Novartis highlights new findings in advancing care for patients with 170 abstracts in breast, lung and blood cancers at ASCO and EHA

May 29, 2013

- - Latest Phase III research on Afinitor® in advanced HER2 positive breast cancer
- - Jakavi™ overall survival advantage evaluated in three-year study in patients with myelofibrosis, a rare and life-threatening blood cancer
- - Multi-year studies evaluating deep molecular response with Tasigna® in patients with Ph+CML
- - Data from LDK378 trial in ALK+ metastatic non-small cell lung cancer; supports recent FDA Breakthrough Therapy designation

EAST HANOVER, N.J., May 29, 2013 /PRNewswire/ -- Novartis will present new findings in the treatment of advanced cancers and other diseases with 170 abstracts at two prominent medical meetings. Research across the extensive Novartis product portfolio and pipeline showcases the progress in advancing care for patients with cancer and hematological diseases.

Clinical data from multiple compounds will be featured at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO) including Afinitor® (everolimus), Tasigna® (nilotinib) and the pipeline compound LDK378[1]. The 18th Congress of the European Hematology Association (EHA) will showcase data from Jakavi™ (ruxolitinib), Tasigna and Exjade® (deferasirox)[2].

"With a pipeline of more than 25 new molecular entities, we are at the forefront of a new era in oncology drug development, working towards advances for cancer patients," said Herve Hoppenot, President, Novartis Oncology. "These data demonstrate our progress in furthering research and development through a highly-targeted approach, matching specific compounds to pathways that are involved in many difficult-to-treat cancers."

Data highlights include:

Studies examining Afinitor in advanced breast cancer at ASCO

- BOLERO-3 study evaluating potential safety and efficacy of Afinitor in combination with trastuzumab and vinorelbine in women with HER2 positive advanced breast cancer who are resistant to trastuzumab and have been pre-treated with a taxane (abstract #505; June 2, 9:15 AM)
- Updates on Afinitor in hormone receptor-positive (HR+) advanced breast cancer, including BOLERO-2 sub-analyses (abstract #553, abstract #557, abstract #558, abstract #561; June 1, 1:15 PM) and a late-breaker examining genetic variations and their potential correlation with benefit (abstract #LBA509; June 3, 1:15 PM)

Survival data from Jakavi in myelofibrosis and analysis on bone marrow fibrosis

- At EHA: Three-year data evaluating overall survival advantage, as well as impact on spleen volume and safety from the Jakavi Phase III COMFORT-II clinical trial program (abstract #S1111; June 16, 8:00 AM)

- At ASCO and EHA: First evidence of the effect of Jakavi on bone marrow fibrosis in myelofibrosis patients at 24 and 48 months from a Phase I/II trial (ASCO abstract #7030; June 4, 8:30 AM; EHA abstract #S591; June 15, 4:15 PM)

Multi-year studies of Tasigna in patients with Ph+ CML

- At ASCO and EHA: Two-year follow-up results from the ENESTcmr study evaluating sustained deep molecular response following a switch to Tasigna in patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase who still had evidence of residual disease after two or more years of Gleevec® (imatinib mesylate)* tablets therapy (ASCO abstract #7053; June 2, 8:00 AM; EHA abstract #P133; June 14, 5:45 PM)
- At ASCO and EHA: Four-year update from the ENESTnd study evaluating molecular response rates of Tasigna compared to Gleevec in patients with newly diagnosed Ph+ CML in chronic phase (ASCO abstract #7052; June 2, 8:00 AM; EHA abstract #P712; June 15, 5:45 PM)
- At ASCO: ENESTnd landmark data correlating early molecular responses in patients with newly diagnosed Ph+ CML in chronic phase with long-term outcomes (abstract #7054; June 2, 8:00 AM)
- At EHA: Phase II GIMEMA study evaluating the sustainability of deep molecular response at five years in patients treated frontline with Tasigna (abstract #P141; June 14, 5:45 PM)

Survival data from PROMID study of Sandostatin® LAR® in NET at ASCO

- Follow-up analysis from the PROMID trial evaluating overall survival in patients with metastatic midgut neuroendocrine tumors (NET) taking Sandostatin LAR Depot (octreotide acetate for injectable suspension) vs. placebo (ASCO abstract #4030; June 3, 1:15 PM)

