



Incyte Provides Statement on World Health Organization Global Medical Product Alert for Iclusig® (ponatinib)

Lausanne, Switzerland, 31 January 2019 – On 31 January 2019, a World Health Organization (WHO) Global Medical Product Alert titled [Falsified ICLUSIG traded globally](#) was published confirming that falsified versions of Iclusig® (ponatinib)* are circulating in the WHO Region of Europe and the WHO Region of the Americas.

Investigations by Incyte and WHO have verified that two versions of falsified Iclusig product and batch numbers are being traded in Turkey, Argentina and Switzerland, and by internet sales. Laboratory analysis of Iclusig 15 mg (UK/Ireland pack, batch number 25A19E09) confirmed that the product does not contain ponatinib, the active pharmaceutical ingredient found in Iclusig, and instead contains a low dose of paracetamol. Laboratory analysis of Iclusig 45mg (UK/Ireland pack, batch number PR072875) is not fully completed, but preliminary results indicate that it also does not contain ponatinib.

Incyte is not aware of additional counterfeit product bearing different batch numbers, and to-date there are no known reported adverse reactions attributed to these falsified products.

As a company committed to research and development, patient safety is Incyte's utmost priority. We are working diligently with key stakeholders in an effort to address this issue and to continue to ensure the safety of patients taking our medicines around the world.

In recognition of the potential efficacy and safety concerns related to falsified products, Incyte urges anyone who has concerns related to the WHO alert or falsified Iclusig to verify the authenticity of the product lots and obtain Iclusig directly from Incyte, its authorized distribution partners or from validated and reliable sources able to demonstrate authenticity of origin. Patients should contact their healthcare providers with any concerns with respect to this product.

Inquiries related to this issue or Iclusig can be made to Incyte Medical Information at eumedinfo@incyte.com or +800 00027423.[†] Country-specific contact information can be found [here](#).

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this statement, including statements regarding efforts to resolve the falsified Iclusig matter, contain predictions, estimates and other forward-looking statements. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including those risks detailed in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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* Iclusig (ponatinib) is approved for use in chronic myeloid leukemia (CML) and Philadelphia-positive (Ph+) acute lymphoblastic leukemia (ALL) patients who are resistant to or intolerant of certain second generation BCR-ABL inhibitors and all patients who have the T315I mutation. Incyte has an exclusive license from Takeda Pharmaceuticals International AG to commercialize Iclusig in the European Union and 28 other countries, including Switzerland, Norway, Turkey, Israel and Russia.

† Please note, per country requirements, you may be required to dial (+), (0), or (00) before the free phone number. The +800 00027423 number is active in the following countries AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, PT, RU, SE, SK, and SI.