT00620594
Contact: Novartis
Telephone: 862-778-8300
Sites: **Nevada Cancer Institute**,
Las Vegas, Nev.
Montessa Linsangan,
702-822-5282
Sarah Cannon Res. Institute,
Nashville, Tenn.
Howard Burris, MD,
615-329-7274

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: **UCLA**, Los Angeles, Calif.
Carolyn Britten, MD
310-825-5268
cbritten@mednet.ucla.edu
DFCI, Boston, Mass.
Melissa Hohos, RN
617-632-2201
Washington University,
St. Louis, Mo.
Paela Fracasso, MD
314-362-5654
Nevada Cancer Institute,
Las Vegas, Nev.
Sunil Sharma, MD
702-822-5360

BIIB021 (CNF2024)

Once or twice daily administration of BIIB021 to solid tumor subjects

Phase: I
Conditions: Advanced Solid Tumors
Strategy: Destroy KIT (HSP-90)
NCT#: NCT00618735
Contact: **Biogen-Idec**
oncologyclinicaltrials@biogenidec.com
Sites: **Premiere Oncology**,
Santa Monica, Calif.
Lee Rosen, MD, 310-633-8400

CNF2024

Oral CNF2024 in advanced solid tumors

Phase: I
Conditions: Tumors/Lymphoma
Strategy: Destroy KIT (HSP-90)
NCT#: NCT00345189
Contact: **Biogen Idec**
oncologyclinicaltrials@biogenidec.com
Sites: **Scottsdale, Ariz.**
New Haven, Conn.
San Antonio, Texas
Cancer Therapy & Res. Center,
San Antonio, Texas
Pat O'Rourke, RN
210-616-5976

GDC-0941

An open-label phase I, dose-escalation study in patients with locally advanced or metastatic solid tumors for which standard therapy is ineffective, intolerable or does not exist

Phase: I
Conditions: Solid Tumors
Strategy: Target KIT downstream signal
(PI3K)
Sites: **DFCI**, Boston, Mass.
Melissa Hohos, RN,
617-632-2201

MP470

MP470 in treating patients with unresectable or metastatic solid tumor or lymphoma

Phase: I
Conditions: Solid Tumors/Lymphoma
Strategy: Multiple Targets
NCT#: NCT00504205
Sites: **Virginia Piper Cancer Center**,
Scottsdale, Ariz.
Raoul Tibes, MD, 480-323-1350
South Texas Accelerated Research Therapeutics (START),
San Antonio, TX
Anthony Tolcher, MD
210-593-5255

TRIALS

From Page 6

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: **OSIP Medical Information**
Medical-information@osip.com
Telephone: 800-572-1932 xt 7821
Sites: **Univ. of Colorado**, Aurora, Colo.
Mary Kay Schultz, 303-266-1740
DFCI, Boston, Mass.
Melissa Hohos, RN,
617-632-2201

SNX5422

Safety and pharmacology of SNX-5422 in patients with refractory solid tumor malignancies

Phase: I
Conditions: Solid Tumor Malignancy
Strategy: Destroy KIT (HSP-90)
NCT#: NCT00506805
Contact: Catherine A. Ross
Telephone: 919-376-1330
Sites: **TGen Clinical Res. Services**
Scottsdale, Ariz.
Joyce Ingold, RN, 480-323-1339
Ramesh Ramanathan, MD
Sarah Cannon Res. Institute
Nashville, Tenn.
Howard Burris III, MD

LBH589

Phase IA, two-arm, multi-center, dose-escalation study, by IV on two dose schedules in adult patients with advanced solid tumors and non-Hodgkins lymphoma

Phase: I
Conditions: Adv. Solid Tumors/Lymphoma
Strategy: Destroy KIT, Inhibit Cell Cycle, Apoptosis
Contact: **Nevada Cancer Institute**, Las Vegas, Nev.
Donna Adkins, RN, 702-822-5173

XL820

XL820 given orally to solid tumor patients

Phase: I
Conditions: Cancer/Solid Tumors
Strategy: Multiple Targets
NCT#: NCT00350831
Sites: **No Longer Recruiting**
Alain C. Mita, MD

STA-9090

Administered once-weekly in solid tumor patients

Phase: I
Conditions: Solid Tumors
Strategy: Destroy KIT (HSP-90)
Sites: NCT00687934
DFCI, Boston, Mass.
Melissa Hohos, RN,
617-632-2201
Geoffrey Shapiro, MD,
617-632-4942
Premiere Oncology,
Santa Monica, Calif.
Lee Rosen, MD, 310-633-8400
Karmanos Cancer Institute,
Detroit, Mich.
Pat LoRusso, MD
315-576-8716

STA-9090

Administered twice-weekly in solid tumor patients

Phase: I
Conditions: Solid Tumors
Strategy: Destroy KIT (HSP-90)
Sites: **DFCI**, Boston, Mass.
Melissa Hohos, RN,
617-632-2201
Geoffrey Shapiro, MD,
617-632-4942
Premiere Oncology,
Santa Monica, Calif.
Lee Rosen, MD, 310-633-8400
Karmanos Cancer Institute,
Detroit, Mich.
Pat LoRusso, MD
315-576-8716

SF1126

Phase I open label, safety, pharmacokinetic & pharmacodynamic dose escalation study of SF1126 given twice weekly by IV to patients with advanced or metastatic tumors

Phase: I
Conditions: Solid Tumors
Strategy: Target KIT downstream signal (PI3K)
Contact: **Semaphore Pharmaceuticals**
Ulrich Schwertschlag
Telephone: 978-257-1926
Sites: **Arizona Cancer Center**,
Tucson, Ariz.
Daruka Mahadevan, MD
530-626-0191
Indiana University, Indianapolis, Ind.
Elena Chiorean, MD
317-278-6942

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
Sites: **DFCI**, Boston, Mass.
Pilar del la Rocha Mur
617-632-5841
Geoffrey Shapiro, MD
Mary Crowley Med. Res. Ctr.,
Dallas, Texas
J. R. Dolan
214-658-1943
Gerard Edelman, MD

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
Sites: **Karmanos Cancer Institute**,
Detroit, Mich.
Theresa Laeder, 313-576-9386
Pat LoRusso, DO
South Texas Accelerated Research Therapeutics (START)
San Antonio, Texas
Gina Mangold, 210-413-3594
Kyriakos Papadopoulos, MD

Adult GIST pamphlet translated into URDU!

The Adult GIST information pamphlet is now available online and for order in Urdu.

What is Urdu?

Well, according to our friends at Wikipedia, "Standard Urdu has approximately the twentieth largest population of native speakers, among all languages. It is the national language of Pakistan as well as one of the 23 official languages of India."

Adult GIST and Pediatric GIST pamphlets can now be viewed in English and Spanish. Plans are in effect to add more languages. If you want to volunteer to help us in our efforts, please email Sara at srothschild@liferaftgroup.org.