

April 2008 US clinical trial update

By Jim Hughes
LRG Science Team Member

Clinical trial contact information for Dana Farber Cancer Institute (DFCI) in Boston has changed. Michael (Travis) Quigley, RN has been replaced by Melissa Hohos, RN. Melissa can be reached at 617-632-2201 or mhohos@partners.org. Melissa is the main contact for all GIST related trials at DFCI.

AMN107 Phase III: The St. Vincent's site in New York, N.Y., is now open. We have heard unofficially that U.S. accrual for this trial is nearly complete and is expected to end March 31, 2008.

Sunitinib or Imatinib Phase III: The Fox Chase Cancer Center (FCCC) site in Philadelphia, Penn. is pending and expected to open shortly. Check with Monica Davey, RN, 215-728-5534.

BIIB021 Phase I & II: New trials. Phase I- This drug from Biogen Idec is a HSP90 inhibitor (Was called CNF2024 in Phase I and administered twice weekly) and will be administered once or twice daily. Phase II- New York site

is open. The Mayo Clinic site in Rochester, Minn. is pending.

Sorafenib Phase II: Sites have been updated. Ohio State University and DFCI have been removed. Added sites can be found in the table on page 8.

XL820 Phase II: A DFCI site has been added. Unofficially, we have been told that eight more sites are pending. Christiaan McEwen at Quintiles is the project manager 415-337-1754, christiaan.mcewen@quintiles.com.

Imatinib & Sunitinib Phase I: This new trial, sponsored by Vanderbilt and the National Cancer Institute. Both are approved GIST treatment, but toxicity and dose optimization studies must be conducted.

IPI-504 Phase I: Trial has met accrual and is no longer accepting patients. Maximum Tolerable Dose (MTD) was also reached. A Phase II trial is planned.

BGT226 Phase I: This new drug from Novartis is a PI3K inhibitor. It acts by inhibiting KIT downstream signaling. PI3K is a key protein in multiple cell functions and in cancer cell signaling including GIST signaling. Researchers

hope to inhibit growth and stimulate cell death by inhibiting PI3K.

GDC-0941 Phase I: This new drug from Genentech is a PI3K inhibitor.

KOS1022 Phase I: According to Kosan's (the manufacturer) press release, drug development will stop with focus shifting to another HSP90 inhibitor.

Perifosine & Sorafenib Phase I: This trial is in the second of a two part Phase I and no longer accrues GIST patients.

SF1126 Phase I: This Phase I trial sponsored by manufacturer, Semafore, tests the safety of SF1126, a pro-drug that produces LY294002 (a pan PI3K inhibitor) in the body. However, Semafore designed SF1126 to concentrate in tumors and thereby avoid toxic side-effects associated with these inhibitors.

STA-9090 Phase I: This is now open at Premiere Oncology in Santa Monica, Calif.

XL147 Phase I: XL147 is a PI3K inhibitor from Exelixis. XL147 targets PI3K primarily and is given orally. XL765, another Exelixis PI3K inhibitor in Phase I (reported in January LRG issue) inhibits both PI3K and mTOR.

AMN107 (nilotinib, Tasigna®)

Efficacy and safety of AMN107 compared to current treatment options in GIST patients who failed imatinib and sunitinib

Phase: III

Conditions: GIST

Strategy: Inhibit KIT

NCT#: NCT00471328

Contact: Novartis # 862-778-8300 refer to trial# CAMN107A2201.

Sites: UCLA, Los Angeles, Calif.

Myung Lee, 310-825-4494

Wash. Cancer Inst., Washington, DC

Jake Paterson, 202-877-5371

H.L. Moffitt Cancer Center (CC), Tampa, Fla.

Bonnie Murray, 813-745-3819

Univ. of Chicago, Chicago, Ill.

773-834-7424

DFCI, Boston, Mass.

Melissa Hohos, RN, 617-632-2201

Karmanos Cancer Institute, Detroit, Mich.

Anne Marie Ferris, 313-576-9373

Washington Univ., St. Louis, Mo.

Nick Fisher, 314-354-5102

St. Vincent's Comprehensive CC

New York, NY, Larry Giove, 212-367-1729

Wake Forest, Winston-Salem, N.C.

Scarlet Hutchins, RN, 336-713-6915

FCCC, Philadelphia, PA

1-800-FOX-CHASE

MD Anderson, Houston, TX

Sylvia Abanto, 713-794-1919

Sunitinib (Sutent®) or

Imatinib (Gleevec®)

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

Phase: III

Conditions: GIST

Strategy: Multiple Targets

NCT#: NCT00372567

Contact: Pfizer- pfizercancertrials@emergingmed.com

Telephone: 877-369-9753

Sites: Contact Pfizer

DFCI, Boston, Mass.

