THE WHITE HOUSE
Office of the Vice President

FOR IMMEDIATE RELEASE
October 17, 2016

FACT SHEET: Vice President Biden Delivers Cancer Moonshot Report, Announces Public and Private Sector Actions to Advance Cancer Moonshot Goals

FACT SHEET EXCERPT. For full Fact Sheet, link here.

Blood Profiling Atlas Pilot **–** In response to the Vice President's call to action and in alignment with the goals of the Cancer Moonshot, representatives from government, academic, pharmaceutical and diagnostic companies are launching a new partnership in pursuit of creating an open database for liquid biopsies to potentially accelerate the development of safe and effective blood profiling diagnostic technologies for patient benefit.

The group of 20 stakeholders will launch a Blood Profiling Atlas pilot to aggregate, make freely available, and harmonize for further analysis, raw datasets from circulating tumor cells (CTC), circulating tumor DNA (ctDNA), and exosome assays as well as relevant clinical data (e.g. clinical diagnosis, treatment history and outcomes), and sample preparation and handling protocols from 13 different studies. These studies will be contributed by AstraZeneca, Eli Lilly and Company, Epic Sciences/ Memorial Sloan Kettering Cancer Center, Foundation Medicine, Genentech, Guardant Health, Novartis, Personal Genome Diagnostics, Pfizer, Thermo Fisher Scientific, University of Michigan, and University of Southern California and the Blood Profiling Atlas pilot datasets will be curated by a partnership between University of Chicago and Seven Bridges. Sage Bionetworks will contribute advanced analytic capabilities to the effort through a crowdsourced challenge sponsored by Celgene. The strategy of developing an open, well-curated public database would be similar to the database that FDA reviewed in clearing a next-generation sequencing based cystic fibrosis (CF) test nearly three years ago. This Blood Profiling Atlas could have the appropriate controls that would allow it to be recognized by FDA as a source of valid scientific evidence, as proposed in FDA's draft guidance document "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics". The Pre-analytics for Precision Medicine Project Team of the College of American Pathologists (CAP) will provide expert input on pre-analytical factors related to cancer patient blood samples at the point of care and in the pathology laboratory to assure that they are fit for purpose and will work with partners to achieve the goals of optimization and implementation of standardized pre-analytical procedures for blood profiling platforms in CAP-accredited laboratories. The Department of Defense, in support of the Applied Proteogenomics OrganizationaL Learning and Outcomes (APOLLO)

network, will work to incorporate standard operating protocols and recommendations from the Blood Profiling Atlas into ongoing solid and blood profiling efforts within APOLLO and Murtha Cancer Center.

The Blood Profiling Atlas will allow approved researchers access to raw unprocessed datasets in a scalable and reproducible manner. The data storage and analytics team will work with the Blood Profiling Atlas members and the research community to develop standards for data use, user authentication and authorization to ensure privacy and security, as well as data annotation and harmonization. Harmonization and data processing methods will be described using portable and reproducible methods to enable widespread adoption of standardized methods.

In support of this overarching mission,

- Open Commons Consortium (OCC) in collaboration with the University of Chicago commits to organizing and operating an open Blood Profiling Atlas Commons. The Commons will be based upon the same open source software stack used by the NCI Genomic Data Commons so that the genomic, image and clinical data in the Commons can be shared with the appropriate security, privacy and compliance controls. To facilitate the rapid development of this critical resource, the OCC / University of Chicago team will contribute up to six months of engineering, bioinformatics and project management resources to the project and up to $500,000 of compute and storage resources for building the commons and for the use of the commons by the research community.

- Seven Bridges will contribute its experience in accelerating pharmaceutical research and development and in building national-scale research systems by developing the Blood Profiling Atlas Analysis Cloud, specifically tailored to the needs of the liquid biopsy community. This environment – based on the company's work partnering with the NCI, Genomics England, the VA and others – will integrate with the Blood Profiling Atlas Commons, allowing molecular, clinical and imaging data to be easily, securely, and cost effectively analyzed by researchers across disciplines. In addition, Seven Bridges will share its expertise in cancer genomics and immunoinformatics analysis. To do so, the company will release algorithms for analyzing liquid biopsy data at scale, committing six months of engineering, bioinformatics and project management resources, and up to $500,000 compute and storage resources to facilitate use of the analysis tools and data donated by the Blood Profiling Atlas community.