First-in-human study of LDK378 in ALK+ metastatic NSCLC at ASCO

- Updated data from the first-in-human Phase I trial of LDK378, a selective inhibitor of the cancer target anaplastic lymphoma kinase (ALK), in patients with ALK+ metastatic non-small cell lung cancer (abstract #8010; June 3, 10:15 AM). In March, the US Food and Drug Administration (FDA) granted LDK378 Breakthrough Therapy designation, a status intended to expedite the development and review of drugs that treat serious or life-threatening conditions

Multi-year analysis of iron overload association with morbidity risk in untreated thalassemia intermedia patients at EHA

- Analysis of association between iron overload and morbidity risk in patients with thalassemia intermedia, a form of non-transfusion-dependent thalassemia (NTDT), over an 11-year period. This retrospective study examined 52 patients with no history of transfusion or iron chelation, from comprehensive care centers in Italy, Lebanon, Oman, Iran and Egypt (abstract #S1172; June 16, 10:30 AM)

Additional pipeline research in melanoma, breast cancer and solid tumors at ASCO

- Initial results from a Phase I study of LGX818 in patients with BRAF V600 mutant advanced or metastatic melanoma (abstract #9028; June 3, 8:00 AM)
- Preliminary results from a Phase Ib/II open-label, dose-escalation study of LGX818 + MEK162† in BRAF V600-dependent advanced solid tumors (abstract #9029; June 3, 8:00 AM)
- Results from the first in-human study of the PI3K inhibitor BYL719 in patients with PIK3CA mutant ER-positive metastatic breast cancer (abstract #2531; June 4, 8:00 AM)

About Afinitor (everolimus)

Afinitor® (everolimus) is approved in the United States for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ breast cancer) in combination with exemestane after failure of treatment with letrozole or anastrozole.

In the United States, Afinitor tablets is approved for the treatment of adult patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib and for the treatment of progressive neuroendocrine tumors of pancreatic origin in adult patients with unresectable, locally advanced or metastatic disease. The US Food and Drug Administration (FDA) determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established.

Afinitor tablets is approved in the United States for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of Afinitor in the treatment of renal angiomyolipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes. Afinitor is also approved in the US as Afinitor tablets and Afinitor Disperz™ for pediatric and adult patients with TSC for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. The effectiveness of Afinitor tablets and Afinitor Disperz is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. Improvement in disease-related symptoms and overall survival in patients with SEGA and TSC have not been demonstrated.

In the United States, Afinitor is available from Novartis in different dosage strengths and for different uses in certain non-oncology patient populations under the trade name Zortress®. Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Not all indications are available in every country. Access to Afinitor outside of the approved indications has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound. As an investigational compound, the safety and efficacy profile of Afinitor has not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that Afinitor will become commercially available for additional indications anywhere else in the world.

Afinitor Important Safety Information
Patients should not take Afinitor or Afinitor Disperz if they are allergic to Afinitor or Afinitor Disperz or to any of its ingredients. Patients should tell their healthcare provider before taking Afinitor or Afinitor Disperz if they are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

Afinitor or Afinitor Disperz can cause serious side effects including lung or breathing problems, infections, and kidney failure, which can even lead to death. If patients experience these side effects, they may need to stop taking Afinitor or Afinitor Disperz for a while or use a lower dose. Patients should follow their healthcare provider's instructions.

In some patients, lung or breathing problems may be severe and can even lead to death. Patients should tell their healthcare provider right away if they have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

Afinitor or Afinitor Disperz may make patients more likely to develop an infection, such as pneumonia, or a bacterial, fungal, or viral infection. Viral infections may include reactivation of hepatitis B in people who have had hepatitis B in the past. In some people these infections may be severe and can even lead to death. Patients may need to be treated as soon as possible. Patients should tell their healthcare provider right away if

they have a temperature of 100.5˚F or above, chills, or do not feel well. Symptoms of hepatitis B or infection may include the following: fever, skin rash, joint pain and inflammation, tiredness, loss of appetite, nausea, pale stools or dark urine, yellowing of the skin, or pain in the upper right side of the stomach.

