

November 2008 US clinical trial update

By Jim Hughes
LRG Clinical Trials Coordinator

United States

Dasatinib Phase 2: This trial has been on-going for over a year. Initially the trial was for 12 different types of sarcoma; GIST has recently been added to the list of conditions that will be accepted for this oral drug. Dasatinib (BMS-354825) was tried in GIST in a Phase 1 trial in 2004 and 2005 for patients failing imatinib. At ASCO 2005, it

was reported that nine GIST patients entered the trial and had mixed results. Since that time recent publications indicate that Dasatinib is a potent in vitro inhibitor of several GIST mutations. These have highlighted the potential of Dasatinib as a second and third line drug especially for PDGFRA mutation GIST. Patients must have failed imatinib to enter this trial. Prior treatment with sunitinib is not required. This trial is open in 12 states and the District of Columbia.

OSI-930 Phase 1: No longer recruiting.

International

Nilotinib Phase 2: Novartis has opened a front line study of Nilotinib for GIST in Bad Saarow, Germany. Patients with unresectable GIST will be given Nilotinib instead of Glivec. Participants may not have had prior nilotinib. This trial plans to accrue 40 patients over the next year. Contact: Novartis Basel + 41 61 324 1111. NCT # 00756509. Novartis internal # CAMN107DDE06. EUDRACT- Nr. 2008-000358-11.

Imatinib + Bevacizumab

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

Phase: III
Conditions: GIST
Strategy: Block KIT Protein and inhibit GIST tumor blood vessel growth
NCT#: NCT00324987
Sites: Approximately 180 sites are recruiting in the US. There is no central contact info. Please check clinicaltrials.gov or cancer.gov for US trial sites
British Columbia Cancer Agency, Vancouver, BC
Charles Blanke, MD, 604-877-6098

Imatinib or Sunitinib

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

Phase: III
Conditions: GIST
Strategy: Block KIT/PDGFR protein
NCT#: NCT00372567
Contact: Pfizer
pfizercancertrials@emergingmed.com
Telephone: 1-877-369-9753
Sites: **Fox Chase Cancer Center (FCCC)**, Philadelphia, Penn.
1-800-FOX-CHASE
Monica Davey, RN
Margaret von Mehren, MD
North Shore Univ. Health System, Evanston, Ill.
Glenview, Ill.
Highland Park, Ill.
Elita Fine, RN, .847-570-2698
Bruce Brockstein, MD
New York, N.Y.

IPI-504

Study of IPI-504 in GIST patients following failure of at least imatinib and sunitinib

Phase: III
Conditions: GIST
Strategy: Destroy mutant KIT/PDGFR protein
NCT#: NCT00688766
Contact: GIST Phase 3 Team, 1-877-504-4634
RINGtrialinfo@INFI.com
Trial Website: www.ringtrial.com
Sites: **Dana Farber Cancer Institute (DFCI)**, Boston, Mass.
Tarsha Colon, RN, BSN,
617-632-5117
Massachusetts General Hospital, Boston, Mass.
Barbara Rattner, RN,
617-724-2333
Edwin Choy, MD, PhD
Oncology Specialists, S.C., Park Ridge, Ill.
Laura Magid, 847-268-8579
Pamela Kaiser, MD
New Bern Cancer Center, New Bern, N.C.
Jenifer Haggard, 252-638-0422
Richard Gorman, MD
FCCC, Philadelphia, Penn.
Monica Davey, RN
1-800-FOX-CHASE
Margaret von Mehren, MD

Nilotinib

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

Phase: III
Conditions: GIST
Strategy: Block KIT/PDGFR protein
NCT#: Not Yet Available
Contact: **FCCC**
Telephone: 1-800-FOX-CHASE
Sites: **FCCC**, Philadelphia, Penn.
Monica Davey, RN
Margaret von Mehren, MD

BIIB021 (CNF2024)

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

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

Dasatinib

Trial of dasatinib in advanced sarcomas

Phase: II
Conditions: GIST
Strategy: Block KIT/PDGFR protein and related GIST tumor signal paths
NCT#: NCT00464620
Contact: There are 19 sites with contact information listed at www.clinicaltrials.gov.