- In support of the Blood Profiling Atlas, AstraZeneca will provide standard operating procedures for ctDNA isolation and library construction for targeted and whole genome/exome sequencing of ctDNA. The AstraZeneca

bioinformatics pipeline for variant calling in ctDNA is available for all interested parties. Furthermore, AstraZeneca will generate ctDNA for comparative studies of other bioinformatics pipelines with the goal to develop best practices in identifying variants in ctDNA after high depth sequencing that will standardize analyses of data acquisition for the Atlas. AstraZeneca will additionally provide data on method comparisons and can assist in data generation for samples provided to this project.

- Eli Lilly and Company is studying approaches for the profiling of exosomes for mRNA and non-coding RNA expression. Lilly will share sample preparation methods, next-generation quantitative PCR-based methods, and Next Generation Sequencing-based methods, along with data related to disease characterization through gene expression analysis.

- Epic Sciences is committed to supporting the Blood Profiling Atlas and will share data on circulating tumor cells in prostate cancer cohorts from the Memorial Sloan Kettering Cancer Center and the Prostate Cancer Clinical Trials Consortium. The data set will include information from thousands of CTCs across multiple lines of therapy. It has been increasingly acknowledged that the cellular diversity of cancer is a key feature of the disease that has blunted the effectiveness of many new classes of drugs. The CTC data to be contributed will shed new light on the diversity of circulating tumor cells in late stage prostate cancer. This data will also provide novel insights as to how numerous CTC species correlate with response or resistance to standard of care treatments. In addition, Epic Sciences will bring its unique expertise in blood processing and long term preservation of circulating tumor cells and leukocytes for complex biomarker analysis.

- Foundation Medicine continues to support the Cancer Moonshot to accelerate research in precision medicine with the goal of advancing patient care. In this most recent endeavor, Foundation Medicine will share with the Blood Profiling Atlas data generated from analytic validation studies of FoundationACT, including analysis using cell line models and real world patient samples. FoundationACT is Foundation Medicine's best-in-class, hybrid capture, blood-based diagnostic for circulating tumor DNA. It is optimized to detect all four classes of clinically relevant genomic alterations (base substitutions, insertion/deletions, copy number alterations and gene fusions) with unparalleled accuracy of 99% sensitivity and 99% specificity (PPV). Foundation Medicine's release of any and all data to the Blood Profiling Atlas is de-identified and HIPPA-compliant. Foundation Medicine has also committed its subject matter experts, including its bioinformatics team, to offer expertise needed as this project is implemented.

- Genentech supports the goals of the Blood Profiling Atlas and will share data generated from over 400 non-clinical trial samples utilizing different blood sample collection and processing methodologies as well as data from Genentech-developed tests to identify and measure circulating tumor DNA (ctDNA) in patients' blood. Genentech scientists will also serve as subject matter experts in biomarker assay development, bioinformatic analysis and clinical translational research.

- Guardant Health Guardant Health is committed to supporting the Blood Profiling Atlas by contributing pre-analytical and genomic data generated from 500 real-world clinical lung cancer patient samples tested by Guardant360, the world's first comprehensive liquid biopsy. Guardant360 uses Digital Sequencing, an error suppressing hybrid-capture next-generation sequencing platform, to simultaneously achieve ultra-high sensitivity and specificity across single-nucleotide, copy-number, insertion/deletion, and structural variants. Guardant360 has been used by >90% of the leading cancer centers in the United States, as well as by thousands of oncologists for nearly 30,000 patients in routine clinical care. Guardant Health is also happy to collaboratively share expertise in reference standards, rare-analyte molecular biology, bioinformatics, and biostatistics.

- Memorial Sloan Kettering Cancer Center: Encouraged by the Cancer Moonshot initiative, Memorial Sloan Kettering Cancer Center (MSK) will share our methods of blood sample collection and the comparative results of different processing methods for cell-free nucleic acid analysis. With the aim of developing the atlas, MSK will share data on circulating tumor cells (CTC) obtained from metastatic prostate cancer patients at decision points in management when a change in systemic therapy is needed. The approach will shed light on the influence of prior treatment on outcome. Further characterization of the cells both at the phenotypic level and genomic level will also provide insights into the sensitivity of an individual patient's disease to different types of therapy, enabling clinicians to better guide therapy and improve patient outcomes.