Melissa Hohos, RN, 617-632-2201

Imatinib (Gleevec®) + 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#: HCI 22172

Contact: University of Utah, Salt Lake City, UT

Huntsman Cancer Institute

Suzanne Dodd, Study Coordinator,

801-581-4477

BIIB021 (also called CNF2024)

Open-Label, 18FDG-PET pharmacodynamic assessment of effect of drug in GIST patients

Phase: II

Conditions: GIST

Strategy: Destroy KIT (HSP90)

NCT#: NCT00618319

Contact: oncologyclinicaltrials@biogenidec.com

Sites: Contact Biogen-Idex

Perifosine+Imatinib (Gleevec®)

Phase II study of Perifosine+Gleevec in GIST patients

Phase: II

Conditions: GIST

Strategy: Multiple Targets

NCT#: NCT00455559

Contact: Online Collaborative Oncology Group

ocogtrials@ocog.net

Telephone: 415-946-2410

Sites: CC at Century City, Los Angeles, Calif.

Sant Chawla, MD

Coeur D'Alene, ID

Oncology Specialists, Park Ridge, Ill.

Kathy Tolzein, RN, 847-268-8200

Grand Rapids, MI

Sayre, PA

MD Anderson, Houston, TX

800-392-1611

TRIALS

From Page 1

Sorafenib (BAY 43-9006, 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: U. of Chicago Cancer Res. Cent., Chicago, IL
 Telephone: 773-834-7424
 Ravii Salgia, MD 773-702-4399
 Sites: **City of Hope**, Duarte, Calif.
 Warren Chow, MD, 626-256-4673
Norris Comp. CC (USC), Los Angeles, Calif.
 Hein-Josef Lenz, MD, 323-865-3955
Univ. of Calif., Davis, Sacramento, Calif.
 David Gandara, MD, 916-734-3771
Decatur Memorial Hospital, Decatur, Ill.
 James Wade III, MD, 217-876-6617
Oncology/Hematology Assoc., Peoria, Ill.
 John Kugler, MD, 309-671-5180
Central Illinois Hem/Onc, Springfield, Ill.
 Edem Agamah, MD, 217-525-2500
Univ. of Michigan, Ann Arbor, Mich.
Memorial Sloan-Kettering CC (MSKCC), New York, N.Y.
 David D'Adamo, MD, 212-639-5720
 Scott Schuetze, MD 734-647-8925
Medical College of Wis., Milwaukee, Wis.
 Stuart J. Wong, MD, 414-805-4603

Imatinib (Gleevec®) + Sunitinib (Sutent®)

Imatinib & sunitinib in treating GIST patients

Phase: I
 Conditions: GIST
 Strategy: Multiple targets
 NCT#: NCT00573404
 Contact: Clinical Trials Office, 800-811-8480
 Jordan D. Berlin, MD
 Sites: **Vanderbilt-Ingram CC**, Nashville, Tenn.

Doxorubicin & Flavopiridol

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

Phase: I
 Conditions: GIST/Sarcoma
 Strategy: Inhibits Production of KIT
 NCT#: NCT00098579
 Sites: **MSKCC**, New York, N.Y.
 David R. D'Adamo, MD, PhD
 212-639-7573

IPI504

Safety of IPI-504 for GIST or soft tissue sarcoma

Phase: I
 Conditions: GIST or Soft Tissue Sarcoma
 Strategy: Destroy KIT, (HSP90)
 NCT#: NCT00276302
 Sites: **This Phase I trial is now closed. A Phase II trial is pending.**

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: Christiaan McEwen, 415-337-1754,
 Sites: **Oncology Specialists**, Park Ridge, Ill.
 Kathy Tolzein, RN, 847-268-8200
DFCI, Boston, Mass.
 Melissa Hohos, RN, 617-632-2201

Perifosine+Sunitinib (Sutent®)

Perifosine + sunitinib for patients with advanced cancers

Phase: I
 Conditions: GIST/ Renal Cancer
 Strategy: Multiple Targets
 NCT#: NCT00399152
 Contact: Oncline Collaborative Oncology Group
 ocogtrials@ocog.net
 Telephone: Telephone:415-946-2410
 Sites: Huntsville, Ala.
Tower Hem./Onc., Beverly Hills, Calif.
 Pomona, Calif.
 Santa Monica, Calif.
Oncology Specialists, Park Ridge, Ill.
 Kathy Tolzien, RN, 847-268-8200
 Kalamazoo, Mich.

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, 800-340-6843
 Sites: **UCLA**, Los Angeles, Calif.
 Carolyn Britten, MD., 310-825-5268
DFCI, Boston, Mass.
 Melissa Hohos, RN, 617-632-2201
 Stephen Hodi, MD, 617-632-5053.
Wash. University, St. Louis, Mo.
 Paula Fracasso, MD, 314-362-5654
Nevada Cancer Institute, Las Vegas, Nev.
 Sunil Sharma, MD, 702-822-5360

BEZ235

A Phase I/II, multi-center, open-label study of BEZ235, administered orally on a continuous daily dosing schedule in adult patients with advanced solid malignancies including patients with advanced breast cancer

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

BIIB021 (also called CNF2024)

