Minutes of The first brain storming meeting for the Win-Win Initiative:

The meeting was held on Saturday 30 May, 2009, 11.30-12.45 PM convention center , Orlando, FL, USA (During the ASCO 2009 Conference) .

Pilots Participants: Prof. David Kerr (President Elect of ESMO), Mr. Doug Pyle (Director of ASCO International Committee), Dr. Joe Harford (Director of international affairs, NCI, USA), Prof. Eduardo Cazap (President of UICC), Prof. Ben Anderson (BHGI, USA), Prof. Heinz Zwierzina (Austria & ICEDOC), Dr. Anne Reeler and Dr. Joseph Saba (from Axios) and Ahmed Elzawawy (ICEDOC & SEMCO).

(The text of the Paragraph* in page 2 is proposed and edited by PACT/IAEA)

Absents : Prof. Sofia Merajver (USA)

Observers from Pharmaceuticals companies: Nancy Cure-Bolt (BMS), Mayada El-Ahmed (BMS), Hesham Hagar (BMS), Alexandros Tseparlis (International Public Policy Manager, Roche).

N.B. Just after the meeting there was a discussion with Prof. Mohamad Hussein, Vice President of Celgene, USA. There was a positive feedback and e-mail after .It is enclosed with the draft of these minutes. (Annex I)

1. Welcome and Statement of Purpose

Prof. David Kerr welcomed the group and reiterated that the meeting was an informal exchange of ideas about the Win-Win initiative and whether it is recommended to go forward in next steps.

2. The Concept of the Win-Win Scientific Approaches:

Ahmed Elzawawy presented:

There is progressive increase in costs of novel cancer drugs that will result in increase of non affordability of these treatments to more increasing number of cancer patients in the world. If this continues, then, the markets of these drugs would be more concentrated in USA, West Europe and Japan, leaving most of patients in *Low and Middle Income Countries* (LMCs) who constitute the majority of patients in the world, without accessibility to these treatments. There could be scientific avenues to be explored in order to a have a win-win outcome for all stakeholders, mainly patients and pharmaceuticals companies. Price of drugs constitutes 10-30% of the cost of treatment. Hence, price of drugs is not obligatory the

sole or the main approach. At present, regarding breast cancer systemic therapy, there are in the literature some encouraging scientific approaches that could lead to lower the cost of treatment without significant evidence of compromising the overall result .These scientific studies deserve to be more explored. More thoughts and researches should be encouraged. This could lead to more resource sparing, cost effective and more affordable breast cancer drug therapy. This would increase –or at least keep- the markets of the leading pharmaceuticals companies in Middle- and consequently- in some of the low income countries.

In addition to novel drugs, the initiative includes also the idea of investigating more uses, ways and schedules of administration, new combinations of older drugs for treating breast cancer that could be cost effective, tailored to each locality and could be much more affordable in developing countries. The initiative implies assurance of the quality and bioequivalence of generics. This would results in benefits to both patients and companies producing drugs of good quality. Also, this could pave environment the way for cost effective use of novel drugs in some countries.

*Breast cancer systemic therapy is a first model. But, The Win-Win is an approach proposed by ICEDOC as a viable option for better leveraging of resources within different cancer management modalities e.g. other drug therapy for other cancers and initiatives for resource sparing and win- win increasing of affordability of Radiation Oncology in the world (ICEDOC's message, September 1996, Vienna, see: www.icedoc.org). Recently, there are more intensive and encouraging efforts, which will can be a promising revival of innovative methods and techniques through the IAEA's PACT by its actions to help reduce the costs associated with radiotherapy and making it a more affordable option for cancer patients in low income countries around the world. PACT has brought together different stakeholders, experts advisors and more to carry out its mission. Hence, it is a pragmatic win-win avenue and it deserves all possible collaboration and cooperation.(The last paragraph is edited by colleagues of PACT/IAEA).

We advised to read two recent articles presenting the Win-Win initiative (Full free texts are available on line):

Elzawawy AM : Breast Cancer Systemic Therapy: The Need for More Economically Sustainable Scientific Strategies in the World. Breast Care 2008;3:434–438 (full text is available online in the website of Breast Care, Karger www.karger.com/brc) or browse: http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstract&ArtikelNr =170233&Ausgabe=243485&ProduktNr=231161

& Elzawawy A : **The "Win-Win" initiative: a global, scientifically based approach to resource sparing treatment for systemic breast cancer therapy** .World Journal of Surgical Oncology 2009, 7;44 (Free full text online browse <u>http://www.wjso.com/content/7/1/44</u>)

(The presentation of May 30, 2009 is attached here with as PowerPoint presentation)

3. Scenario Analyses and Discussion

There was a discussion of how we could develop different treatment schedules depending on the more scientific, pharmacologic, phamcogenomic, cost effective breast cancer drug therapy –as a start for cancer therapy as a whole- in each locality and with consideration the available resource environment and the overall outcome.

Potential frequently asked difficult questions were raised by Dr. Joe Harford and Prof. Eduardo Cazap (See Annex II)

4. Developing Collaboration

There was an open discussion of how the industry, international and regional scientific bodies and, institutes could contribute to the Win-Win initiative.

Prof. David Kerr, came to the main critical point and objective of the meeting. He asked a direct clear question that whether every one of the participants would like to go forward with the initiative. All participants agreed that the initiative was worth pursuing and to be developed with next step after this 1st brain storming meeting. Hence, more discussion is needed to come with focused objectives and guiding principles that would lead to concrete pilot initiatives and projects.

5. Review Next Steps and Assignments

-Prof.David Kerr and Prof. Eduardo Cazap issued that it was agreed that the initiative was worth pursuing.

- The suggestion of Heinz Zwierzina was accepted. It is to form a small task force.

- Anne Reeler and Ahmed Elzawawy will continue to coordinate the progress of the initiative. They will assist –with the group- in contacting the pharma representatives that were present at the meeting with regard to presenting further clarification on the more concrete aspects of the Win-Win

initiative including the business case in the proposal. Anne and Ahmed will contact the rest of the members to discuss different aspects.

-The meeting was a brain storming. In the future , the win-win initiative could be linked to the CanTreat group. Also, it is hopped that the Win-Win Initiative would have links to the ESMO under the presidency of Prof. David Kerr, and with BHGI, with AXIOS and with all possible active contributors.

- We don't claim that we have a ready made magic stick .The challenges are complicated. The way is not so smooth. But, smart and scientific approaches and the will to do –together- would help in going forward in next calculated steps:

- Formation of a working task force (Suggestion of Heinz Zwierzina ,and feedback from colleagues): to run communications, to make a brief for a mission statement, to enhance constructive discussions with potentials partners, collaborators, supports and with Pharmaceuticals companies and to arrange for the next steps

- Making a data base. (SEMCO starts to initiate it after the feedback of H.khaled and A. Elzawawy. But, collaboration is opened)

- Arrangement for a workshop for two days ,coming to it with proposals and to go out with concrete priorities of feasible actions and scientific works (A road map for actionable strategy). It is a workshop for 2 days with thorough discussions and plans of actions. The participants would be 8-12 persons (15 max.) .It is not one hour brain storming meeting that had already done

. A published report

- Pilot projects-protocols with collaborators.

The present situation in the world- is not acceptable. It would aggravate to more tragic and complicated escalation for both the users-the cancer patients- and the manufacturers.

In the win-win initiative all will be done with the ambiance of collaboration, cooperation and coordination and with stressing on Win-Win scenarios in which no one-including pharmaceuticals companies-would lose.

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