- Novartis is evaluating the performance of different methods to test circulating tumor DNA ("ctDNA") including PCR-based methods and Next Generation Sequencing-based methods. Novartis will share (i) standard operating procedures for plasma collection for ctDNA; (ii) results from evaluation of different commercially available ctDNA extraction kits (iii) evaluation of ctDNA technology performance using contrived samples. In addition, Novartis will share data and/or samples generated from these evaluations.

- Personal Genome Diagnostics (PGDx) is committed to realizing the potential of liquid biopsy to improve the lives of cancer patients. PGDx will strongly support the Blood Profiling Atlas and will share expertise, protocols, and non-proprietary ctDNA profiling data generated with their PlasmaSELECT platform. PGDx will submit data from 500 samples during the pilot phase of the Blood Profiling Atlas and work with their academic, pharma/biotech, and molecular lab partners to enable their contribution of data to the Atlas. Additionally, PGDx is offering the expertise of its team of genomic, computational, and diagnostic scientists to support the initiative.

- Pfizer intends to share de-identified data from cfDNA analysis (digital PCR) of clinical trial samples from two different clinical programs, subject to internal approvals for public disclosure. Data from one of the clinical programs, anticipated to be available in a six to nine month time frame, will be derived from a Phase 3 trial in breast cancer and will include clinical outcome and baseline characteristics, as well as data from cfDNA analysis, on 395 patients. Similar data from the second clinical program involving an ongoing Phase 1 / 2 NSCLC trial is anticipated to be available to share the latter half of 2017 to 2018, pending publication and regulatory approvals, for 40 and 200 patients for Phase 1 and Phase 2, respectively.

- Thermo Fisher Scientific is enthusiastic about the Blood Profiling Atlas and will contribute a combination of internal and customer validation data sets on more than 5,000 measurements involving multiple operators and instruments. The datasets include more than 20 samples (in replicate) and this number is likely to grow rapidly as their kits have recently been commercialized with analytical validation at 0.1% LOD achieved at 90% sensitivity, 98.4% specificity and high reproducibility.

- The research teams of Muneesh Tewari, Daniel Hayes, Scott Tomlins and Todd Morgan at the University of Michigan (UM) provide their enthusiastic support for the Blood Profiling Atlas. They will share droplet digital PCR data from a comparison of multiple specimen collection tubes for stability of plasma cell-free tumor DNA over time, plasma whole genome sequencing data from up to 30 patients with advanced cancer, plasma cell-free RNA next generation sequencing data from up to 100 individuals as it becomes available in the coming year, and potentially circulating tumor cell enumeration and phenotype data from up to 100 patients with solid tumors. They will also share standard operating procedures for blood specimen collection and processing for cell-free DNA and RNA, experience in longitudinal blood sample collection, and expertise in generation and bioinformatic analysis of plasma cell-free RNA sequencing data. UM research teams will collectively commit up to $100,000 in investigative personnel, laboratory, bioinformatics and clinical research

resources for activities contributing to the Cancer Moonshot Blood Profiling Atlas in the coming year.

- The Kuhn Laboratory at the University of Southern California commits to sharing data from the High-Definition Single Cell Analysis (HD-SCA) for the Blood Profiling Atlas on circulating tumor cell morphology, genomics and proteomics with simultaneous cell-free genomics on over 100 patients with breast cancer. Both cell-based and cell-free analyses are derived from the same blood sample and provide an initial concept for the Blood Profiling Atlas design. They will also share the visualization tools and infrastructure of the HD-SCA with the Open Commons Consortium to support the utilization of the Blood Profiling Atlas. They will also share clinical protocols and results from all pre-analytical variables and validation studies of the HD-SCA to support design of future Blood Profiling Atlas studies.

Celgene will contribute advanced analytic capabilities to the effort and sponsor a crowdsourced Challenge for patient benefit in the blood profiling domain. Celgene has budgeted $150,000 to fully sponsor the Challenge and is partnered with Sage Bionetworks and the open sciences DREAM Challenges community to bring together a diverse community of scientists and analysts to develop and share predictive models in an open-access environment