Afinitor or Afinitor Disperz may cause kidney failure. In some people this may be severe and can even lead to death. Patients should have tests to check their kidney function before and during their treatment with Afinitor or Afinitor Disperz.

Common side effects include mouth ulcers. Afinitor or Afinitor Disperz can cause mouth ulcers and sores. Other common side effects include infections, feeling weak or tired, nausea and vomiting, skin problems, headache, weight loss, loss of appetite, cough, diarrhea, fever, swelling of the hands, arms, legs, feet, face or other parts of the body, joint pain, abnormal taste, stomach-area (abdomen) pain, nose bleeds, seizure, increased blood cholesterol and sugar levels, decreased blood phosphate levels, low red and white blood cells, and the absence of menstrual periods (menstruation).

Please see full Prescribing Information for Afinitor and Afinitor Disperz available at afinitor.com.

Rapamune® (sirolimus) and Torisel® (temsirolimus) are registered trademarks of Wyeth Pharmaceuticals Inc.

About Jakavi (ruxolitinib)

Jakavi® (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases and was approved by the European Commission in August 2012 for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. Jakavi is approved in more than 35 countries, including the member states of the European Union, Canada and some countries in Asia, Latin and South America. Additional worldwide regulatory filings are underway.

Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the United States. Both the European Commission and the US Food and Drug Administration (FDA) granted ruxolitinib orphan drug status for myelofibrosis. Jakavi is marketed in the United States by Incyte Corporation under the name Jakafi® for the treatment of patients with intermediate or high-risk myelofibrosis.

The recommended starting dose for Jakavi is 15 mg twice daily for patients with a platelet count between 100,000 cubic millimeters (mm^3) and 200,000 mm^3, and 20 mg twice daily for patients with a platelet count of >200,000 mm^3. Doses may be titrated based on safety and efficacy. There is limited information to recommend a starting dose for patients with platelet counts between 50,000/mm^3 and <100,000/mm^3. The maximum recommended starting dose in these patients is 5 mg twice daily and patients should be titrated cautiously.

Jakavi is a registered trademark of Novartis AG in countries outside the United States. Jakafi is a registered trademark of Incyte Corporation.

Jakavi Important Safety Information

Jakavi® can cause serious side effects, including a decrease in blood cell count and infections. Complete blood count monitoring is recommended. Dose reduction or interruption may be required in patients with severe hepatic or renal impairment or in patients developing hematologic adverse reactions such as thrombocytopenia, anemia and neutropenia. Dose reductions are also recommended when Jakavi is co-administered with strong CYP3A4 inhibitors or fluconazole. Use of Jakavi during pregnancy is not recommended and women should avoid becoming pregnant during Jakavi therapy. Women taking Jakavi should not breast feed.

The most common adverse drug reactions, occurring at any level of severity (incidence >10%) are urinary tract infections, anemia, thrombocytopenia, neutropenia, hypercholesterolemia, dizziness, headache, alanine aminotransaminase increased, asparte aminotransferase increased, bruising, bleeding and increased blood pressure. Other common adverse drug reactions (incidence 1 to 10%) are herpes zoster, weight gain, flatulence and tuberculosis (1%). Progressive multifocal leukencephalopathy (PML) has been reported. Physicians should be alert for neuropsychiatric symptoms suggestive of PML.

Please see full Prescribing Information available at www.jakavi.com.

About Tasigna

Tasigna® (nilotinib) is approved for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of Tasigna for this indication is based on major molecular response and cytogenetic response rates at 12 months. The study is ongoing and further data will be required to determine long-term outcome.

Tasigna is also approved in more than 90 countries for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to at least one prior therapy, including Gleevec. The effectiveness of Tasigna for this indication is based on hematologic and cytogenetic response rates.

BOXED WARNING and Important Safety Information for Tasigna (nilotinib):

WARNING: QT PROLONGATION AND SUDDEN DEATHS

Tasigna prolongs the QT interval. Prior to Tasigna administration and periodically, monitor for hypokalemia or hypomagnesemia and correct deficiencies. Obtain ECGs to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, and follow any dose adjustments.

