

## MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

# Novartis settles patent litigation on Gleevec® (imatinib mesylate) with Sun Pharma subsidiary

- Litigation settlement upholds validity of U.S. patents covering polymorphic forms of Gleevec and permits Sun Pharma subsidiary to launch a generic version on February 1, 2016
- Patents are vital to the ability of innovative companies like Novartis to invest in high-risk research to advance breakthrough treatments for patients

**East Hanover, NJ, May 14, 2014** -- Novartis Pharmaceuticals Corporation has settled its litigation with a subsidiary of Sun Pharmaceutical Industries Ltd. relating to Novartis patents covering the use of certain polymorphic forms of Gleevec<sup>®</sup> (imatinib mesylate), which expire in 2019 (including pediatric exclusivity). The basic compound patent for Gleevec expires in the U.S. on July 4, 2015.

As a result of the settlement, Novartis will permit Sun Pharma's subsidiary to market a generic version of Gleevec in the United States on February 1, 2016. The terms of the settlement agreement are otherwise confidential. Sun Pharma's subsidiary has received tentative approval from the U.S. Food and Drug Administration (FDA) for its generic version of imatinib mesylate.

Patents are vital to the ability of innovative companies like Novartis to invest in high-risk research to advance breakthrough treatments for patients without treatment options. This settlement validates the Novartis patents while allowing Sun Pharma's subsidiary to enter the market with its generic product.

Novartis is the first healthcare company with a global leadership position in both patented prescription and generic pharmaceuticals. Offering high-quality generics through its Sandoz division plays a critical role in the Novartis strategy of offering a complete range of treatment options to patients, physicians and healthcare providers worldwide.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as "permits," "to launch," "expire," "will," "tentative," "to enter," "strategy," or similar terms, or by express or implied discussions regarding potential future revenues from Gleevec. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Gleevec will be commercially successful in the future. In particular, management's expectations regarding Gleevec could be affected by, among other things, the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected regulatory actions or delays or government regulation

generally; unexpected manufacturing issues; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit <a href="http://www.novartis.com">http://www.novartis.com</a>.

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