

CML Community Advisory Board (CML-CAB)

Report of the meeting between the CML-CAB and representatives from Novartis held at the Marriott Hotel, Lisbon, from 14:00-18:00 on 16th May 2019

PUBLIC COMMUNITY VERSION, FOR DISTRIBUTION TO MEMBERS OF CML ADVOCATES NETWORK

CML-CAB Members

Jan Geissler, Germany (CML-CAB chair)
Pat Garcia-Gonzalez, USA, The Max Foundation (Co-chair)
Giora Sharf, Israel (Europe)
Jana Pelouchova, Czech Republic (Central and Eastern Europe)
Mercedes Arteaga, Argentina (representing Latin America)
Gail Sperling, USA (representing North America)
Bahija Gouimi, Morocco (representing Africa and Middle East)
Rita Christensen, Denmark (representing Western Europe)
Rod Padua, Philippines (representing East Asia and Pacific)
Felice Bombaci, Italy (representing Western Europe)
Silvia Castillo De Armas, Guatemala (Latin America)
Sarunas Narbutas, Lithuania (Central & Eastern Europe, & West Asia)
Lisa Machado, Canada (North America)
Yair Bar David, Israel
Cornelia Borowczak, Germany (Paediatrics)
Zack Pemberton-Whiteley, United Kingdom (Western Europe)
Jelena Cugurovic, Serbia (Eastern Europe)
Parameswaran Puthen, India (East Asia/Pacific)
Eunice Orekha, Nigeria (Africa)

Lidija Pecova (LePAF, Programme Manager)
Celia Marin (LePAF, Programme Manager)

Novartis

Mohit Rawat, Executive Director, Global Marketing
Geoff Cook, Executive Director External & Patient Relations
Paul Robinson, Development Unit Head, Trial Operations Management
Alexey Salamakha, Director, Patient Relations, Global Oncology
Louise Huneault, Patient Relations Head, Oncology Region Europe
Paola Aimone, Global Program Clinical Head
Lynnette Van Heerden, Global Drug Development Communications
Jasminka Taleska, Country Manager/Public Affairs Manager lead for Central Eastern Cluster and RU countries

Meeting moderated by:
Kathy Redmond, Moderator/Facilitator

Report prepared by:
Katy Munns

Background

CML-CAB meetings provide an opportunity to foster mutual understanding and build a meaningful relationship between pharmaceutical companies and the patient community in overcoming the challenges and needs associated with CML. The CML Advocates Network is one of the largest disease-specific networks in the world and includes 122 patient organizations in 92 countries on 6 continents. The CML-CAB members represent 233 years of patient life with CML, have an outreach to 115,000 CML patients and to an additional 110,000 cancer patients worldwide.

CAB members set the agenda for meetings with companies and discussions are confidential until there is mutual agreement content can 'leave the room'. Topics dealt with at this seventh CML-CAB meeting included progress on agreed actions, patient-focused outcomes, the set-up status of clinical trial sites and access to nilotinib and asciminib in low and middle-income countries (LMIC).

The meeting was dedicated to the memory of Ferdinand Mwangura, our patient advocacy leader from Kenya, who we lost to CML recently.

CML-CAB strategic priorities 2019

To determine its strategic goals for the coming year, CML-CAB undertook a review of its collaboration with corporate supporters. A Report-Card System was used to summarise how CAB advice had been acted upon and the CAB's assessment of Novartis' activity in clinical research projects, access and educational materials was shared.

CML-CAB's strategic priorities for 2019 are based on two strategic pillars, research and access, underpinned by focused goals. For research these focused goals are participation in clinical trials in low & middle-income countries; increased quality of life of CML patients (which may include side effect management and therapy-free remission); and achieving a cure. For access the goals are improving access to treatment and improving access to monitoring.

The group expressed a wish to gain a better understanding of the cross over between its strategy and Novartis' goals and in response the company presented an overview of the 'Novartis Commitment and Collaboration' with CML-CAB. This has four key dimensions: integrate the patient perspective in the asciminib program; drive awareness of unmet need in CML; expand access in countries with limited access options; demonstrate the value of patient engagement. The company is also keen to explore a multi-stakeholder coalition on access in low income countries.

Recap of November 2018 actions

Actions agreed at the last meeting were presented and it was noted that the process for providing updates needs to be improved. In future, follow-up between CML-CAB meetings will be agreed. A workgroup model was suggested in which a subgroup of CML-CAB member could be consulted for advice, with the possibility to consult additional CML-CAB members.

Novartis intended to create a blueprint for trial recruitment (how many patients, who) to aid collaboration and explained that there is a requirement for every Novartis clinical development programme – from proof of concept through approval and launch – to have metrics on patient engagement in place. The company is moving to a point where it can demonstrate that studies which engage with the patient community well can generate more meaningful data and eventually have a positive impact on outcomes and access.

Clinical Development Updates

An overview of progress with recruitment to the ASCSEMBL trial was provided, with a focus on the newly added countries of Latin America, Asia, Middle East and Southeast Europe. The group discussed a number of different factors which impact on the company's ability to place trials in certain countries, for example, where the comparator product has not been approved for use in third line, slow approvals for EPRO translations and delays in obtaining import licenses. Novartis feasibility assessments for each country could be discussed at a future meeting to determine how the community can help resolve problems. The group said it would be helpful to build a core list of barriers and lessons to overcome them for use in other disease areas.

CML-CAB stressed that it is important for patients in countries that do not have a trial to be able to access those taking place in neighbouring countries. For example, from Macedonia to Bulgaria and Serbia. This is a model that, subject to local laws, could be tried in other regions.

Patient-focused outcomes as measured in the asciminib programme

Novartis presented a summary of the patient-related measures being used across asciminib phase II and III studies. CML-CAB fed back that the community is most concerned about successful navigation of the HTA process, toxicity and quality of life differences when compared to other products. It was proposed that a discussion should take place once the data becomes available.

On compassionate use, the CML-CAB fed back that manufacturing delays are compromising the value of the MAP programme to patients, and it was agreed that Novartis would follow up internally and provide an update in time for the next meeting.

Access to PCR Testing

CML-CAB believes access to PCR testing is a critical aspect of unmet need that needs to be addressed and that the profile of the issue needs to be maintained. Country by country solutions are needed and it was agreed that advocacy groups could work with companies in cases where national authorities are the main barrier to long term provision.

Access to nilotinib and asciminib in Low and Middle-Income Countries (LMIC)

The challenge for low income countries is how to create sustainable solutions. In countries where there are no generics available and no government commitment to treat cancer, Novartis' Path to Care can be put in place. More countries had moved to this programme since the CML-CAB last met (the programme has been outsourced to the Max Foundation), but there are still outliers. A willingness for governments to accept a shared responsibility and a willingness to engage is necessary. The meeting discussed a number of country-specific issues and Novartis asked if CML-CAB could prioritise countries for action as well as provide specific information on where patient populations are unable to gain access? It was therefore agreed that CML-CAB would provide Novartis with a list of countries it suggests might be included in Path to Care. Novartis advised the group that it is committed to look at all access issues that CML-CAB members raise and will represent these internally. The company is also committed to working with the community to advocate policies for change.

Two further requests were made: that issues faced in richer countries should also be on the CML-CAB agenda; and there should be a discussion on the overall global access strategies for nilotinib, how it differed from the approach for imatinib, and how access to asciminib will be different.