

MEETING MINUTES

7th CML Community Advisory Board (CML-CAB) with Incyte/Takeda on March 5, 2019

All trademarks are the property of their respective owners.

Executive Summary

CAB meetings provide an opportunity to build a meaningful relationship between pharmaceutical companies and the patient community to overcome the challenges and needs associated with chronic myeloid leukaemia (CML). The main objectives of this 7th CML Community Advisory Board (CML-CAB) meeting were to foster a mutual understanding and to take tangible actions forward for Incyte who commercializes ICLUSIG® (ponatinib) in European Union and Takeda who commercializes ICLUSIG in the United States, the patient community and both in collaboration. Topics discussed during the meeting included collaboration between the CML community and Takeda, Incyte & alliance partners, access, clinical use of and research on ponatinib and Takeda's and Incyte's commitment to the CML community.

On the subject of access, the CML-CAB suggested a meeting with CML-CAB and Takeda's alliance partners / distributors on access to ponatinib at EHA to educate at a high level, foster understanding of community frustration surrounding this topic, and work towards solutions. Takeda and Incyte informed that they plan to explore improving access to and prescribing of mutation testing and address physician perception about next-generation sequencing (NGS) testing as a marketing exercise. Incyte and Takeda committed to consider cascading Incyte's TTT Think Test Treat initiative, as well as other similar initiatives currently being undertaken by Takeda, on mutation testing in CML and Ph+ ALL initiative on mutation testing to other alliance partners and explore the possibility of adapting such programs to interested PAGs.

In connection with the clinical use of ponatinib, CML-CAB agreed to report on progress of a tracking app with a goal to improve side effect management. Takeda and Incyte will continue to partner with the CML community to address concerns about adverse events and proper management of side effects, and explore the creation and further refinement of patient materials on managing side effects.

On the subject of research on ponatinib, Takeda stated that they have a strong interest in making ponatinib available for children. Additionally, Takeda and Incyte are committed to exploring real world evidence studies on dose, mutation testing and side effects for ICLUSIG and look into development of mechanism for early and systematic patient engagement in study protocol design and drug development cycle.

The donation of ponatinib to a pediatric patient with Ph+ ALL in Lithuania which involved collaboration of over 50 people and to a Palestinian CML patient and one CML patient in the Ukraine were highlighted as recent examples of successful collaboration between the CML community and Incyte. Furthermore, collaboration between Incyte and The Max Foundation resulted in 23 new patients in 7 countries in 2018 and a total of 37 patients still benefiting ponatinib. There were 60 "active" slots in 2019.

Finally, Takeda's commitment to the CML community included continuing to bring Takeda team members devoted to the CML space to CML-CAB meetings, continuing to consult with patients beyond

the US where possible and work with alliance partners in the remaining regions, continuing to explore trial sites in areas of unmet need, and continuing to support CML community initiatives.

All parties found the open dialogue fruitful and expressed their clear commitment to meet again and continue discussions to foster understanding and find solutions.

Meeting moderated by:

Kathy Redmond, Moderator/Facilitator

Minutes prepared by:

Lisa Machado and Nicole Schröter (based on confidential minutes developed by Marion Alzer (Medical Writer)