University Hospitals
Seidman Cancer Center

Stem Cell Transplant and Hematologic Malignancies NEWSLETTER

October 2016

This issue of the newsletter highlights our rapidly expanding multiple myeloma study pipeline.

2015 was a groundbreaking year in the fight against multiple myeloma. The Food and Drug Administration approved four new drugs: Darzalex (Daratumumab), Empliciti (Elotuzumab), Ninlaro (Ixazomib) and Farydak (Panobinostat), increasing the number of myeloma medications on the market to 10. Despite this increase, there is still a need for studies that will help define the role of these and newer drugs, and also determine the best way to combine and move new treatments up front and on the salvage setting.

We offer a robust portfolio of myeloma studies, bringing a new generation of trials with immunotherapy to patients who are in different disease stages. Options include a variety of immune-based strategies such as monoclonal antibodies, myeloma vaccine and immune checkpoint inhibitors.

Autologous stem cell transplant remains a cornerstone of myeloma therapy. It is an essential part of treatment for young and fit myeloma patients, supported by the recently reported Intergroupe Francophone du Myelome (IFM) trial. We consider autologous stem cell transplant for patients up to 75 years old.

The following studies are currently recruiting:

Immunotherapy and New Monoclonal Antibodies for Myeloma Patients
MRK1A15: A Phase III study of Pomalidomide and low-dose Dexamethasone with or without Pembrolizumab (MK3475) in refractory or relapsed and refractory multiple myeloma
Pembrolizumab belongs to the family of novel immune checkpoint inhibitors, as they unleash the immune response against myeloma. This trial studies the efficacy of

Pembrolizumab in combination with standard-of-care Pomalidomide.

For more information, contact Ehsan Malek, MD, at Ehsan.Malek@UHhospitals.org.

JAN1A14: Bortezomib, Melphalan, Prednisone and Daratumumab for untreated myeloma patients

Daratumumab is a monoclonal antibody directed against CD38 that facilitates immune recognition and subsequent destruction of myeloma cells. It is an FDA-approved drug as a single agent for relapsed disease. This randomized phase III trial aims at improving the outcomes of standard induction therapy combined with Daratumumab for newly diagnosed multiple myeloma.

For more information, contact Ehsan Malek, MD, at Ehsan.Malek@UHhospitals.org.

S1211: Elotuzumab and Bortezomib, Dexamethasone and Lenalidomide for newly diagnosed high-risk myeloma patients

Elotuzumab is a monoclonal antibody targeting CS1, a glycoprotein found exclusively in myeloma cells and Natural Killer cells, a crucial part of the innate immune system. It is FDA-approved for use in combination with Lenalidomide for relapsed disease. This trial aims to determine the efficacy of Elotuzumab combined with standard induction myeloma therapy.

For more information, contact Ehsan Malek, MD, at Ehsan.Malek@UHhospitals.org.

BMT CNT 1401: Dendritic cell/myeloma fusion vaccine for multiple myeloma

Dendritic cells are antigen-presenting cells that are a crucial part of the immune system. This study uses patients' myeloma cells to activate autologous dendritic cells with the goal of enabling the immune system to track and attack myeloma cells. The myeloma vaccine is administered after autologous stem cell transplant.

For more information, contact Hillard M. Lazarus, MD, at Hillard.Lazarus2@UHhospitals.org.

Novel Drug Combinations for Relapsed Myeloma Patients

CASE4A13: Ixazomib plus Panobinostat and Dexamethasone for relapsed myeloma

This Phase II study is evaluating the efficacy of a combination of two novel agents: the oral proteasome inhibitor, Ixazomib, and the histone deacetylase inhibitor, Panobinostat. Both agents are FDA-approved for relapsed multiple myeloma. This trial aims to test this combination to increase anti-myeloma efficacy.

For more information, contact Ehsan Malek, MD, at Ehsan.Malek@UHhospitals.org.

Immunomodulatory Therapy for Patients with Myeloma

CLGN1A14: Pomalidomide in combination with low-dose Dexamethasone in subjects with relapsed and refractory multiple myeloma following Lenalidomide plus low-dose Dexamethasone as second line treatment

This trial evaluates the efficacy and safety of this combination in patients with relapsed myeloma who have received lenalidomide.

For more information, contact Ehsan Malek, MD, at Ehsan.Malek@UHhospitals.org.

E3A06: Lenalidomide for patients with high-risk smoldering myeloma

The standard management strategy for smoldering myeloma is watchful waiting. This important multicenter study is evaluating the benefit of Lenalidomide therapy for patients that have smoldering myeloma with high risk of progression to active disease.

For more information, contact Hillard M. Lazarus, MD, at Hillard.Lazarus2@UHhospitals.org.

Stem Cell Transplant for Patients with Myeloma

DFCI1A14: A randomized, Phase III study comparing conventional-dose treatment using a combination of Lenalidomide, Bortezomib and Dexamethasone (RVD) to high-dose treatment with peripheral stem cell transplant in the initial management of myeloma in patients up to 65 years of age

This trial studies the efficacy of a combination of drugs when given alone or along with a stem cell transplant to treat newly diagnosed multiple myeloma. Untreated myeloma patients are eligible.

For more information, contact Hillard M. Lazarus, MD, at Hillard.Lazarus2@UHhospitals.org.

BMT CTN 1302: A multicenter Phase II, placebo-controlled trial of maintenance Ixazomib after allogeneic hematopoietic stem cell transplantation for high-risk multiple myeloma

This trial recruits patients with high-risk myeloma. Patients are randomized to receive an allogeneic stem cell transplant with or without post-transplant Ixazomib. There is evidence that donor cells may exert a graft-versus-myeloma effect and that ixazomib maintenance may modulate this effect.

For more information, contact Hillard M. Lazarus, MD, at

Hillard.Lazarus2@UHhospitals.org.

We hope you find this information useful. We welcome questions and referrals regarding clinical studies in myeloma, other hematologic malignancies and stem cell transplant.

Paolo Caimi, MD Ehsan Malek, MD Marcos de Lima, MD

University Hospitals, 11100 Euclid Avenue, Cleveland, Ohio 44106
216-844-3800
UHSeidman.org