Sudden deaths have been reported in patients receiving nilotinib. Do not administer Tasigna to patients with hypokalemia, hypomagnesemia, or long QT syndrome.

Avoid use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors.

Patients should avoid food 2 hours before and 1 hour after taking dose.

Treatment with Tasigna can cause Grade 3/4 thrombocytopenia, neutropenia, and anemia. Complete blood counts should be performed every 2 weeks for the first 2 months and then monthly thereafter.

Caution is recommended in patients with a history of pancreatitis.

The use of Tasigna may result in elevations in bilirubin, AST/ALT, and alkaline phosphatase.

Tasigna can cause hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, and hyponatremia (see

Boxed WARNING).

The concomitant use of strong CYP3A4 inhibitors or anti-arrhythmic drugs (including, but not limited to, amiodarone, disopyramide, procainamide, quinidine, and sotalol) and other drugs that may prolong the QT interval (including, but not limited to, chloroquine, clarithromycin, haloperidol, methadone, moxifloxacin, and pimozide) should be avoided. Grapefruit products should also be avoided.

The concomitant use of strong CYP3A4 inducers should be avoided (including, but not limited to, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, and St. John's wort).

Tasigna must not be taken with food.

Tasigna exposure is increased in patients with impaired hepatic function.

Cases of tumor lysis syndrome have been reported in Tasigna treated patients with resistant or intolerant CML. Due to potential for tumor lysis syndrome, maintain adequate hydration and correct uric acid levels prior to initiating therapy with Tasigna.

The exposure of Tasigna is reduced in patients with total gastrectomy.

Since the capsules contain lactose, Tasigna is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency with a severe degree of intolerance to lactose-containing products, or of glucose-galactose malabsorption.

Women of childbearing potential should avoid becoming pregnant while taking Tasigna and should be advised of the potential hazard to the fetus if they do. The safety and effectiveness of Tasigna in pediatric patients have not been established.

In newly diagnosed Ph+ CML-chronic phase, the most commonly reported nonhematologic adverse drug reactions (>10%) were rash, pruritus, headache, nausea, fatigue, and myalgia.

In resistant or intolerant Ph+ CML-chronic phase, the most commonly reported nonhematologic adverse drug reactions (≥10%) were rash, pruritus, nausea, fatigue, headache, constipation, diarrhea, vomiting, and myalgia.

In resistant or intolerant Ph+ CML-accelerated phase, the most commonly reported nonhematologic adverse drug reactions (≥10%) were rash, pruritus, and fatigue.

Tasigna may need to be temporarily withheld and/or dose reduced for QT prolongation, hematologic toxicities that are not related to underlying leukemia, clinically significant moderate or severe nonhematologic toxicities, laboratory abnormalities, or concomitant use of strong CYP3A4 inhibitors.

Please see full Prescribing Information including Boxed Warning.

About Gleevec

Gleevec® (imatinib mesylate) tablets are indicated for newly diagnosed adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP). Gleevec is also indicated for the treatment of patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in CP after failure of interferon-alpha therapy.

Gleevec Important Safety Information

Gleevec can cause fetal harm when administered to a pregnant woman. Women should not become pregnant, and should be advised of the potential risk to the unborn child.

Gleevec is often associated with edema (swelling) and serious fluid retention. Studies have shown that edema (swelling) tended to occur more often among patients who are 65 and older or those taking higher doses of Gleevec.

Cytopenias (reduction or lack of certain cell elements in blood circulation), such as anemia, have occurred. If the cytopenia is severe, your doctor may reduce your dose or temporarily stop your treatment with Gleevec.

Severe congestive heart failure and left ventricle dysfunction have been reported, particularly in patients with other health issues and risk factors. Patients with heart disease or risk factors or history of renal failure will be monitored and treated for the condition.

Severe liver problems (hepatotoxicity) may occur. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of Gleevec.

Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with KIT+ GIST. GI tumor sites may be the cause of this bleeding; therefore, GI symptoms should be monitored at the start of treatment.

In patients with hypereosinophilic syndrome (a condition with increased eosinophils, which are a type of white blood cell) and heart involvement, cases of heart disease (cardiogenic shock/left ventricular dysfunction) have been associated with the initiation of Gleevec therapy.

