ICU
MANAGEMENT & PRACTICE

Hematology/Oncology: New Results from Clinical Research Program

Hematology/oncology: AOP Health's expanding clinical research program delivers new results.

AOP Orphan Pharmaceuticals GmbH (AOP Health) continues a successful clinical research program in hematology/oncology with two abstracts accepted for presentation at the European Hematology Association (EHA) 2024 hybrid congress in Madrid, Spain. One results in an oral presentation of the latest results from the PROUD-PV and CONTINUATION-PV-trials. The outcomes show a correlation between the changes at genetic level (molecular response) and event-free survival (EFS) among patients with a rare blood cancer (polycythemia vera /PV) who received a certain interferon (ropeginterferon alfa-2b/BESREMi®) or best available treatment.[1] A second accepted abstract reports on AOP Health's recently initiated phase III clinical study extending investigation of ropeginterferon alfa-2b to patients with another rare blood cancer, essential thrombocythemia (ET).[2] In a further signal of AOP Health's commitment to innovative research, early development of a first-in-class investigative oncology drug is progressing towards clinical trials.

Reduction of mutated cells improves event free survival in patients with PV and is effectively achieved by ropeginterferon alfa-2b

The latest findings of the large randomised controlled PROUD-PV trial and its extension CONTINUATION-PV3 showed that ropeginterferon alfa-2b reduced the amount of cells that carried a mutation of a certain gene (JAK2V617F, a gene, which regulates cellular growth) in the patient population studied.[3] Analysis of all patients included in the trial over at least 6 years showed significantly prolonged event free survival (period in which patients remain free from events that the treatment was intended to prevent or delay) among patients in which the amount of mutated cells were reduced at the last available assessment.

Professor Jean-Jacques Kiladjian from the University of Paris, France and first author of the paper emphasizes:

> This new evidence supports the clinical relevance of reducing the load resulting of JAK2V617F mutations to improve long-term outcomes in patients with PV, which should be considered as an aim of treatment. Ropeginterferon alfa-2b targets mutated blood-forming stem cells and is highly effective in decreasing the burden resulting from the mutation of JAK2V617F gene.
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> **Jean-Jacques Kiladjian**
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> UNIVERSITY OF PARIS

Phase III clinical study of ropeginterferon alfa-2b in ET underway in Europe

With the aim of examining the potential utility of ropeginterferon alfa-2b in ET patients with significant unmet need, AOP Health has rolled out the ROP-ET trial, a prospective, multicenter, single-arm phase III study to assess the long-term safety and efficacy of ropeginterferon alfa-2b in ET patients unable to receive available cytoreductive therapies.[4] The trial is being conducted at 36 sites in 10 countries in Europe. Almost 50 % of the required number of patients have already been enrolled in the study. This fast recruitment underlines the importance of the clinical trial.

New drug candidate: official start of clinical development imminent

Building on proven success in the development of cancer stem cell targeting therapies, AOP Health is expanding into a new area of research with a first-in-class investigational oncology drug candidate. This orally available, highly selective serotonin receptor 1B antagonist was discovered and initially developed by Leukos Biotech based on research performed at the Josep-Carreras Leukemia Research Institute and licensed by AOP Health for further development and commercial rights. SERONCO-1, a phase I, first-in-human trial in patients with solid tumors

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and lymphomas will be conducted in collaboration with Leukos Biotech at the Vall d'Hebron Institute of Oncology (VHIO) with partial funding from the Spanish Ministry of Science and Innovation through the Public-Private Partnership Program (CPP2021-008715). A subsequent trial in acute myeloid leukemia is expected to commence in 2026.

Source & Image Credit: AOP Health

References

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4. Kiladjian JJ, Marin FF, Al-Ali HK, et al. ROP-ET: a prospective phase III trial investigating the efficacy and safety of ropeginterferon alfa-2b in essential thrombocyth

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