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: Block KIT/PDGFR protein and stimulate immune system to destroy GIST cells
NCT#: NCT00585221
Contact: **Ongoing but no longer recruiting Huntsman Cancer Institute**
University of Utah, Salt Lake City, Utah
Jessica Moehle
801-587-4438
Suzanne Dodd
801-587-9834

Perifosine + Imatinib

Phase II study of Perifosine + Gleevec in GIST patients

Phase: II
 Conditions: GIST
 Strategy: Block KIT/PDGFR protein and downstream signal path
 NCT#: NCT00455559
 Contact: **Online Collaborative Onc. Group**
 ocotrials@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

XL820

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

Phase: II
 Conditions: GIST
 Strategy: Block KIT/PDGFR protein and inhibit GIST tumor blood vessel growth
 NCT#: NCT00570635
 Contact: **Ongoing but not recruiting patients**

Doxorubicin + Flavopiridol

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

Phase: I
 Conditions: GIST/Sarcoma
 Strategy: Freeze the GIST cell division cycle
 NCT#: NCT 00098579
 Contact: David D'Adamo, MD
 Telephone: 212-639-7573
 Sites: **MSKCC**, NY, N.Y.

Imatinib + Sunitinib

Imatinib & sunitinib in treating GIST patients

Phase: I
 Conditions: GIST
 Strategy: Block KIT/PDGFR protein
 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: Block KIT/PDGFR protein, downstream KIT/PDGFR signal path and related GIST tumor signal paths
 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 Schuetze, MD, 734-647-8925
MSKCC, New York, N.Y.
 David D'Adamo, MD, 212-639-5720
Medical College of Wisconsin
 Milwaukee, Wis.
 Stuart Wong, MD, 414-805-4603

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: Block KIT/PDGFR downstream signal path
 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 Burriss, 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 mutant KIT/PDGFR
 NCT#: NCT00526045
 Contact: **Novartis**
 Telephone: 800-340-6843
 Sites: **UCLA**, Los Angeles, Calif.
 Carolyn Britten, MD, 310-825-5268
DFCI, Boston, Mass.
 Tarsha Colon, RN, BSN
 617-632-2201
Washington University,
 St. Louis, Mo.
 Paella Fracasso, MD, 314-362-5654
Nevada Cancer Institute,
 Las Vegas, Nev.
 Sunil Sharma, MD, 702-822-5360
Medical College of Georgia,
 Augusta, Ga.
 Thomas Samuel, MD, 706-721-2505
Cancer Therapy and Research Center,
 San Antonio, T.X.
 Monica Mita, MD, 210-562-1797
MD Anderson Cancer Center (MDA),
 Houston, T.X.
 Vassiliki Papadimitrakopoulou, MD,
 703-792-6363

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: Block KIT/PDGFR downstream signal path
 NCT#: NCT00600275
 Contact: Novartis
 Telephone: 800-340-6843
 Sites: **Nevada Cancer Institute**,
 Las Vegas, Nev.
 Sunil Sharma, MD
DFCI, Boston, Mass.
 Kathryn Josephs, 617-632-7652
 Ian Krop, M.D.
Massachusetts General Hospital,
 Boston, Mass.
 Natasha Isaac, 617-726-6225
 Steven Isakoff, M.D.
Cancer Therapy and Research Center (CTRC),
 San Antonio, T.X.
 Jerry Medina, 210-450-1789
 Francis J. Giles, MD

BIIB021 (CNF2024)

Once or twice daily administration of BIIB021 to solid tumor subjects

Phase: I
 Conditions: Advanced Solid Tumors
 Strategy: Destroy mutant KIT/PDGFR
 NCT#: NCT00618735
 Contact: **Biogen-Idec**
 oncologyclinicaltrials@biogenidec.com
 Sites: **Premiere Oncology**,
 Santa Monica, Calif.
 Lee Rosen, MD, 310-633-8400
So. TX Accelerated Research Therapeutics (START), San Antonio, TX
 210-593-5265

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: Block KIT/PSGFRA downstream signal path
 Sites: **DFCI**, Boston, Mass.
 Tarsha Colon, RN, BSN,
 617-632-5117
TGen, Scottsdale, Ariz.
 Joyce Ingold, RN, 480-323-1339

