



The Minister for Health and Social Services in Wales ratified the positive recommendation from the All Wales Medicines Strategy Group (AWMSG) that Iclusig® (ponatinib) is a cost-effective treatment option for use within its licensed indication in chronic myeloid leukaemia and Philadelphia chromosome positive acute lymphoblastic leukaemia

The positive assessment from the AWMSG is the first UK Health Technology Assessment (HTA) of Iclusig

Leatherhead, UK, 9 January 2015 -- The Minister for Health and Social Services in Wales has ratified the recommendation from the All Wales Medicines Strategy Group (AWMSG) to approve Iclusig® (ponatinib) as a cost effective treatment to be used in NHS Wales for the treatment of all phases of chronic myeloid leukaemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), in accordance with Iclusig's licensed indication.

CML is a cancer of the white blood cells that is diagnosed in approximately 7,000 patients each year in Europe.ⁱ The incidence of CML in Wales is 1.4 and 0.9 per 100,000 males and females, respectively.ⁱⁱ Iclusig is a targeted cancer medicine discovered and developed at ARIAD Pharmaceuticals, Inc.

"We are delighted that the Minister has endorsed the positive AWMSG recommendation, recognising the innovative nature of Iclusig and the potential benefit it can bring to cancer patients in Wales," said Mark Tanner, General Manager, ARIAD UK. "Our goal is to deliver innovative solutions that address gaps in care for patients who are left with few clinical treatment options. Iclusig offers a new treatment option for many of these patients."

The approval by the AWMSG was based on results from the pivotal Phase 2 PACE (Ponatinib Ph+ ALL and CML Evaluation) trial in patients with CML or Ph+ ALL who were resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy, or who had the T315I mutation of BCR-ABL. In Europe, Iclusig was approved in July 2013 for the treatment of adult patients with:

- Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation;
- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent

treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

“We welcome the ratification of the recommendation from the AWMSG for the treatment of CML and Ph+ ALL with Iclusig in all its licensed indications,” commented David Ryner, Chair of the Chronic Myeloid Leukaemia Support Group. “Although the number of patients qualifying for treatment will be limited, access to Iclusig represents an opportunity to make a significant difference to their lives. We would like to see the same opportunity made available to all other qualifying patients, no matter where they live in the UK.”

About Iclusig® (ponatinib)

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig was designed using ARIAD's computational and structure-based drug design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

About CML and Ph+ ALL

CML is a cancer of the white blood cells that is diagnosed in approximately 7,000 patients each year in Europe. Error: Reference source not found CML is characterised by an excessive and unregulated production of white blood cells by the bone marrow due to a genetic abnormality that produces the BCR-ABL protein. After a chronic phase of production of too many white blood cells, CML typically evolves to the more aggressive phases referred to as accelerated phase and blast crisis. Ph+ ALL is a subtype of acute lymphoblastic leukaemia that carries the Ph+ chromosome that produces BCR-ABL. It has a more aggressive course than CML and is often treated with a combination of chemotherapy and tyrosine kinase inhibitors. The BCR-ABL protein is expressed in both of these diseases.

About ARIAD

ARIAD Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts and Lausanne, Switzerland, is an integrated global oncology company focused on transforming the lives of cancer patients with breakthrough medicines. ARIAD is working on new medicines to advance the treatment of various forms of chronic and acute leukaemia, lung cancer and other difficult-to-treat cancers. ARIAD utilises computational and structural approaches to design small-molecule drugs that overcome resistance to existing cancer medicines. For additional information, visit <http://www.ariad.com> or follow ARIAD on Twitter ([@ARIADPharm](https://twitter.com/ARIADPharm)).

Iclusig® is a registered trademark of ARIAD Pharmaceuticals, Inc.

This press release contains “forward-looking statements” including, but not limited to, updates on regulatory developments in Europe. Forward-looking statements are based on management's expectations and are subject to

certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to the impact of the strengthened warnings on sales of Iclusig; difficulties in commercializing Iclusig arising from the post-marketing approval review process or from its results; the emergence of other safety concerns based on additional adverse events in patients being treated with Iclusig and other risk factors detailed in the Company's public filings with the U.S. Securities and Exchange Commission. The information contained in this press release is believed to be current as of the date of original issue. The Company does not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in the Company's expectations, except as required by law.

References

ⁱ Rohrbacher M, Hasford J. Epidemiology of chronic myeloid leukaemia (CML). [Best Pract Res Clin Haematol](#). 2009 Sep;22(3):295-302. Based on current estimate of population of Europe (738,199,000 in 2010).

ⁱⁱ Welsh Cancer Intelligence & Surveillance Unit. Cancer Incidence in Wales 2005-2009 (Annual Publication No. SA11/01). 2014. Available at: <http://www.wcis.u.wales.nhs.uk/sitesplus/documents/1111/incpub2011.pdf>. Accessed on: April 2014.

CONTACTS:

For Investors
For U.S. Media
For EU Media

Kendra Adams
Liza Heapes
Gemma White

Kendra.adams@ariad.com

liza.heapes@ariad.com

gwhite@biosector2.co.uk

+01 (617) 503-7028

+01 (617) 621-2315

+44 (0)20 337 25 221

###

Source: ARIAD Pharmaceuticals, Inc.