Skin reactions, such as fluid-filled blisters, have been reported with the use of Gleevec.

Clinical cases of hypothyroidism (reduction in thyroid hormones) have been reported in patients taking levothyroxine replacement with Gleevec.

Long-term use may result in potential liver, kidney, and/or heart toxicities; immune system suppression may also result from long-term use.

GI perforation (small holes or tears in the walls of the stomach or intestine), in some cases fatal, has been reported.

Growth retardation has been reported in children taking Gleevec. The long-term effects of extended treatment with Gleevec on growth in children are unknown.

Cases of tumor lysis syndrome (TLS), which refers to a metabolic and electrolyte disturbance caused by the breakdown of tumor cells, have been reported and can be life-threatening in some cases. Correction of clinically significant dehydration and treatment of high uric acid levels are recommended prior to initiation of Gleevec.

Reports of motor vehicle accidents have been received in patients receiving Gleevec. Caution patients about driving a car or operating machinery.

Almost all patients treated with Gleevec experience side effects at some time. Some common side effects you may experience are fluid retention, muscle cramps or pain and bone pain, abdominal pain, loss of appetite, vomiting, diarrhea, decreased hemoglobin, abnormal bleeding, nausea, fatigue and rash.

Gleevec is sometimes associated with stomach or intestinal irritation. Gleevec should be taken with food and a large glass of water to minimize this problem. There have been rare reports, including deaths, of stomach or intestinal perforation (a small hole or tear).

If you are experiencing any of the mentioned side effects, please be sure to speak with your doctor

immediately.

Do not take any other medications without talking to your doctor or pharmacist first, including Tylenol® (acetaminophen); herbal products (St. John's wort, Hypericum perforatum); Coumadin® (warfarin sodium); rifampin; erythromycin; metoprolol; ketoconazole; and Dilantin® (phenytoin). Taking these with Gleevec may affect how they work, or affect how Gleevec works.

You should also tell your doctor if you are taking or plan to take iron supplements. Patients should also avoid grapefruit juice and other foods that may affect how Gleevec Works.

Please See Full Prescribing Information.

About Sandostatin LAR Depot
Sandostatin® LAR® Depot (octreotide acetate for injectable suspension) is indicated for patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated for:

- Long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option (the goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal).
- Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
- Long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and Sandostatin LAR Depot on tumor size, rate of growth and development of metastases has not been determined.

Important Safety Information for Sandostatin LAR Depot

Warnings and Precautions:

- Gallbladder abnormalities may occur: Patients should be monitored periodically.
- Glucose Metabolism: Hypoglycemia or hyperglycemia may occur. Blood glucose levels should be monitored when Sandostatin LAR Depot treatment is initiated or when the dose is altered. Antidiabetic treatment should be adjusted accordingly.
- Thyroid Function: Hypothyroidism may occur. Baseline and periodic assessment of thyroid function (TSH, total and/or free T4) is recommended.
- Cardiac Function: Bradycardia, arrhythmia, conduction abnormalities, and other EKG changes may occur. The relationship of these events to octreotide acetate is not established because many of these patients have underlying cardiac disease. Use with caution in at-risk patients.
- Nutrition: Octreotide may alter absorption of dietary fats. Monitoring of vitamin B12 levels is recommended during therapy with Sandostatin LAR Depot. Patients on total parenteral nutrition (TPN) and octreotide should have periodic monitoring of zinc levels.

Drug Interactions:

The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, bromocriptine. Octreotide has been associated with alterations in nutrient absorption, so it may have an effect on absorption of orally administered drugs. Drugs mainly metabolized by CYP3A4 and which have a low therapeutic index should be used with caution.

