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US/Global Policymakers Urged to Accelerate Cancer Research, Biomedical Discovery *As Global Cancer Rates Increase, Inefficiencies and Regulatory Barriers Impede Progress*

San Francisco, CA [December 8, 2014] – As researchers attending the 2014 American Society of Hematology (ASH) Annual Meeting & Exposition discuss the latest medical advances in leukemia, lymphoma, multiple myeloma and blood disorders like MDS (Myelodysplastic syndromes), the National Patient Advocate Foundation (NPAF) – a Washington, DC based non-profit organization providing the patient’s voice in improving access to quality cancer care – issued this call to the global cancer community: accelerating the delivery of promising new treatments to patients must be an international priority.

The reason, according to Charles M. Balch, M.D., FACS, Chair of NPAF’s Scientific Advisory Committee and Professor of Surgery at the University of Texas Southwestern Medical Center, are the pervasive logistical, bureaucratic, institutional and regulatory obstacles that are slowing the pace of cancer research at a time when global cancer cases are projected to reach 22 million annually by 2035, up from 14 million yearly cases today.

Speaking at an international journalists’ briefing held during the ASH annual meeting, Dr. Balch relayed the conclusions of a landmark white paper – *Securing the Future of Innovation in Cancer Treatment* – that finds the greatest challenge facing cancer researchers and biopharmaceutical manufacturers is the high cost of bringing a promising new treatment to patients. Behind these escalating costs are inefficiencies in the clinical trials process, increasing regulatory requirements and delays in review decisions, all of which add years to scientific discovery and drug development. Today, 40 percent of cancer research and development costs spent by the biopharmaceutical industry go to the administration of clinical trials and it takes nine or more years from discovery to approval for a new cancer therapy in the US compared to an average time of two years for HIV drugs. The briefing was co-hosted by NPAF in conjunction with the International Myeloma Foundation (IMF), the Lymphoma Research Foundation (LRF) and the MDS Foundation.

At the same time, the white paper, which was drafted through a collaborative effort led by NPAF, documents a significant return on investment from accelerating cancer discovery. Innovations in cancer detection and treatment are associated with a four year average increase in life expectancy for cancer survivors between 1988 and 2000, translating into 23 million additional life-years and roughly \$1.9 trillion of additional social value.

“Given these trends, it is imperative that cancer research is accelerated: it is the only way nations will improve patient outcomes, reduce the costs of cancer care and increase productivity,” said Dr. Balch. “Cancer already costs governments around the world \$1.16 trillion annually and there is little hope of bending the cost curve unless there is continued progress in preventing, detecting, diagnosing and treating the more than 200 types of cancer through cancer innovation.”

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With the white paper as the call-to-action, NPAF is spearheading Project Innovation, a new US initiative supported by a national coalition of healthcare stakeholders to build support for policy solutions that will reduce the regulatory and logistical obstacles that delay drug development, encourage a new wave of experimentation through research funding, and enhance the delivery of innovation through improved communication and coordination between providers and patients.

On a global level, policy options include:

- Facilitating collaboration among biopharmaceutical companies and research institutions to speed drug development by creating common clinical trial protocol templates, developing clinical trial networks and establishing a global investigator registry
- Establishing a centralized hub from which clinical trials data, particularly outcomes data, can be accessed and shared among government and non-government stakeholders
- Utilizing more standardized review processes that will allow for more predictability and should lead to quicker approvals and denials
- Advancing policies that support shared decision-making, a new hallmark for patient-centered care where patients and clinicians decide together on the course of treatment based on each patient's needs and goals

At the same time, Project Innovation has identified a range of options to address inequities that limit patient access to innovative cancer treatments. These include:

1. Applying the lessons learned from the United Kingdom, which established a National Cancer Research Network (NCRN) to expand patient access to a portfolio of clinical trials across the UK, to increase the number of Americans participating in cancer clinical trials. Only two percent to five percent of US adult patients enroll in cancer clinical trials compared to 17 percent of the UK population, the highest national rate world.
2. Instituting policies that encourage more venture capital investment in next-generation cancer therapies and incentivize innovator companies to conduct more clinical trials in the US. Currently, 70 percent of clinical trials are conducted outside the U.S, significantly limiting the ability of American cancer patients to get access to promising new interventions that may extend their lives.
3. Addressing the inequities limiting patient access to innovative cancer treatments, especially the practice by Medicare and commercial health insurers to move newer cancer therapies into the highest "specialty tier" and charge patients a percentage of the drug's cost, from 25 percent up to 71 percent, according to recent estimates.

"Cancer affects all of us through its toll in lives lost, human suffering, lost productivity and cost to the economy. Everyone – from patients and clinicians to research scientists, biomedical innovators and policymakers – has a stake in accelerating the pace of progress against cancer," Dr. Balch stated.

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About Project Innovation

Managed by the National Patient Advocate Foundation (NPAF), Project Innovation is a new initiative to highlight the need to stabilize and accelerate innovation in cancer care. Specific remedies will be driven by a national group of stakeholders called the Cancer Innovation Coalition.

The impetus for Project Innovation was the release in June 2014 of a new white paper, *Securing the Future of Innovation in Cancer Treatment*, which identified institutional, regulatory and funding hurdles that are driving up the costs and delaying the development of new cancer therapies – factors that ultimately limit patient access to much needed treatment. Primary funding for this initiative comes from NPAF with additional support through educational grants from Celgene Corporation, Eli Lilly, Novartis and Pfizer.

Members of the Cancer Innovation Coalition are: Amgen, American Association for Cancer Research, American Cancer Society Cancer Action Network, Association of Community Cancer Centers, Bladder Cancer Advocacy Network, Bristol-Myers Squibb, Cancer Support Community, Celgene Corporation, Colon Cancer Alliance, Community Oncology Alliance, Council for Affordable Health Care, CureSearch, Cutaneous Lymphoma Foundation, Fight Colorectal Cancer, Friends of Cancer Research, Eli Lilly & Company, Genentech, GlaxoSmithKline, National Patient Advocate Foundation, Novartis, Oncology Nursing Society, Personalized Medicine Coalition, Pfizer, Prevent Cancer Foundation, and US Oncology Network.

More information about Project Innovation is available at www.projectinnovation.org, @projectinno on Twitter and <https://facebook.com/ProjectInno> on Facebook.

About the National Patient Advocate Foundation

Based in Washington, DC, the National Patient Advocate Foundation (NPAF) is a national non-profit organization providing the patient voice in improving access to, and reimbursement for, high-quality healthcare through regulatory and legislative reform at the state and federal levels. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from NPAF's companion organization, Patient Advocate Foundation (PAF).

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