MEDIA RELEASE

First myelofibrosis medication for life-threatening blood cancer approved in Singapore

- First oral medication approved by Health Sciences Authority Singapore for the treatment of myelofibrosis

- In Singapore, an estimated 120 patients with myelofibrosis are seen each year and these include patients with primary and secondary myelofibrosis.

- Ongoing studies show Jakavi® helps to reduce the risk of death and maintained spleen reductions at three years compared to conventional therapy and placebo

- Similar survival benefit seen in patients with and without high-risk mutations

**Singapore, 15 May, 2014** – Novartis announced today, the launch of Jakavi, the first and only approved oral medication to treat patients suffering from myelofibrosis in Singapore, and across more than 50 countries. Jakavi® (INC 424, ruxolitinib) is a JAK 1 and JAK 2 inhibitor for the treatment of disease-related splenomegaly and/or symptoms in adult patients with myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Myelofibrosis is an uncommon and a particular type of life-threatening blood cancer (myeloid neoplasm) characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms, severely impacting people’s quality of life. In Singapore, Myeloid Neoplasms, a group of blood cancers, constitute one of the top 10 cancers in males across all ethnic groups as well as in females of Malay and of Indian ethnicity. Studies show that patients with myelofibrosis have a median overall survival of less than 6 years and traditionally, prognosis of this condition is poor and treatment options are limited. Patients suffer symptoms arising from insufficient numbers of normal blood cells and chronic inflammation. These include but are not limited to extreme fatigue, night sweats and intractable pruritus (itching), poor quality of life and weight loss, as well as fatality 1.

“The approval of Jakavi® by the Health Sciences Authority brings an urgently needed new treatment option to patients with myelofibrosis,” said Dr. Grace Kam, Hematologist at Singapore General Hospital. “By targeting the JAK-STAT pathway which is dysregulated in myelofibrosis, Jakavi® delivers a rapid and durable benefit that has the potential to make a real difference in the lives of patients with myelofibrosis.”

“Beyond patients residing in Singapore, the availability of Jakavi® – currently the only treatment to myelofibrosis – in Singapore would also benefit patients from some countries in South East Asia, where Jakavi® is currently unavailable and stem cell transplant may not be feasible,” said Dr. Daryl Tan, Specialist in Haematology & Consultant at Raffles Cancer Centre. The launch of Jakavi® reinforces Singapore’s reputation as a medical hub in addition to its internationally accredited healthcare providers and modern approach to medicine in the region.

“Jakavi® will address the unmet treatment needs for myelofibrosis patients in Singapore,” said Parames Suwansiri, Business Unit Head, Oncology, Novartis Singapore. “We are committed to the development of innovative treatments for orphan diseases, and are furthering research to assess the
potential of targeting Jakavi therapy for other malignancies associated with a dysregulated JAK pathway.”

A pooled overall survival analysis of the ongoing Controlled Myelofibrosis Study with Oral JAK Inhibitor Therapy (COMFORT-I and – II) studies showed risk of death at three years was reduced by 35% in patients initially randomized to treatment with Jakavi® compared to those randomized to the placebo group. Among all patients in the study, bigger spleen size before treatment was associated with higher risk of death. In analysing the impact of disease mutations on spleen size reduction, anemia development and overall survival in patients with myelofibrosis initially randomized to treatment showed Jakavi had a similar effect in patients with certain disease mutations as well as for patients without these mutations.

A two-year Controlled Myelofibrosis Study with Oral JAK Inhibitor Therapy showed patients who are on the Jakavi® treatment has also resulted in sustained reductions in spleen size, a hallmark of myelofibrosis, while also improving quality of life and extending overall survival compared to placebo or the best available therapy (BAT).

Jakavi is now available in Singapore and approved by the Health Sciences Authority Singapore.

**About Myelofibrosis**

Myelofibrosis is a life-threatening blood cancer with a poor prognosis and limited treatment options. Studies show that patients with myelofibrosis have a decreased life expectancy, with a median survival of 5.7 years. Although allogeneic stem cell transplantation may cure myelofibrosis, the procedure is associated with significant morbidity and transplant-related mortality and is available to less than 5% of patients who are young and fit enough to undergo the procedure.

**About Jakavi®**

Jakavi® (INC424, ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases4. The recommended starting dose for Jakavi is 15 mg twice daily for patients with a platelet count between 100,000 cubic millimeters (mm3) and 200,000 mm3, and 20 mg 3/5 twice daily for patients with a platelet count of >200,000 mm3. Doses may be titrated based on safety and efficacy. Novartis licensed INC424 (ruxolitinib) from Incyte for development and potential commercialization outside the US. Incyte has retained rights for the development and commercialization of INC424 (ruxolitinib) in the US. Both the European Commission and the US Food and Drug Administration (FDA) granted INC424 (ruxolitinib) orphan drug status for myelofibrosis. Incyte received FDA approval for INC424 (ruxolitinib) in November 2011 under the name Jakafi® for the treatment of patients with intermediate or high-risk myelofibrosis. As part of the Novartis clinical development program, Jakavi® is also being investigated in clinical trials for the treatment of polycythemia vera. Jakavi® is a registered trademark of Novartis AG in countries outside the United States.

**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 (incidence >10%) are urinary tract infections, anemia, thrombocytopenia, neutropenia, hypercholesterolaemia, 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.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as "potential," "committed," "potentially," "being investigated," or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Jakavi, or regarding the potential approval of new indications or labeling for Jakavi, and the timing of any such approvals, or regarding potential future revenues from Jakavi. 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 with Jakavi to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Jakavi will be approved for sale in any additional markets, or for any additional indications or labeling, or at any particular time. Neither can there be any guarantee that Jakavi will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Jakavi could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; government, industry and general public pricing pressures; unexpected manufacturing issues; competition in general; 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 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 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 126,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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Reference

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