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

Updated 3 May 2019

Lausanne, Switzerland – 3 May 2019 – The World Health Organization (WHO) Global Medical Product Alert has published several global confirming that falsified versions of Iclusig® (ponatinib)* are circulating in the WHO Regions of Europe, the Americas and in Asia.

Investigations by Incyte, its collaboration partners at Takeda[†] and WHO have verified that several versions of falsified Iclusig product and batch numbers have been distributed to wholesalers in multiple regions, including Turkey, Argentina, Malaysia and Colombia, and also to individuals by internet sales. Additionally, Incyte and Takeda have been informed that some units of the falsified product and batch numbers have also been purchased by European traders with intent for exportation outside of Europe.

The falsified batches identified to date include:

- Iclusig 15 mg (UK/Ireland pack, batch number 25A19E09)
- Iclusig 45 mg (UK/Ireland pack, batch number PR072875[‡])
- Iclusig 45 mg (German pack, batch number PR0834170)

Laboratory analysis conducted on samples of the falsified batches confirmed that the analyzed tablets do not correspond to authentic Iclusig tablets and either do not contain any active ingredient at all or do not contain the active ingredient as approved by regulatory authorities. The complete composition of the falsified tablets could not be determined. Any situation in which a patient receives a product from an unlawful source and containing unknown substances has potential major safety and efficacy implications.

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 and Takeda urge 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	**Takeda Medical Information**
eumedinfo@incyte.com	GlobalOncologyMedInfo@takeda.com
+800 00027423[§]	U.S.: +1-844-ONC-TKDA (+1-844-662-8532)
Country-specific contact information can be found here.	Ex-U.S.: +1-510-740-1273
	www.takedaoncology.com/contact-us

Inquiries specifically related to the investigation regarding Iclusig can be made to Takeda Global Product Protection at GlobalProductProtect@takeda.com.

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 Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including those risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended March 31, 2019. Incyte disclaims any intent or obligation to update these forward-looking statements.

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Media Contact:

Global		**Europe**	
Catalina Loveman	+1 302 498 6171 cloveman@incyte.com	Ela Zawislak	+41 21 343 3113 ezawislak@incyte.com

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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. Iclusig is marketed by Takeda Pharmaceuticals International AG in the U.S.

‡ UK/Ireland pack, batch number PR072875 is confirmed to be falsified product. The same batch number exists in Germany, however German pack, batch number PR072875 is genuine. Concerns or questions related to UK/Ireland pack, batch number PR072875 or German pack, batch number PR072875 should be directed to eumedinfo@incyte.com.

§ 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.