Adverse Reactions:

The most common adverse reactions occurring in patients receiving Sandostatin LAR Depot are:

- Acromegaly: biliary abnormalities (52%), diarrhea (36-48%), cholelithiasis (13-38%), abdominal pain or discomfort (11-29%), flatulence (26%), influenza-like symptoms (20%), constipation (19%), headache (15%), anemia (15%), hyperglycemia (15%), injection site pain (2-14%), hypertension (13%), dizziness (12%), fatigue (11%), nausea (10%), vomiting (7%), hypothyroidism (2%), hypoglycemia (2%), and goiter (2%).
- Carcinoid Tumors and VIPomas: biliary abnormalities (62%), injection site pain (20-50%), nausea (24-41%), abdominal pain (10-35%), fatigue (8-32%), headache (16-30%), hyperglycemia (27%), back pain (8-27%), constipation or vomiting (15-21%), dizziness (18-20%), sinus bradycardia (19%), pruritus (18%), URTI (10-18%), myalgia (4-18%), flatulence (9-16%), arthropathy (8-15%), rash (15%), generalized pain (4-15%), sinusitis (5-12%), conduction abnormalities (9%), hypoglycemia (4%), and arrhythmia (3%).

Please see full Prescribing Information for Sandostatin LAR Depot.

About Exjade
In the US, Exjade is now indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 mg of iron per gram dry weight (mg Fe/g dw) and a serum ferritin measurement greater than 300 micrograms per liter. The basis of this indication is data showing achievement of an LIC less than 5 mg Fe/g dw after treatment with Exjade. An improvement in survival or disease-related symptoms has not been established.

Since 2005, Exjade has been approved in the US for the treatment of chronic iron overload due to blood transfusions in adult and pediatric patients (aged 2 years and over). Exjade is approved in over 100 countries including the US, Switzerland, Japan and the countries comprising the European Union. The approved indication may vary depending upon the individual country.

Exjade Important Safety Information
Exjade is contraindicated in patients with creatinine clearance <40 mL/min or serum creatinine >2 times the age-appropriate upper limit of normal; poor performance status and high-risk myelodysplastic syndromes or advanced malignancies: platelet counts <50 x 10^9/L; known hypersensitivity to deferasirox or any component of Exjade.

There have been postmarketing reports of acute renal failure, hepatic failure and cytopenias. Renal failure requiring temporary or permanent dialysis, renal tubulopathy and interstitial nephritis have been reported. Upper gastrointestinal ulceration and hemorrhage, sometimes fatal, have been reported. Caution should be used in elderly patients due to a higher frequency of adverse reactions. Exjade is not recommended in patients with a short life expectancy (e.g., high-risk myelodysplastic syndromes), especially when co-morbidities could increase the risk of adverse events.

Skin rashes, serious hypersensitivity reactions, decreased hearing and lens opacities have been reported. The most common adverse reactions are nausea, vomiting, diarrhea, abdominal pain, rash, non-progressive increases in serum creatinine, increased transaminases, abdominal distension, constipation, dyspepsia, proteinuria and headache.

Please visit www.exjade.com. The full prescribing information including the Boxed Warning for Exjade is available at http://www.pharma.us.novartis.com/product/pi/pdf/exjade.pdf.

About LDK378, LGX818, BYL719 and MEK162

Because these are investigational compounds, the safety and efficacy profile of LDK378, LGX818, BYL719 and MEK162 have not yet been established. Access to these investigational compounds is available only through carefully controlled and monitored clinical trials. These trials are designed to understand better the potential benefits and risks of the compound. Because of uncertainty of clinical trials, there is no guarantee that LDK378, LGX818, BYL719 and MEK162 will ever be commercially available anywhere in the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "Breakthrough Therapy," "will," "potential," "advancing," "pipeline," "progress," "investigational," "working towards" or similar expressions, or by express or implied discussions regarding potential new indications or labeling for existing products, potential submissions for or approvals in any indication for investigational compounds, or regarding potential future revenues from such compounds and products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that of the investigational compounds referred to in this release will be submitted or approved for sale in any market, or that the existing products referred to in this release will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that any of the investigational compounds or products referred to in this release will achieve any particular levels of revenue in the future. In particular, management's expectations regarding such products could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

* Known as Glivec® (imatinib) outside the US, Canada and Israel
† MEK162 is licensed from Array BioPharma Inc.

References
(1) American Society of Clinical Oncology. ASCO Annual '13 Meeting Program. Available at: http://abstracts2.asco.org/. Accessed May 2013.

(2) European Hematology Association. EHA Annual Meeting Program. Available at: https://b-com.mci-group.com/EventProgramme/EHA18.aspx. Accessed May 2013.

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