NIH partners with 11 leading biopharmaceutical companies to accelerate the development of new cancer immunotherapy strategies for more patients

Supports Cancer Moonshot goal to bring immunotherapy success to more patients in half the time.

The National Institutes of Health and 11 leading biopharmaceutical companies today launched the Partnership for Accelerating Cancer Therapies (PACT), a five-year public-private research collaboration totaling \$215 million as part of the Cancer Moonshot. PACT will initially focus on efforts to identify, develop and validate robust biomarkers – standardized biological markers of disease and treatment response – to advance new immunotherapy treatments that harness the immune system to attack cancer. The partnership will be managed by the Foundation for the National Institutes of Health (FNIH).

"This new public-private partnership is a significant step forward in the battle against cancer and a real boost to the potential of immunotherapy," said Acting Health and Human Services Secretary Eric Hargan. "We are excited for this partnership, which will strengthen efforts already underway across HHS."

New immunotherapies have resulted in dramatic responses in certain cancer cases. They have also been the focus of intense investment by biopharmaceutical companies seeking to provide new options for patients who do not respond to other cancer therapies, but they don't work for all patients. Development and standardization of biomarkers to understand how immunotherapies work in some patients, and predict their response to treatment, are urgently needed for these therapies to provide benefit to the maximum number of people.

"We have seen dramatic responses from immunotherapy, often eradicating cancer completely for some cancer patients," said NIH Director Francis S. Collins, M.D., Ph.D. "We need to bring that kind of success — and hope — for more people and more types of cancers, and we need to do it quickly. A systematic approach like PACT will help us to achieve success faster."

PACT will facilitate systematic and uniform clinical testing of biomarkers to advance our understanding of the mechanisms of response and resistance to cancer therapy. The research conducted under the partnership will also integrate immune and other related oncology biomarkers into clinical trials by defining a set of standardized biomarkers to be tested across a variety of studies. This approach will allow for consistent generation of data, uniform and harmonized assays to support data reproducibility, comparability of data across trials, and discovery and validation of new biomarkers for immunotherapy and related combinations. PACT will also facilitate information sharing by all stakeholders to better coordinate clinical efforts, align investigative approaches, reduce duplication, and enable more high-quality trials to be conducted.

"A scientific and organizational challenge this complex cannot be addressed effectively by any one organization acting alone," said Maria C. Freire, Ph.D., President and Executive Director

of the FNIH. "Instead, it requires the energies and resources of public and private partners working in close collaboration."

PACT partners include AbbVie, North Chicago, Illinois; Amgen, Thousand Oaks, California; Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany; Bristol-Myers Squibb, New York; Celgene Corporation, Summit, New Jersey; Genentech, a member of the Roche Group, San Francisco; Gilead Sciences, Foster City, California; GlaxoSmithKline plc, Brentford, United Kingdom; Janssen Pharmaceutical Companies of Johnson & Johnson, New Jersey; Novartis Institutes for Biomedical Research, Basel, Switzerland; and Pfizer, Inc., New York. Additional support has been provided by the Pharmaceutical Research and Manufacturers Association (PhRMA). The 11 partner organizations will contribute up to \$1 million per year for five years through the FNIH for a total private sector contribution of \$55 million. NIH will contribute \$160 million over the five years of the partnership, pending availability of funds.

NIH's National Cancer Institute (NCI) recently awarded cooperative agreements to support four Cancer Immune Monitoring and Analysis Centers (CIMACs) and a Cancer Immunologic Data Commons (CIDC) with a total of \$53.6 million in funding over five years. The four CIMACs and one CIDC will form a network of laboratory centers that will support both adult and pediatric immunotherapy trials. Researchers at the CIMACs will perform deep tumor and immune profiling. The resulting data will be collected in the CIDC database for exploration of biomarkers of immune response. This network will also provide a foundation for the core laboratory, assay development and database functions required by PACT.

"NCI's long-term support for basic and translational research in immunotherapy paved the way for the recent dramatic clinical successes in this area," said Douglas R. Lowy, M.D., Acting Director of NCI. "This partnership, and the data the partners have committed to making publicly accessible to the broader research community, will facilitate our continued progress in helping to find the cancer treatments that benefit the greatest number of patients."

The NCI cooperative agreements have been awarded to Dana-Farber Cancer Institute, Boston (CIMAC and CIDC); Stanford Cancer Institute, Stanford, California (CIMAC); Precision Immunology Institute and the Tisch Cancer Institute at Icahn School of Medicine at Mount Sinai, New York (CIMAC) and University of Texas MD Anderson Cancer Center, Houston (CIMAC).

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About the Foundation for the National Institutes of Health (FNIH): The FNIH creates and manages alliances with public and private institutions in support of the mission of the NIH. The FNIH works with its partners to accelerate biomedical research and strategies against diseases and health concerns in the United States and across the globe. Established by Congress in 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit fnih.org.

About the National Cancer Institute (NCI): NCI leads the National Cancer Program and NIH's

efforts to dramatically reduce the prevalence of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI website at <u>cancer.gov</u> or call NCI's Contact Center (formerly known as the Cancer Information Service) at 1-800-4-CANCER (1-800-422-6237).

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <u>nih.gov</u>.