IPI-493

Phase I dose escalation study of IPI-493

Phase: I
 Conditions: Advanced malignancies
 Strategy: Destroy mutant KIT/PDGFR
 NCT#: NCT00724425
 Sites: **Premiere Onc.**, Scottsdale, Ariz.
 Patricia Shannon, RN
 480-860-5000 ext 223
 David Mendelson, MD
Premiere Onc., Santa Monica, Calif.
 Marilyn Mulay, NP, 310-633-8400
 Lee Rosen, MD
San Diego Pacific Onc. and Hem. Assoc., Encinitas, Calif.
 Karen Brady, RN, 760-752-3340
 Richard Just, M.D
Univ. of Colorado Health Science Center, Aurora, Colo.
 Stacy Grolnic, RN, 720-848-0655
 Colin Weekes, MD, PhD

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: Unblock GIST cell death genes
 Sites: **Nevada Cancer Inst.**, Las Vegas, Nev.
 Donna Adkins, RN, 702-822-5173
 Sunil Sharma, MD

PX866

Phase I trial of oral PX866

Phase: I
 Conditions: Advanced Solid Tumors
 Strategy: Block KIT/PDGFR downstream signal path
 NCT#: NCT00726583
 Sites: **Univ. of Colorado Health Sciences Center**, Aurora, Colo.
 Sharon Hecker, 720-848-0667
 Antonio Jimeno,
MDA, Houston, T.X.
 Rhonda Clement, 713-563-3559
 Roy Herbst, MD

SF1126

Phase I open label, safety, pharmacokinetic & pharmacodynamic dose escalation study

Phase: I
 Conditions: Solid Tumors
 Strategy: Block KIT/PDGFR downstream signal path
 Contact: **Semaphore Pharmaceuticals**
 Telephone: Ulrich Schwertschlag, 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

SNX5422

Safety and pharmacology in patients with refractory solid tumor malignancies

Phase: I
 Conditions: Solid Tumor Malignancy
 Strategy: Destroy mutant KIT/PDGFR
 NCT#: NCT00506805
 Contact: Pfizer Onc. Clinical Trial Information
 Telephone: 1-877-369-9753
 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

STA-9090

Once-weekly study in solid tumor patients

Phase: I
 Conditions: Solid Tumors
 Strategy: Destroy mutant KIT/PDGFR
 NCT: NCT00687934
 Sites: **DFCI**, Boston, Mass.
 Pilar De La Roche Mur, 617-632-5841
 Geoffrey Shapiro, MD, 617-632-4942
Karmanos Cancer Inst. (KCI), Detroit, Mich.
 Pat LoRusso, MD, 315-576-8716
 (# for all sites)
Mass. Gen., Boston, Mass.
 Boston, Mass.
 Pilar De La Roche Mur
Beth Israel Deaconess Med. Center (BIDMC), Boston, Mass.
 Pilar De La Roche Mur

STA-9090

Administered twice-weekly in solid tumor patients

Phase: I
 Conditions: Solid Tumors
 Strategy: Destroy mutant KIT/PDGFR
 Sites: **Premiere Oncology**,
 Santa Monica, Calif.
 Lee Rosen, MD, 310-633-8400
US Onc. Dayton Onc. & Hem., P.A
 Kettering, Ohio
 Robert Raju, MD

XL147

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

Phase: I
 Conditions: Cancer
 Strategy: Block KIT/PDGFR downstream signal path
 NCT#: NCT00486135
 Sites: **DFCI**, Boston, Mass.
 Tarsha Colon, RN, 617-632-5117
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: Block KIT/PDGFR downstream signal path
 NCT#: NCT00485719
 Sites: **KCI**, Detroit, Mich.
 Theresa Laeder, 313-576-9386
 Pat LoRusso, DO
START, San Antonio, Texas
 Gina Mangold, 210-413-3594
 Kyriakos Papadopoulos, MD

OSI-930

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

Phase: I
 Conditions: Solid Tumors/Sarcoma
 Strategy: Block mutant KIT/PDGFR
 NCT#: NCT00513851
 Contact: **Ongoing but not recruiting**

CNF2024

Oral CNF2024 in advanced solid tumors

Phase: I
 Conditions: Tumors/Lymphoma
 Strategy: Destroy mutant KIT/PDGFR
 NCT#: NCT00345189
 Contact: **Active, not recruiting**