HARMONY
Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology

Press Release

HARMONY: European Network of Excellence for Big Data in Hematology and Big Data to present new bench-to-bedside projects during the 22nd Annual Congress of the European Hematology Association

Madrid, June 23, 2017 - **Providing the right treatment in time for patients with hematologic malignancies: that is the ambition of the HARMONY Alliance, European Network of Excellence in Hematology and Big Data. HARMONY will make use of today's Big Data technologies in order to accelerate more efficient drug development, regulatory evaluation, access appraisal and treatment strategies.**

The HARMONY Alliance was launched in January 2017 and is funded through the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

Tomorrow, June 24, at the 22nd Congress of the European Hematology Association, HARMONY will present its goals and objectives at an Introductory and Onboarding Session.

Presenting the first two bench-to-bedside projects
At the June 24 session, HARMONY will be presenting its first two bench-to-bedside research projects. One is the proof-of-concept study in acute myeloid leukemia, 'Big Data for Better AML Outcomes', focusing on the impact of genomics and value of intensive treatment approaches in MDS/AML. The second project,'Prognostic factors of treatment with hypomethylating agents (HMA) in higher risks MDS and advanced CMML'. This project focuses on the impact of genomics and value of intensive treatment approaches in MDS/AML. A third project is expected to start in the near future.

1. A proof-of-concept study in AML: Big Data for Better AML Outcomes
While mechanisms of clonal leukemia evolution and disease dynamics are on the verge of being understood, studies have not been large enough to take into account multiple competing clones coexisting at any disease time point and to have sufficient patient numbers to determine the impact on outcome. In addition, today it is still not clear whether high risk MDS cases that are treated like AML patients benefit from intensive treatment approaches.

Goal: The AML pilot study 'Big Data for Better AML Outcomes' aims at evaluating gene-gene interactions in a large data set, comprising data from public repositories (TCGA, Leucegene), at least three large European cooperative working groups (AMLSG, HOVON and MRC AML), as well as data from industry led trials (data contribution from EFPIA). The pilot project will also allow to address an important clinical question that will provide results of immediate relevance to patients.

Impact: This project will contribute to novel biological insights based on which personally tailored management decisions might become feasible. These could help better guide hematopoietic cell transplants in AML and improve overall survival rates. Furthermore, the data of the Proof-of-Concept AML study will form the basis for a HARMONY knowledge bank that facilitates personally tailored therapeutic decisions.

2. Prognostic factors of treatment with hypomethylating agents (HMA) in higher risk MDS and advanced CMML.
HMAs have become the first line treatment of almost all higher risk MDS, and to a lesser extent, of advanced CMML. They can increase median survival from 15 months to about 20-24 months. Response to HMAs is however seen in only 50-60% of the patients, for a median duration of 9 to 12 months. Prognostic factors in the setting of treatment with HMAs remain uncertain, especially because predictors of response may differ from prognostic factors of long-term survival, and as published studies were based on relatively small patient numbers.

Goal: This study will include patients with higher risk MDS and CMML, treated with an HMA, as well as patients who were treated with intensive chemotherapy, a relatively rare approach since the advent of HMAs.
The outcomes will be analyzed to assess prognostic factors for the treatment with an HMA. So far, groups from Italy, Spain, Germany, France, Nordic countries and the UK group have joined the study, totaling about 2500 patients.

Impact: Although it has improved survival, treatment with HMAs alone in higher risk MDS/CMML remains insufficient. Identifying molecular prognostic response of response/ no response should help combine new drugs to HMAs in different genetic contexts, while dynamics of those genetic abnormalities with HMAs versus chemotherapy should guide the strategy of candidates for subsequent transplant. Potential differential effects of the available HMAs (azacitidine, decitabine, SGI 110, CC486) could better guide their differential use.

Harmony in Hematology
The Harmony Alliance consists of 51 partners and brings together key stakeholders from a broad spectrum of disciplines from 11 European countries. Expertise is drawn from academic institutions, national clinical disease networks, European organizations, patient advocacy groups, clinicians, and pharmaceutical companies, as well as regulatory agencies, experts in economics and ethics, and information and technology (ICT) specialists.

More information: **www.harmony-alliance.eu**

Contact: HARMONY Communications Office: Ellen de Waal, Communication Manager
+31654711703, communications@harmony-alliance.eu

HARMONY has received funding from IMI 2 Joint Undertaking and is listed under grant agreement No. 116026. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA).
IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.