Once or twice daily administration of BIIB021 to solid tumor subjects

Phase: I
 Conditions: Advanced Solid Tumors
 Strategy: Destroy KIT (HSP90)
 NCT#: NCT00618735
 Contact: Biogen Idec,
 oncologyclinicaltrials@biogenidec.com
 Sites: **Premiere Onc.**, Santa Monica, Calif.
 Lee Rosen, MD, 310-633-8400

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 signaling (PI3K)
 NCT#: NCT00600275
 Contact: Novartis, 800-340-6843
 Sites: **Nevada CC**, Las Vegas, Nev.
 Sunil Sharma, MD

CNF2024

Oral CNF2024 in advanced solid tumors

Phase: I
 Conditions: Tumors/Lymphoma
 Strategy: Destroy KIT, (HSP90)
 NCT#: NCT00345189
 Contact: Biogen Idec
 oncologyclinicaltrials@biogenidec.com
 Sites: Scottsdale, Ariz.
 New Haven, Conn.
Cancer Therapy and Research Center,
 San Antonio, TX
 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 signaling (PI3K)
 Sites: **DFCI**, Boston, Mass.
 Melissa Hohos, RN, 617 632-2201

LBH589

Phase IA, two-arm, multicenter, dose-escalating study administered by IV on two dose schedules in adult patients with advanced solid tumors and non-Hodgkin's lymphoma

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

TRIALS

From Page 2

KOS-1022

Oral drug in patients with advanced solid tumors

Phase: I
 Conditions: Advanced Solid Tumors
 Strategy: Destroy KIT (HSP90)
 Study#: COMIRB 05-0627
 Contact: ***Drug development stopped (see page 3)**

OSI-930

Phase I dose escalation study of daily oral OSI-930 in patients with advanced solid tumors

Phase: I
 Conditions: Solid Tumors
 Strategy: Multiple targets including inhibit KIT
 NCT#: NCT00513851
 Contact: OSIP Medical Information
 medical-information@osip.com
 Telephone: 800-572-1932, xt 7821
 Sites: **Univ. of Colorado CC**, Aurora, Colo.
 Mary Kay Schultz, 303-266-1740
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 Tumor/Lymphoma
 Strategy: Multiple Targets
 NCT#: NCT00504205
 Sites: **Virginia Piper CC**, Scottsdale, Ariz.
 Raoul Tibes, MD, 480-323-1350
S. TX Accelerated Research Therapeutics,
 San Antonio, TX
 Anthony Tolcher, MD, 210-593-5255

SNX-5422

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#: NCT 00506805
 Contact: Catherine A. Ross, 919-376-1330
 Sites: **TGen Clin. Res. Services**, Scottsdale, AZ
 Joyce Ingold, RN 480-323-1339
 Ramesh Ramanathan, MD
Sarah Cannon Res. Inst., Nashville, Tenn.

XL147

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

Phase: I
 Conditions: Cancer
 Strategy: Target KIT downstream signaling
 NCT#: NCT00486135
 Sites: **DFCI**, Boston, Mass.
 Pilar de la Rocha Mur, 617-632-5841
Mary Crowley Med. Res. Center, Dallas, TX
 J. R. Dolan, 214-658-1943

Perifosine+Sorafenib

Phase I study of Perifosine + Sorafenib for patients with advanced cancers

Phase: I
 Conditions: Renal Cancer/Tumors
 Strategy: KIT downstream targets, Multiple targets
 NCT#: NCT00398814
 Contact: ***GIST patients are no longer being accrued (See page 3).**

STA-9090

Phase I clinical trial of STA-9090

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

SF1126

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

Phase: I
 Conditions: Solid Tumors
 Strategy: Target KIT downstream signaling (PI3K)
 Contact: Semaphore Pharmaceuticals,
 Ullrich Schwertschlag, 978-257-1926,
 ullrich@semaforepharma.com
 Sites: **Arizona CC**, Tucson, Ariz.
 Daruka Mahadevan, MD, 520-626-0191
Indiana University CC, Indianapolis, Ind.
 Elena Chiorean, MD, 317-278-6942

XL765

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

Phase: I
 Conditions: Cancer
 Strategy: Target KIT downstream signaling
 NCT#: NCT 00485719
 Sites: **Karmanos Cancer Institute**,
 Detroit, Mich.
 Theresa Laeder, 313-576-9386
 Pat LoRusso, MD
S. TX Accelerated Research Therapeutics,
 San Antonio, TX
 Gina Mangold, 210-413-3594
 Kyriakos Papadopoulos, MD

XL820

XL820 given orally to solid tumor patients

Phase: I
 Conditions: Cancer/Solid Tumors
 Strategy: Multiple Targets
 NCT#: NCT00350831
 Sites: **The Cancer Institute of NJ**, New Brunswick, NJ
 Pamela Scott, 732-235-7459
 Mark Stein, MD
Cancer Therapy and Res. Center,
 San Antonio, TX
 Pat O'Rourke, 210-616-5976
 Alain C. Mita, MD

Editor's Note

While every effort has been made to list trials by phase, strategy and alphabetical order, position changes are unfortunately necessary when editing. We want to remind our readers that no special priority has been given to any clinical trial.